Kenneth W. Dawes, MD

Dawes Fretzin Clinical Research Group, LLC
7910 North Shadeland Avenue
Indianapolis, Indiana 46250
Phone (317) 516-5030
Fax (317) 516-5031
E-mail: kdawes@ecommunity.com

Dawes Fretzin Dermatology Group, LLC
7910 North Shadeland Avenue
Indianapolis, Indiana 46250
Phone (317) 516-5000
Fax (317) 516-5031

Education

Indiana University Medical Center (Indianapolis, IN)
Dermatology Residency, 1992-95

St. Vincent Hospitals and Health Services (Indianapolis, IN)
Internal Medicine Residency, 1989-92

Indiana University School of Medicine (Indianapolis, IN)
Medical Doctorate, 1989

Indiana University (Bloomington, IN)
Bachelor of Arts in Biology, 1985

Northfield High School (Wabash County, IN)
Diploma, 1981

Professional Experience

Dawes Fretzin Clinical Research Group, LLC (Indianapolis, IN)
Investigator, 2004-Present

Dawes Fretzin Dermatology Group, LLC (Indianapolis, IN)
Dermatologist, 1995-Present
Investigator, 2002-Present

Walker Clinical Evaluations (Indianapolis, IN)
Sub investigator, 1994-1995

Vencor Hospital (Indianapolis, IN)
House Physician, 1993-1995

Robert J. Steele, Internal Medicine (Kokomo, IN)
Cross-coverage for multiple physicians, 1992-1995

Johnson County Internal Medicine (Franklin, IN)
Hospital-based coverage, 1992-1995

Physician's Weight Loss Center (Indianapolis, IN)
House Physician, 1992

8/19/22

Northside Cardiology P.C. (Indianapolis, IN)

Hospital-based coverage, 1990-1992

Professional Experience (Cont)

St. Vincent Hospitals and Health Services (Carmel, IN)
House Physician, 1990-1992

St. Vincent Hospitals and Health Services (Indianapolis, IN)
House Extern, 1989-1990

Honors and Awards

1995	Young Investigator's Award, Second place, Journal of Dermatologic surgery and Oncology
1994-95	Chief Resident, Dermatology
1985	Cum Laude at Indiana University, Bloomington, Indiana
1981	Phi Beta Kappa, Indiana University, Bloomington, Indiana
1981	Valedictorian, Northfield High School

Clinical Study Experience

Sponsor: Celgene ***PSI: SAF*** ***Phase: 3***
A PHASE 3B, MULTI CENTER, OPEN-LABEL LONGTERM EXTENSION STUDY OF APREMILAST (CC- 10004) IN PEDIATRIC SUBJECTS FROM 6 THROUGH 17 YEARS OF AGE WITH MODERATE TO SEVERE PLAQUE PSORIASIS
July 2019- present

Sponsor: Arcutis ***PSI: KWD*** ***Phase: 2b***
ARQ-154-204: A Phase 2b, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-154 Foam 0.3% Administered QD Adolescents and Adults with Scalp and Body Psoriasis
October 2019- Present

Sponsor: Abbvie ***PSI: SAF*** ***Phase: 3b***
M19-164: A Phase 3b, Multicenter, Interventional, Open Label Study of adult patients with moderate to severe plaque psoriasis who have a suboptimal response to secukinumab or ixekinumab and are switched to risankizumab
October 2019- Present

Sponsor: Arcutis ***PSI: KWD*** ***Phase: 3***
A Phase 3, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-151 Cream 0.3% Administered QD in Subjects with Chronic Plaque Psoriasis
October 2019- Present

Sponsor: Arcutis ***PSI: KWD*** ***Phase: 3***
A Phase 3, Multicenter, Open-Label Extension Study of the Long-Term Safety of ARQ-151 Cream 0.3% in Subjects with Chronic Plaque Psoriases who have Completed Preeceding Studies ARG-151-301 or ARQ-151-302
ARQ-151-306
December 2019- Present

Sponsor: Arcutis ***PSI KWD*** ***Phase: 3***
A Phase 3, 8-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of

ARQ-151 Cream o.3% Administered QD in Subjects with Chronic Plaque Psoriasis
October 2019- Present

Sponsor: Celgene ***PSI: SAF*** ***Phase: 3***
CC-10004-PSOR-025: A PHASE 3, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF THE EFFICACY AND SAFETY OF APREMILAST (CC-10004) IN SUBJECTS WITH MODERATE TO SEVERE GENITAL PSORIASIS
August 2019- Present

Sponsor: Lilly ***PSI: SAF*** ***Phase: 1***
J1P-MC-KFAC: A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous LY3471851 in Patients with Psoriasis
November 2019- Present

Sponsor: Dermavant ***PSI: KWD*** ***Phase: 2/3***
DMVT-505-3003 A Long-Term, Open-Label, Extension Study to Evaluate the safety of Tapinarof cream, 1% for the Treatment of Plague Psoriasis in Adults
December 2019- Present

Sponsor: Dermavant ***PSI: SAF*** ***Phase: 3***
DMVT-505-3001 A Phase 3 Efficacy and Safety of Tapinarof for the Treatment of Plaque Psoriasis in Adults
January 2019- Present

Sponsor: PCORI LITE PCS ***PSI: SAF*** ***Phase: 2/3***
A pragmatic trial of home versus based narrow band ultraviolet B phototherapy for the treatment of psoriasis
April 2019- Present

Sponsor: Lilly ***PSI: SAF*** ***Phase: 2/3***
Protocol I6T-MC-AMBK
An Open-Label Evaluation of Mirikizumab following Subcutaneous Administration Using Prefilled Syringe or Auto Injector in Patients with Moderate-to-Severe Plaque Psoriasis-I6T-MC-AMBK
February 2019- Present

Sponsor: Novartis ***PSI: KWD*** ***Phase 2/3***
Novartis Pharmaceuticals trial entitled: a randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab dose regimens in adult patients with moderate to severe hidradenitis suppurativa (SUNRISE)
Protocol No: CAIN457M2302
March 2019- Present

Sponsor: Akros Pharma ***PSI: SAF*** ***Phase: 2/3***
A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group Study to Evaluate the Efficacy and Safety of JTE-451 Administered for 16 Weeks in Subjects with Moderate to Severe Plaque Psoriasis (IMPACT-PS)
February 2019- Present

Sponsor: Menlo Therapeutics ***PSI: KWD*** ***Phase: 2/3***
A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy, Safety, and Tolerablility of Serlopitant for the Treatment of Chronic Pruritus of Unknown Origin.
January 2019- Present

Sponsor: Anaptys Bio ***PI: SAF*** ***Phase: 2***
A phase II, Randomized, Placebo-controlled, Double-blind, Multiple Dose study to Evaluate the Efficacy

and Safety of ANBO19 in Subjects with Palmoplantar Pustulosis.
November 2018- Present

Sponsor: Anaptys Bio ***PI: SAF*** ***Phase: 2/3***
A Single Arm Multiple Dose Study to Assess the Efficacy and Safety of ANB019 in Subjects with Generalized Pustular Psoriasis
November 2018- Present

Sponsor: Celgene ***PI: SAF*** ***Phase: 3***
A PHASE 3, MULTI-CENTER, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF THE EFFICACY AND SAFETY OF APREMILAST (CC-10004) IN SUBJECTS WITH MILD TO MODERATE PLAQUE PSORIASI
Number of Patient consent: 0
September 2018- Present

Sponsor: Celgene ***PI: SAF*** ***Phase: 3***
A PHASE 3, MULTI-CENTER, RANDOMIZED, DOUBLE- BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF APREMILAST (CC-10004) IN PEDIATRIC SUBJECTS FROM 6 THROUGH 17 YEARS OF AGE WITH MODERATE TO SEVERE PLAQUE PSORIASIS
Number of Patient consent: 2
September 2018- Present

Sponsor: Novartis ***PI: KWD*** ***Phase:***
Novartis Pharmaceuticals trial entitled: A randomized, double-blind, placebo- and active controlled multi-center trial to demonstrate efficacy of subcutaneous secukinumab compared to placebo and etanercept (in a single-blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in subjects from 6 to less than 18years of age with severe chronic plaque psoriasis.
Number of Patient consent: 0
February 2018- October 2018

Sponsor: Lilly ***PI: SAF*** ***Phase: 4***
I1F-MC-RHCR
Phase IV
A 24-Week Multicenter, Randomized, Double-Blind, Parallel-Group Study Comparing the Efficacy and Safety of Ixekizumab to Guselkumab in Patients with Moderate-to-Severe Plaque Psoriasis
Number of Patient consent: 9
March 2019- Present

Sponsor: Novartis ***PI: SAF*** ***Phase: 3***
Novartis Pharmaceuticals trial entitled: A randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of sub-cutaneous secukinumab in subjects of body weight 90 kg or higher with moderate to severe chronic plaque-type psoriasis
Number of Patient consent: 5
June 2018- Present

Sponsor: Lilly ***PI: SAF*** ***Phase: 3***
I6T-MC-AMAH A Multicenter, Long-Term Extension to Evaluate the Long-term Safety and Maintenance of Treatment Effect of Mirikizumab in Patients with Moderate-to-Severe Plaque Psoriasis
OASIS-3
Number of Patient consent: 4
June 2018- Present

Sponsor: BI ***PI: SAF*** ***Phase: 2***
Phase II evaluation of safety, tolerability, and efficacy of BI 730357 in patients with moderate-to-severe plaque psoriasis.- 1407-0030
August 2018- Present

Sponsor: Eli Lilly ***PI: SAF*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of Mirikizumab to Secukinumab and Placebo in Patients with Moderate-to-Severe Plaque Psoriasis- I6T-MC-AMAJ
June 2018- Present

Sponsor: Dr. Reddy's Lab ***PI: SAF*** ***Phase: 2***
A Randomized, Double-Blind, Placebo-Controlled, Multicenter, 24- week Study to Assess the Efficacy and Safety of PPC-06 (Tepilamide Fumarate) Extended Release Tablets in Subjects with Moderate to Severe Plaque Psoriasis. PPC-06-CD-004
April 2018- Present

Sponsor: Sienna ***PI: KWD*** ***Phase: 2***
An Exploratory, Randomized, Double-Blind, Placebo-Controlled, Mutlicenter, Phase 2 Study to Evaluate the Safety, Tolerability, and Efficacy of SNA-120 (Pegcantratinib) Ointment for the Symptomatic Treatment of Persistent Pruritus and Psoriasis in Subjects Being Treated with Calcipotriene Ointment. SNA-120-202
April 2018- February 2019

Sponsor: Allergan ***PI: SAF*** ***Phase: 2b***
A Randomized, Double-Blind, Placebo-Controlled, Study to Assess the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of AGN-242428 in Patients with Plaque Psoriasis: 1957-201-001
January 2018- May 2018

Sponsor: Janssen ***PI: KWD*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind Study Evaluating the Comparative Efficacy of CNTO 1959 (Guselkumab) and Secukinumab for the Treatment of Moderate to Severe Plaque-type Psoriasis: CNTO1959PSO3009
May 2017- October 2018

Sponsor: Novartis ***PI: KWD*** ***Phase: 4***
A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study to explore changes in subcutaneous adipose tissue and modulation of skin inflammation after 12 weeks of treatment with secukinumab, compared to placebo, and up to 52 weeks of treatment with secukinumab in adult patients with moderate to severe plaque psoriasis (ADIPSO): CAIN457AUS07
April 2017- June 2019

Sponsor: Pfizer ***PI: SAF*** ***Phase: 2A***
A Phase IIa, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Efficacy of PF-06700841 in Subjects with Moderate to Severe Plaque Psoriasis. B7931004
March 2017- May 2018

Sponsor: Bristol-Myers Squibb ***PI: KWD*** ***Phase: 2***
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase 2 Study to Evaluate the Clinical Efficacy and Safety of BMS-986165 in Subjects with Moderate to Severe Psoriasis. BMS IM011011
March 2017- August 2017

Sponsor:AbbVie ***PI: SAF*** ***Phase: 3***
A Multicenter, Open-Label Study to assess the safety and efficacy of rIsankizuMab for maintenance in moderate to severe plaque type psoriasis. M15-997
March 2017- Present

Sponsor:Janssen ***PI: KWD*** ***Phase: 3***

A Phase III Open-Label Study to Assess the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Ustekinumab in the Treatment of Moderate to Severe Chronic Plaque Psoriasis in Pediatric Subjects >/= 6 to < 12 Years of Age. CNTO1275PSO3013
January 2017- October 2017

Sponsor: UCB BioPharma ***PI: SAF*** ***Phase: 2B***
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Ranging Study to Evaluate the Safety, Efficacy, Pharmacokinetics, and Pharmocodynamics of Bimekizumab in Adult Subjects with Moderate to Severe Chronic Plaque Psoriasis. PS0010
October 2016- June 2017

Sponsor: Eli Lilly ***PI: SAF*** ***Phase: 1***
A Multi-Dose, Dose-Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LY3041658 in Patients with Neutrophilic Skin Diseases. I7P-MC-DSAB
September 2016-August 2019

Sponsor: Kadmon ***PI: SAF*** ***Phase: 2***
A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study to Evaluate the Safety, Tolerability, and Efficacy of KD025 in Adult Subjects with Moderate to Severe Chronic Plaque Psoriasis who are Candidates for Systemic Therapy or Phototherapy. KD025-211
September 2016-November 2019

Sponsor: Novartis ***PI: KWD*** ***Phase 3***
A 52-week, Multicenter, Randomized, Double-Blind Study of secukinumab (300 mg) to demonstrate the efficacy as assessed by Psoriasis Area and Severity Index and Investigator's Global Assessment after 12 weeks of treatment, compared to ustekinumab, and to assess long term safety, tolerability, and efficacy in subjects with moderate to severe plaque psoriasis. CAIN457A2326
August 2016- Present

Sponsor: Evidera/Eli Lilly and Company ***PI: SAF*** ***Phase: 4***
Assessment of the Content Validity of the Psoriasis Symptoms Scale (PSS). – EVA-18225-01
June 2016- Present

Sponsor: Eli Lilly ***PI: SAF*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Ixekizumab Versus Placebo in Patients with Moderate-to-Severe Genital Psoriasis. – I1F-MC-RHBQ(1)
April 2016- May 2018

Sponsor: Boehringer Ingelheim ***PI: SAF*** ***Phase:***
BI 655066 versus Ustekinumab and placebo comparators in a Randomized Double-Blind Trial for Maintenance use in Moderate to severe plaque type psoriasis-2 (U1tIMMa-2) – 1311.28
March 2016 – November 2017

Sponsor: Evidera/Eli Lilly and Company ***PI: SAF*** ***Phase: 4***
Cognitive Interviewing of the Subcutaneous Administration Assessment Questionnaire (SQAAQ) in Patients with Moderate to Severe Plaque Psoriasis – EVA-18225
February 2016 – June 2016

Sponsor: Promius Pharma, LLC ***PI: KWD*** ***Phase: 3***
A Randomized, Double-Blind, Vehicle-Controlled, Multicenter, Parallel Group Study of the Efficacy and Safety of DFD-06 Cream in the Treatment of Moderate to Severe Plaque Psoriasis for 14 Days – DFD06-CD-005
November 2015 to September 2016

Sponsor: Baxalta US, Inc./Baxalta Innovations GmbH PI: SAF ***Phase:3***
A Phase III Randomized, Double-blind, Multicenter Study to Evaluate Efficacy, Safety, and Immunogenicity of an Adalimumab Biosimilar (M923) and Humira® in Subjects with Moderate to Severe

Chronic Plaque-type Psoriasis – 911401
October 2015 to October 2017

Sponsor: Eli Lilly and Company PI:SAF Phase: 3
A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Ixekizumab Dosing Regimens in Patients with Moderate-to-Severe Plaque Psoriasis – I1F-MC-RHBP
August 2015 to June 2017

Sponsor: Corrona, LLC PI:SAF Phase: 1
Corrona Psoriasis Registry – Corrona PSO-500
July 2015 to Present

Sponsor: UCB Biopharma, SPRL / Dermira, Inc. PI: SAF Phase: 3
A Phase III, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-and-Active-Controlled Study Followed by a Placebo-Controlled Maintenance Period and Open-Label Follow-up to Evaluate the Efficacy and Safety of Certolizumab Pegol in Subjects with Moderate to Severe Chronic Plaque Psoriasis – PSO003
May 2015 to Present

Sponsor: Amgen, Inc. PI: KWD Phase: 1
A Prospective, Observational Study to Estimate the Proportion of Subjects With Plaque Psoriasis who Achieve Complete Clearance on Biologics - 20120363
May 2015 to April 2017

Sponsor: TOLMAR, Inc. PI:SAF Phase: 3
A Double-Blind, Randomized, Parallel-Group, Vehicle-Controlled, Multicenter Study Comparing TOLMAR Calcipotriene Ointment, 0.005% to Reference Listed Drug in the Treatment of Plaque Psoriasis – TOL2707A
March 2015 to June 2016

Sponsor: Amgen, Inc. PI: SAF Phase: 4
A Single-arm Study to Assess the Immunogenicity and Safety of Etanercept Produced Using a Modified Process in Subjects With Plaque Psoriasis. Phase 4 Study - 20101177
February 2015 to March 2016

Sponsor: Pfizer, Inc. PI: Phase: 2
A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety and Efficacy of PF-04965842 in Subjects with Moderate to Severe Psoriasis – B7451005
November 2014 to September 2015

Sponsor: Janssen Research and Development, LLC PI: SAF Phase: 2
A Phase II Multicenter, Randomized, Double-blind, Placebo-Controlled Trial to Evaluate Toreforant (JNJ-38518168) for the Treatment of Subjects with Moderate to Severe Plaque type Psoriasis – 38518168PSO2001
November 2014 to January 2016

Sponsor: Janssen Research and Development, LLC PI: SAF Phase: 3
A Phase III, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Guselkumab for the Treatment of Subjects With Moderate to Severe Plaque-Type Psoriasis and Inadequate Response to Ustekinumab – CNTO1959PSO3003
November 2014 to July 2016

Sponsor: Janssen Research and Development, LLC PI: SAF Phase: 3
A Phase III, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects with Moderate to

Severe Plaque-type Psoriasis Incorporating Randomized Withdrawal and Retreatment – CNTO1959PSO3002
November 2014 to Present

Sponsor: Novartis Institutes for BioMedical PI: Phase:
A Randomized, Double-Blind, Placebo and Positive Controlled, Single and Multiple Dose Study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of CJM112 in chronic plaque-type psoriasis patients – CCJM112X2101
November 2014 to January 2016

Sponsor: Hexal AG/Sandoz, Inc. PI: SAF Phase: 3
A Randomized, Double-Blind, Multicenter Study to demonstrate equivalent efficacy and to compare safety and immunogenicity of a biosimilar adalimumab (GP2017) and Humira® in patients with moderate to severe chronic plaque-type psoriasis – GP17-301
July 2014 to July 2016

Sponsor: Amgen, Inc. PI: Phase:
A Study to Assess the Clinical Meaningfulness and Interpretability of Improvement in patient-reported psoriasis symptom severity over the course of treatment for chronic plaque psoriasis – 20130126 (HRA 1603A)
May 2014 to February 2016

Sponsor: AbGenomics PI: Phase:2
Efficacy, safety, tolerability, and pharmacokinetics of multiple doses of AbGn-168H administered by intravenous infusion to patients with moderate to severe chronic plaque psoriasis (randomized, double-blind, placebo-controlled) – 2014.002.01
May 2014 to April 2015

Sponsor: Novartis Pharmaceuticals PI: SAF Phase: 3
A 52-week, Multicenter, Randomized, Double-Blind Study of subcutaneous secukinumab to demonstrate efficacy as assessed by Psoriasis Area and Severity Index at 16 weeks of treatment compared to ustekinumab and to assess long-term safety, tolerability and efficacy in subjects with moderate to severe plaque psoriasis – CAIN457A2317
May 2014 to November 2016

Sponsor: Janssen Research and Development PI: Phase: 1
Exploratory Genetic Study in Subjects with Moderate to Severe Psoriasis – NOCOMPOUNDPSO0001
March 2014 to September 2014

Sponsor: Amgen, Inc. PI: Phase:
A Comparison of Psoriasis Symptom Severity and Health-Related Quality of Life in Patients With Clear and Almost Clear Levels of Skin Improvement – 20130127 (HRA 1889A)
October 2013 to August 2014

Sponsor: Novartis Pharmaceuticals PI: KWD Phase: 3
A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Study to demonstrate the efficacy at 16 weeks of secukinumab 150 and 300 mg s.c. and to assess safety, tolerability and long-term efficacy up to 80 weeks in subjects with moderate to severe nail psoriasis – CAIN457A2313
September 2013 to April 2017

Sponsor: Novartis Pharmaceuticals PI: KWD Phase: 3
A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to demonstrate the efficacy at 16 weeks of secukinumab 150 and 300 mg s.c. and to assess safety, tolerability and long-term efficacy up to 80 weeks in subjects with moderate to severe palmoplantar psoriasis – CAIN457A2312
September 2013 to April 2017

Sponsor: Maruho North American, Inc. PI: Phase: 3

A Randomized, Vehicle-Controlled, Double-Blind, Parallel Group, Multi-Center Phase III Study to Evaluate the Safety and Efficacy of M518101 in Subjects with Plaque Psoriasis – M518101-US02
August 2013 to September 2015

Sponsor: AbGenomics BV ***PI:*** ***Phase:***
Efficacy, safety, tolerability, and pharmacokinetics of multiple doses of AbGn-168H administered by intravenous infusion to patients with moderate to severe chronic plaque psoriasis (randomized, double-blind, placebo-controlled) – 2012.005.01
May 2013 to April 2014

Sponsor: Eli Lilly and Company ***PI:*** ***Phase:3***
Pharmacokinetic Evaluations of Ixekizumab following Subcutaneous Administration Using Prefilled Syringe or Auto-Injector in Patients with Moderate-to-Severe Plaque Psoriasis – I1F-MC-RHBL
April 2013 to October 2013

Sponsor: Eli Lilly and Company ***PI: SAF*** ***Phase: 3***
A 12-Week Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of LY2439821 to Etanercept and Placebo in Patients with Moderate to Severe Plaque Psoriasis with a Long-Term Extension Period – I1F-MC-RHBC
February 2013 to Present

Sponsor: Merck Sharp & Dohme Corp. ***PI:SAF*** ***Phase: 3***
A 64-Week, Phase III, Randomized, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous SCH 900222/MK-3222, Followed by an Optional Long-Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis – MK-3222-010
January 2013 to Present

Sponsor: Novartis Pharmaceuticals ***PI: SAF*** ***Phase: 3***
A Multicenter, Double-Blind and Open Label, 4-year Extension Study of subcutaneous secukinumab in prefilled syringes, assessing long-term safety, tolerability and efficacy in subjects with moderate to severe chronic plaque-type psoriasis treated with either a fixed dose regimen or on a retreatment at start of relapse regimen – CAIN457A2304E1
November 2012 to October 2017

Sponsor: Novartis Pharmaceuticals ***PI: SAF*** ***Phase: 3***
A Multicenter, Double-Blind, Randomized Withdrawal Extension Study of subcutaneous secukinumab in prefilled syringes to demonstrate long-term efficacy, safety and tolerability up to 4 years in subjects with moderate to severe chronic plaque-type psoriasis completing preceding psoriasis phase III studies with secukinumab – CAIN457A2302E1
October 2012 to November 2017

Sponsor: Celgene Corporation ***PI: SAF*** ***Phase:3B***
A Phase IIIb, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Double-Dummy, Study of the Efficacy and Safety of Apremilast (CC-10004), Etanercept, and Placebo, in Subjects with Moderate to Severe Plaque Psoriasis - CC-10004-PSOR-010
September 2012 to July 2015

Sponsor: Novartis Translational Sciences ***PI:*** ***Phase: 2***
Phase II Randomized Double Blinded Placebo-Controlled, Multiple-Dose regimen study to assess the rate of histological clearance and effect on molecular pathways as well as on biomarkers of 12 months secukinumab 300 mg s.c. treated patients with chronic plaque-type psoriasis – CAIN457A2223
August 2012 to May 2015

Sponsor: Amgen, Inc. ***PI:*** ***Phase: 3***
Phase III Study to Evaluate the Efficacy and Safety of Induction and Maintenance Regimens of

Brodalumab Compared With Placebo and Ustekinumab in Subjects With Moderate to Severe Plaque Psoriasis: AMAGINE-3 - 20120104
August 2012 to December 2015

Sponsor: Leo Pharmaceuticals ***PI:*** ***Phase: 2***
A Phase II Study comparing treatment with LEP 90100 with betamethasone dipropionate in LEO 90100 vehicle and calcipotriol in LEO 90100 vehicle in subjects with psoriasis vulgaris – LEO 90100-7
May 2012 to December 2012

Sponsor: Leo Pharmaceuticals ***PI:*** ***Phase: 2***
A Phase II Study comparing treatment with LEO 90100 with calcipotriol plus betamethasone ointment, LEO 90100 vehicle and ointment vehicle in subjects with psoriasis vulgaris – LEO 90100-35
May 2012 to November 2012

Sponsor: Stiefel Laboratories, Inc. ***PI: KWD*** ***Phase: 1***
A Phase I, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of Calcipotriene Foam, 0.005%, Applied Under Maximal-Use Conditions in Adolescent Subjects (Ages 12 to 16 Years) with Plaque Psoriasis – STF 115750
March 2012 to August 2017

Sponsor: Eli Lilly and Co., Inc. ***PI:SAF*** ***Phase: 3***
A Multicenter Study with a Randomized, Double-Blind, Placebo-Controlled Induction Dosing Period Followed by a Randomized Maintenance dosing Period and a Long-Term Extension Period to Evaluate the Efficacy and Safey of LY2439821 in Patients with Moderate-to-Severe Plaque Psoriasis – I1F-MC-RHAZ
February 2012 to Present

Sponsor: Janssen Research and Development, Inc. PI: ***Phase: 2***
A Phase II Multicenter, Randomized, Placebo- and Active-Comparator-Controlled, Dose-Ranging Trial to Evaluate CNTO 1959 for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis – CNTO1959PSO2001
January 2012 to November 2013

Sponsor: Novartis ***PI:*** ***Phase: 3***
A Randomized, Double-Blind, Multicenter Study of subcutaneous secukinumab, assessing Psoriasis Area and Severity Index (PASI) response and maintenance of response in subjects with moderate to severe chronic plaque-type psoriasis on either a fixed dose regimen or on a retreatment at start of relapse regimen. (SCULPTURE) – CAIN 457A2304
October 2011 to September 2013

Sponsor: Novartis ***PI:*** ***Phase: 3***
A Randomized, Double-Blind, Double-Dummy, Placebo Controlled, Multicenter Study of subcutaneous secukinumab to demonstrate efficacy after twelve weeks of treatment, compared to placebo and etanercept, and to assess the safety, tolerability and long-term efficacy up to one year in subjects with moderate to severe chronic plaque-type psoriasis. (FIXTURE) – CAIN457A2303
September 2011 to October 2013

Sponsor: Pfizer ***PI: KWD*** ***Phase: 3***
A Phase III Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy And Safety Of 2 Oral Doses Of Cp-690,550 In Subjects With Moderate To Severe Chronic Plaque Psoriasis – A3921078/A3921061
April 2011 to October 2016

Sponsor: Maruho ***PI:*** ***Phase: 2B***
A Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Multi-Center Phase IIb dose finding study of M518101 in plaque psoriasis patients – M518101-US01
March 2011 to March 2012

Sponsor: Schering-Plough/Merck ***PI:*** ***Phase: 2***
A Phase II, Randomized, Double-Blinded, Placebo-Controlled, Parallel-Design, Dose-Range Finding Study of Subcutaneous SCH 900222 in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis - P05495
December 2010 to January 2013

Sponsor: LEO Pharma ***PI:*** ***Phase:***
Calcipotriol plus betamethasone dipropionate topical suspension compared to betamethasone dipropionate in the topical suspension vehicle, calcipotriol in the topical suspension vehicle and the topical suspension vehicle alone in psoriasis vulgaris – LEO 80185-G23
September 2010 to July 2011

Sponsor: Celgene Corporation ***PI:SAF*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Efficacy And Safety Study Of Apremilast (CC-10004) In Subjects With Moderate To Severe Plaque Psoriasis – CC-1004-PSOR-008
August 2010 to October 2016

Sponsor: **Wyeth** **PI:** **Phase: 1**
A Phase I, Single Dose Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Clinical Activity of ILV-095 Administered Subcutaneously to Subjects With Psoriasis – 3226K1-1002-WW
April 2010 to September 2011

Sponsor: Amgen ***PI:*** ***Phase: 3***
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Adding Methotrexate to Etanercept in Subjects With Moderate to Severe Plaque Psoriasis - 20070559
February 2010 to February 2011

Sponsor: Astellas Pharma Inc. ***PI:*** ***Phase:***
Assessment and Tracking of Long-term Alefacept (LFA-3IgG1 Fusion Protein) Safety (ATLAS)
August 2009 to September 2012

Sponsor: Celgene Corporation ***PI:*** ***Phase: 2B***
A Phase IIb, Multicenter, Treatment-Arm Blind, Safety And Efficacy 32-Week Extension Study Of Apremilast (CC-10004) In Subjects Who Completed The Treatment Phase Of The Core Study CC-10004-PSOR-005 – CC-10004-PSO-005E
April 2009 to December 2010

Sponsor: Eli Lilly and Company ***PI:*** ***Phase: 1***
A Phase I, LY2439821 (Anti-IL-17 Humanized Antibody) Multiple-Dose Safety and Tolerability Study in Subjects with Psoriasis Vulgaris – I1F-MC-RHAG
January 2009 to June 2010

Sponsor: Abbott Laboratories ***PI:*** ***Phase:***
A 10-Year, Post-marketing, Observational Study of HUMIRA® (Adalimumab) in Patients with Chronic Plaque Psoriasis (ESPRIT) – P10-023
November 2008 to Present

Sponsor: Celgene Corporation ***PI:*** ***Phase: 2B***
A Phase IIb, Multicenter, Randomized, Double-blind, Placebo-controlled, Dose-Ranging, Efficacy and Safety Study of Apremilast (CC-10004) in Subjects with Moderate to Severe Plaque-Type Psoriasis – CC-10004-PSO-005
October 2008 to January 2010

Sponsor: Novo Nordisk ***PI:*** ***Phase: 1***
A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Dose, Dose-Escalation Trial of Anti-IL-20 (109-0012) 100 mg/vial in psoriatic subjects, followed by an expansion phase – NN8226-1848

October 2008 to January 2011

Sponsor: Genzyme Corporation ***PI:*** ***Phase:***
A Multicenter, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Assess the Efficacy and Safety of Doxercalciferol Capsules in the Treatment of Subjects with Moderate to Severe Chronic Plaque Psoriasis – HECTPSO2507
August 2008 to 2009

Sponsor: Centocor, Inc. ***PI:*** ***Phase:***
A Multicenter, Open Registry of Patients with Psoriasis Who Are Candidates for Systemic Therapy Including Biologics (PSOLAR) – C0168Z03
May 2008 to Present

Sponsor: Abbott Laboratories ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study Comparing the Efficacy and Safety of ABT-874 to Etanercept and Placebo in Subjects with Moderate to Severe Chronic Plaque Psoriasis – M10-114
March 2008 to 2009

Sponsor: Abbott Laboratories ***PI:*** ***Phase: 3***
A Phase III Multicenter, Open-Label Continuation Study in Moderate to Severe Chronic Plaque Psoriasis Subjects who completed a Preceding Psoriasis Study with ABT-874 - M10-016
March 2008 to March 2012

Sponsor: Genentech, Inc. ***PI:*** ***Phase: 4***
A Phase IV Randomized, Double-Blind, Placebo Controlled Study To Evaluate the Safety and Efficacy of XXXXX in Adult Patients with Moderate to Severe Plaque Psoriasis with Involvement of the Scalp.
March 2008 to 2009

Sponsor: Abbott Laboratories ***PI:*** ***Phase: 3***
Open-label Study of Adalimumab in Subjects Who Have a Sub-optimal Response to Systemic Therapy or Phototherapy.
November 2007 to November 2009

Sponsor: Abbott Laboratories ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of Two Dosing Regimens of ABT-874 to Placebo in Subjects with Moderate to Severe Chronic Plaque Psoriasis.
October 2007 to October 2009

Sponsor: Wyeth ***PI:*** ***Phase: 1***
A Phase I, Ascending Multiple Dose Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Clinical Efficacy of ILV-094 Administered Subcutaneously or Intravenously to Subjects With Psoriasis
October 2007 to June 2010

Sponsor: Centocor, Inc. ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized Study Comparing CNTO 1275 and Etanercept for the Treatment of Moderate to Severe Plaque Psoriasis. (T12)
March 2007 to October 2009

Sponsor: Amgen, Inc. ***PI:*** ***Phase:***
Observational Post-Marketing Safety Surveillance Registry of Etanercept for the Treatment of Psoriasis. (OBSERVE)
July 2006 to Present

Sponsor: Genentech, Inc. ***PI:*** ***Phase: 4***
A Phase IV Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of

1.0 mg/kg Efalizumab in Adult Subjects with Chronic Moderate or Worse Plaque Psoriasis Who Have Had an Inadequate Response to an Anti-TNF Agent
July 2006 to August 2007

Sponsor: Galderma Laboratories, L.P. ***PI:*** ***Phase: 4***
A Phase IV, Open-Label Multicenter Community-Based 4-Wk Trial to Assess Efficacy, Tolerance to Tx & Patient Satisfaction w/ CLOBEX® Spray When Used as Mono- or Add-on Therapy to Existing Systemic/Topical Agents for Tx of Plaque Psoriasis
February 2006 to June 2006

Sponsor: Centocor, Inc. **PI:** **Phase: 3**
A Phase III Trial Evaluating the Efficacy and Safety of CNTO1275 in the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis. (T09)
January 2006 to December 2011

Sponsor: Genentech, Inc. ***PI:*** ***Phase: 4***
A Phase IV Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of 1.0 mg/kg Efalizumab in Adult Patients with Moderate to Severe Plaque Psoriasis Involving the Hands and/or Feet
January 2006 to April 2007

Sponsor: Centocor, Inc. ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial Evaluating the Efficacy and Safety of CNTO 1275 in the Treatment of Subjects with Moderate to Severe Plaque-type to Severe Plaque-type Psoriasis (T08)
January 2006 to July 2011

Sponsor: Abbott Laboratories ***PI:*** ***Phase: 2***
A Phase II, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of Subcutaneous Injections of ABT-874 vs. Placebo in Subjects with Moderate to Severe Chronic Plaque Psoriasis.
December 2005 to September 2008

Sponsor: Astellas Pharma US, Inc. ***PI:*** ***Phase: 3***
A Phase III, Long-Term, Open Label Study to Evaluate the Safety of Twice-Daily Tacrolimus Cream-B in the Treatment of Psoriasis
September 2005 to April 2007

Sponsor: Genentech, Inc. ***PI:*** ***Phase:***
Raptiva Epidemiologic Study of Psoriasis Outcomes and Safety Events (RESPONSE) in Patients with Chronic Moderate to Severe Plaque Psoriasis.
April 2004 to November 2009

Sponsor: Abbott Laboratories ***PI:*** ***Phase: 3***
A Phase III, Multicenter Study of the Efficacy and Safety of Long-Term Adalimumab Treatment in Subjects with Moderate to Severe Chronic Plaque Psoriasis.
October 2004 to December 2005

Sponsor: Centocor, Inc. ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Trial Evaluating the Efficacy and Safety of Infliximab Induction Therapy Followed by Multiple Regimens of Maintenance Infliximab Therapy in Subjects with Plaque-type Psoriasis
February 2004 to June 2005

Sponsor: Amgen, Inc. ***PI:*** ***Phase: 4***
A Multicenter, Open-Label, Prospective Study to Evaluate the Effectiveness and Safety of Etanercept in the Treatment of Subjects with Psoriasis
March 2004 to November 2004

Kenneth W. Dawes, MD

Sponsor: Fujisawa Healthcare, Inc. ***PI:*** ***Phase: 3***
A Phase III, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Once Daily 0.3% FK506 Gel versus Gel Vehicle in the Treatment of Psoriasis
March 2004 to November 2004

Sponsor: Centocor, Inc. ***PI:*** ***Phase: 2***
A Phase II, Randomized, Double-blind, Placebo-controlled, Parallel Study of Single and Multiple Dosing Regimens with Subcutaneous CNTO 1275 (Human Monoclonal Antibody to IL-12) in Subjects with Moderate to Severe Psoriasis
November 2003 to June 2005

Sponsor: Genentech, Inc. ***PI:*** ***Phase: 4***
An Open-Label, Multicenter Study to Evaluate the Safety of 1.0 mg/kg Subcutaneously Administered Efalizumab in Adults with Plaque Psoriasis Previously Enrolled in Study ACD2600g.
September 2002 to March 2004

Sponsor: Genentech, Inc. ***PI:*** ***Phase: 3B***
A Phase IIIb, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Evaluate the Safety of 1.0 mg/kg Subcutaneously Administered Efalizumab in Adults with Moderate to Severe Plaque Psoriasis Who Are Candidated for Systemic Therapy.
September 2002 to January 2003

Sponsor: Amgen, Inc. ***PI:*** ***Phase: 4***
A Multicenter, Open-Label to Observe the Effects of XXXXX on Joint and Skin Disease in Subjects with Psoriatic Arthritis
July 2003 to August 2004

Sponsor: Novartis ***PI: KWD*** ***Phase: 3***
A randomized, double-blind, placebo- and active controlled multi-center trial to demonstrate efficacy of subcutaneous secukinumab compared to placebo and etanercept (in a single-blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in subjects from 6 to less than 18years of age with severe chronic plaque psoriasis. – CAIN457A2310
February 2018- October 2018

Sponsor: Evidera ***PI: SAF*** ***Registry***
Concept Elicitation and Cognitive Interviews Among Pediatric Patients with Plaque Psoriasis. – EVA-20259
December 2017- October 2018

Sponsor: Galderma ***PI: SAF*** ***Phase: 4***
A Multicenter Open Label Uncontrolled Study of the long term safety and efficacy of calcitriol 3 mcg/g ointment applied twice daily for 26 weeks in pediatric subjects (2 to 16 years and 11 months of age) with mild to moderate plaque psoriasis. – RD.06.SPR.18131
June 2016- August 2018

Sponsor: Galderma R&D, LLC ***PI:*** ***Phase:***
Pharmacokinetics and pharmacodynamics of calcitriol 3mcg/g ointment applied twice daily for 14 days under conditions of maximal use in pediatric subjects (2 to 12 years of age) with plaque psoriasis – RD.06.SPR.18104
April 2013 to February 2016

Sponsor: Regeneron ***PI: SAF*** ***Phase 3***
An open-label extension study to assess the long-term safety and efficacy of dupilumab in patients ≥6 months to <18 years of age with Atopic dermatitis R668-AD-1434
August 2017- Present

Sponsor: Janssen ***PI: KWD*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis- CNTO1959PSA3002
July 2017- July 2018

Sponsor: Janssen ***PI: KWD*** ***Phase:3***
A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis including those Previously Treated with Biologic Anti-TNFα Agent(s): CNTO1959PSA3001
July 2017- July 2018

Sponsor: AbbVie ***PI: SAF*** ***Phase:***
Cross-Sectional Observational Study Evaluating Clinical Specialty Setting as Determinant of Management in Patients with Psoriatic Arthritis – H15-457
March 2017- October 2017

Sponsor: Janssen Research and Development PI: SAF ***Phase: 2A***
A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects With Active Psoriatic Arthritis – CNTO1959PSA2001
April 2015 to March 2017

Sponsor: Janssen Research and Development PI: ***Phase: 3***
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Golimumab, an Anti-TNFα Monoclonal Antibody, Administered Intravenously, in Subjects with Active Psoriatic Arthritis – CNTO148PSA3001
August 2014 to September 2015

Sponsor: Novartis Pharmaceuticals ***PI: KWD*** ***Phase: 3***
A Phase III, Randomized, Double-Blind, Placebo-Controlled Multicenter Study of subcutaneous secukinumab in autoinjectors, to demonstrate efficacy at 24 weeks and to assess the long term safety, tolerability and efficacy up to 3 years in subjects with active Psoriatic Arthritis – CAIN457F2318
June 2014 to September 2018

Sponsor: Celgene Corporation ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of Two Doses Of Apremilast (CC-10004) In Subjects With Active Psoriatic Arthritis And A Qualifying Psoriasis Lesion – CC-10004-PSA-004
January 2011 to December 2012

Sponsor: Centocor, Inc **PI:** **Phase: 3**
A Phase III Multicenter, Randomized, Double Blind, Placebo Controlled Trial of Ustekinumab, a Fully Human Anti IL -12p40 Monoclonal Antibody, Administered Subcutaneously in Subjects With Active Psoriatic Arthritis and Previously Treated With Biologic Anti-TNF Agent(s) – CNTO1275PSA3002
November 2010 to November 2012

Sponsor: Centocor, Inc **PI:** **Phase: 3**
A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Ustekinumab, a Fully Human Anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Psoriatic Arthritis – CNTO1275PSA3001
February 2010 to August 2013

Sponsor: Centocor, Inc. ***PI:*** ***Phase: 2***
A Phase II, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of XXXXX a Fully Human

Anti-IL-12 Monoclonal Antibody, Administered Sub-Cutaneously, in Subjects with Active Psoriatic Arthritis. (T10)
January 2006 to November 2007

Sponsor: Lilly ***PSI: SAF*** ***Phase: 2***
Protocol J1P-MC-KFAD(a) A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous LY3471851 in Patients with Atopic Dermatitis
September 2019- Present

Sponsor: Pfizer ***PSI: SAF*** ***Phase: 3B***
Protocol Number B7451050: A PHASE 3B RANDOMIZED, DOUBLE-BLIND, DOUBLE DUMMY, ACTIVE CONTROLLED MULTI-CENTER STUDY ASSESSING THE EDICACY AND SAFETY OF ABROCITINIB COMPARED WITH DUPILUMAB IN ADULT PARTICIPANTS ON BACKGROUND TOPICAL THERAPY WITH MODERATE TO SEVERE ATOPIC DERMATITIS
January 2020- Present

Sponsor: Galderma ***PI: SAF*** ***Phase: 2/3***
RD.o6.SPR.118380
Protocol Title: A Randomized, Double-Blind, Placebo-Controlled Study to Assess Immunization Responses in Adult and Adolescent Subjects with Moderate-to-Severe Atopic Dermatitis Treated with Nemolizurnab
December 2019- Present

Sponsor: Rapt ***PI: KWD*** ***Phase: 1***
Title: A phase 1, randomized, double-blind, placebo-controlled, single-does escalation, multiple-dose escalation, and food effect study of RPT193 in healthy subjects and patients with moderate to severe dermatitis
December 2019- Present

Sponsor: Abbvie ***PI: SAF*** ***Phase: 1***
M16-049: An Open-lable Multiple-Dose Study to Evaluate the Pharmacokinetics, Safety and Tolerablility of Upadacitinib in Pediatric Subjects with Severe Atopic Dermatitis
October 2019- Present

Sponsor: Arcutis ***PI: KWD*** ***Phase: 2***
TITLE: A Phase 2, 4-week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-151 Cream 0.05% and ARQ-151 Cream 0.15% Administered QD in Adolescent and Adult Subjects with Atopic Dermatitis
May 2019- Present

Sponsor: Galderma ***PI: SAF*** ***Phase: 2/3***
RD.06.SPR.118161
A randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD 14152) in Subjects with Moderate-to-severe Atopic Dermatitis
July 2019- Present

Sponsor: AbbVie ***PI: SAF*** ***Phase: 3b***
Protocol M16-046: A Phase 3b Multicenter, Randomized, Double-Blind, Double-Dummy, Active Controlled Study Comparing the Safety and Efficacy of Upadacitinib to Dupilumab in Adult Subjects with Moderate to Severe Atopic Dermatitis
May 2019- Present

Sponsor: Arcutis ***PI: KWD*** ***Phase: 2***
TITLE: A Phase 2, 4-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-151 Cream 0.05% and AFQ-151 Cream 0.15% Administered QD in Adolescent and

Adult Subjects with Atopic Dermatitis
July 2019- Present

Sponsor: Sanofi/IQVIA ***PI: SAF*** ***Phase:***
EVALUATION OF BIOMARKERS OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH TOPICAL PRESCRIPTION THERAPIES OR WHEN THOSE THERAPIES ARE NOT MEDICALLY ADVISABLE
April 2019- Present

Sponsor: Galapagos ***PI: KWD*** ***Phase: 2***
MORE106-CL-204 A randomized, double-blind, placebo-controlled, multicenter Phase 2 study to evaluate the safety and tolerability of subcutaneous MOR 106 administered concomitantly with topical corticosteroids for eight weeks, in adult subjects with moderate to serve atopic dermatitis
February 2019- Present

Sponsor: LEO ***PI: SAF*** ***Phase: 1***
LP0133-1181: A phase 1 open-label, multi-center, single-arm trial to evaluate the safety and pharmacokinetics (including MUsT) of twice daily topical application of digacetinin cream for 8 weeks in adults, adolescents, and children with moderate to severe atopic dermatitis
February 2019- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase: 3***
A PHASE 3, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, MULTI-CENTER STUDY INVESTIGATION THE EFFICACY AND SAFETY OF PF 04965842 CO ADMINISTERED WITH BACKGROUND MEDICATED TOPICAL THERAPY IN ADOLESCENT PARTICIPANTS 12 TO <18 YEARS OF AGE WITH MODERATE-TO-SEVERE ATOPICAL DERMATITIS B7451036, site 1006
January 2019- Present

Sponsor: Ralexar ***PI: KWD*** ***Phase: 2***
A PHASE 2, RANDOMIZED, DOUBLE-BLIND, VEHICLE CONTROLLED, PARALLEL-GROUP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF ALX-101 TOPICAL GEL ADMINISTERED TWICE DAILY IN ADULT AND ADOLESCENT SUBJECTS WITH MODERATE ATOPIC DERMATITIS
Code Number: ALX-101-ATOP-204
March 2019 – January 2020

Sponsor: Kyowa Hakko ***PI: SAF*** ***Phase: 2***
4803-006 – A Phase 2, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-Controlled Study of an Anti-OX 40 Monoclonal Antibody (KHK4083) in Subjects with Moderate to Severe Atopic Dermatitis.
December 2018- Present

Sponsor: Kiniksa ***PI: KWD*** ***Phase: 1b***
A Phase Ib, Double-Blind, Randomized, Placebo-Controlled Study to Assess the Safety, Tolerability, and Pharmacokinetics of Single and Repeated Doses of KPL-716
October 2018- July 2019

Sponsor: Incyte ***PI: SAF*** ***Phase: 3***
A Phase 3, Double-blind, Randomized, 8-Week, Vehicle-Controlled Efficacy and Safety Study of Ruxolitinib Cream Followed by a Long-Term Safety Extension Period in Adolescents and Adults with Atopic Dermatitis
March 2019 - Present

Sponsor: Asana ***PI: KWD*** ***Phase: 2***
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 2 STUDY TO EVALUATE THE EFFICACY, SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF ASN002 IN SUBJECTS WITH SEVERE CHRRONIC HAND ECZEMA REFRACTORY TO TOPICAL CORTICOSTEROID THERAPY
November 2018-Present

Kenneth W. Dawes, MD

Sponsor: XBiotech ***PI: KWD*** ***Phase: 2***
A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Bermekimab in Patients with Moderate to Severe Atopic Dermatitis
Number of Patient consent: 4
February 2020- Present

Sponsor: Qurient ***PI: SAF*** ***Phase: 2***
Q301-AD-P2-US002 A MULTICENTER, RANDOMIZED, PHASE 2, DOUBLE-BLIND, VEHICLECONTROLLED,
PARALLEL GROUP COMPARISON STUDY TO EVALUATE THE SAFETY AND EFFICACY OF Q301 CREAM IN ADOLESCENTS AND ADULTS WITH MILD TO MODERATE ATOPIC DERMATITIS
Number of Patient Consent: 9
September 2018- January 2020

Sponsor: BMX ***PI: KWD*** ***Phase:***
A Randomized, Placebo-Controlled, Dose-Escalation Trial to Evaluate the Safety, Clinical Effects, and Systemic Exposure of a Topical Application of BMX-010 in Subjects with Atopic Dermatitis and Plaque Psoriasis
Number of Patient consented: 6
August 2018- present

Sponsor: Abbvie ***PI: SAF*** ***Phase: 3***
Clinical Study Protocol M16-045: A Phase 3 Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Upadacitinib in Adolescent and Adult Subjects with Moderate to Severe Atopic Dermatitis
Number of Patients consented: 7
May 2018- Present

Sponsor: LEO ***PI: KWD*** ***Phase: 3***
Long-term extension trial for in patients previously treated with Tralokinumab monotherapy for moderate to severe atopic dermatitis.
Number of Patient consented: 6
November 2018- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase:3***
A PHASE 3 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, MULTI-CENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PF-04965842 MONOTHERAPY IN SUBJECTS AGED 12 YEARS AND OLDER, WITH MODERATE TO SEVERE ATOPIC DERMATITIS- B7451013
Number of patient consented : 0
September 2018- June 2019

Sponsor: Sanofi ***PI: SAF*** ***Registry***
Prospective, observational, longitudinal study in pediatric patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not medically advisable- OBS15333

December 2018-Present

Sponsor: Asana ***PI: KWD*** ***Phase: 2***
A Phase 2, Multicenter, Open-Label Extension Study to Evaluate the long-term Safety, Tolerability and Efficacy of ASN002 in Subjects with Moderate to Severe Atopic Dermatitis.- ASN002AD-201-EXT
November 2018- Present

Sponsor: Eli Lilly ***PI: SAF*** ***Phase: 3***
A Multicenter, Open-Label, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Moderate to Severe Atopic Dermatitis - I4V-MC-JAIX

January 2019- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase 3***
A PHASE 3 RANDOMIZED WITHDRAWAL, DOUBLE BLIND, PLACEBO CONTROLLED, MULTI CENTER STUDY INVESTIGATING THE EFFICACY AND SAFETY OF PF 04965842 IN SUBJECTS AGED 12 YEARS AND OVER, WITH MODERATE TO SEVERE ATOPIC DERMATITIS WITH THE OPTION OF RESCUE TREATMENT IN FLARING SUBJECTS- B7451014
August 2018- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase: 3***
A PHASE 3 RANDOMIZED, DOUBLE-BLIND, MULTI-CENTER, LONG-TERM EXTENSION STUDY INVESTIGATING THE EFFICACY AND SAFETY OF PF-04965842, WITH OR WITHOUT TOPICAL MEDICATIONS, ADMINISTERED TO SUBJECTS AGED 12 YEARS AND OLDER WITH MODERATE TO SEVERE ATOPIC DERMATITIS- B7451015
June 2018- Present

Sponsor: Asana **PI: KWD** **Phase: 2B**
A Randomized, Double-Blind, Placebo-Controlled, Phase 2B Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of ASN002 in Subjects with Moderate to Severe Atopic Dermatitis ASN002AD-201
April 2018-September 2019

Sponsor: Eli Lilly ***PI: SAF*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Moderate to Severe Atopic Dermatitis. I4V-MC-JAIW
April 2018- Present

Sponsor: Novan ***PI: SAF*** ***Phase: 1b***
A Phase 1b Multi-Center, Double-Blind, Randomized, Vehicle-Controlled Study Assessing the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of SB414 in Subjects with Atopic Dermatitis. NI-AD101
February 2018- June 2018

Sponsor: Dermira ***PI: SAF*** ***Phase: 2b***
A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Lebrikizumab in Patients with Moderate to Severe Atopic Dermatitis. DRM06-AD01
February 2018- July 2019

Sponsor: Pfizer ***PI: SAF*** ***Phase: 3***
A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Evaluate the Efficacy and Safety of PF-04965842 Monotherapy in Subjects Aged 12 Years and Older, with Moderate to Severe Atopic Dermatitis. B7451012
February 2018- May 2019

Sponsor: Dermavant ***PI: KWD*** ***Phase: 1b***
Open-Label Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of RVT-501 Topical Ointment in Pediatric Patients with Atopic Dermatitis. RVT-501-2007
February 2018 – August 2018

Sponsor: Pfizer ***PI: SAF*** ***Phase: 1***
A Phase 1, Randomized, Double-Blind, Therapy-Party Open, Placebo-Controlled, Dose Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single, and/or Mutliple Intravenous and/or Subcutaneous Doses of PF-06817024 in Healthy Subjects who may be Mildly Atopic, Subjects with Chronic Rhinosinusitis with Nasal Polyps, and Subjects with Moderate-Severe Atopic Dermatitis. C0341001
January 2018- Present

Sponsor: Regeneron ***PI: SAF*** ***Phase: Observation***
A PROSPECTIVE OBSERVATIONAL STUDY OF ADULT PATIENTS RECEIVING DUPIXENT® FOR ATOPIC DERMATITIS- R668-AD-1762
January 2018-March 2018

Sponsor: Leo ***PI: KWD*** ***Phase: 2***
Tralokinumab monotherapy for moderate to severe atopic dermatitis: LP0162-1326
August 2017- October 2019

Sponsor: Regeneron ***PI: SAF*** ***Phase: 2***
A Randomized, Double-Blind, Placebo-Controlled Study To Investigate The Efficacy And Safety Of Dupilumab Monotherapy In Patients ≥12 To <18 Years Of Age, With Moderate-To-Severe Atopic Dermatitis: R668-AD-1526
August 2017-July 2018

Sponsor: Regeneron ***PI: SAF*** ***Phase: 1***
An Open-Label, Randomized, Actual Use Study of Dupilumab Auto-Injector Device in Patients with Atopic Dermatitis- R668-AD-1607
May 2017- April 2018

Sponsor: GSK ***PI: SAF*** ***Phase: 2***
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Investigate the Efficacy and Safety of Mepolizumab Administered Subcutaneously in Subjects with Moderate to Severe Atopic Dermatitis- 205050
November 2016- January 2018

Sponsor: Incyte ***PI: KWD*** ***Phase: 2***
A Phase II, Randomized, Dose-Ranging, Vehicle-Controlled and Triamcinolone 0.1% Cream- Controlled Study to Evaluate the Safety and Efficacy of INCB018424 Phosphate Cream Applied Topically to Adults with Atopic Dermatitis.- INCB18424-206
April 2017- May 2018

Sponser: Pfizer ***PI: SAF*** ***Phase: 2B***
A Phase IIb Randomized, Double-Blind, Placebo-Controlled, Parallel, Multicenter, Dose-Ranging, Study to Evaluate the Efficacy and Safety Profile of PF-04965842 in subjects with Moderate to Severe Atopic Dermatitis.- B7451006
April 2016- May 2017

Sponsor: GlaxoSmithKline ***PI: SAF*** ***Phase: 2***
A Randomized, Blinded, Vehicle-Controlled, Dose-Finding Study of GSK2894512 Cream for the Treatment of Atopic Dermatitis - 203121
February 2016 to March 2017

Sponsor: MedImmune, Limited ***PI: SAF*** ***Phase: 2A***
A Phase IIa, Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MEDI9929 in Adult Subjects with Moderate-to-Severe Atopic Dermatitis - D5240C00001
August 2015 to September 2016

Sponsor: Regeneron Pharmaceuticals, Inc. PI: SAF ***Phase: 3***
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Investigating the Efficacy and Safety of Multiple Dupilumab Dose Regimens Administered as Monotherapy for Maintaining Treatment Response in Patients with Atopic Dermatitis - R668-AD-1415
July 2015 to February 2017

Sponsor: Regeneron Pharmaceuticals, Inc. PI: SAF ***Phase: 3***
An Open-Label Study of Dupilumab in Patients with Atopic Dermatitis Who Participated In Previous

Dupilumab Clinical Trials - R668-AD-1225
June 2015 to September 2017

Sponsor: Regeneron Pharmaceuticals PI: SAF Phase: 3
A Phase III Confirmatory Study Investigating the Efficacy and Safety of Dupilumab Monotherapy Administered to Adult Patients with Moderate-to-Severe Atopic Dermatitis – R668-AD-1334
February 2015 to June 2016

Sponsor: Regeneron Pharmaceuticals, Inc. PI: Phase: 2
A Randomized, Double-Blind, Placebo-Controlled, Study Investigating Vaccine Responses in Adults with Moderate to Severe Atopic Dermatitis Treated with Dupilumab – R668-AD-1314
September 2014 to December 2015

Sponsor: Anacor Pharmaceuticals, Inc. PI: Phase: 3
A Multicenter, Open-Label Study of the Long-Term Safety of AN2728 Topical Ointment, 2% in the Treatment of Children and Adolescents (Ages 2–17 Years) With Atopic Dermatitis - AN2728-AD-303
February 2014 – November 2015

Sponsor: Anacor Pharmaceuticals, Inc. PI: Phase: 3
A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Study of the Safety and Efficacy of AN2728 Topical Ointment, 2% in Children, Adolescents, and Adults (Ages 2 Years and Older) With Atopic Dermatitis - AN2728-AD-302
February 2014 – August 2015

Sponsor: Chugai Pharmaceutical Co., Ltd. PI: SAF Phase: 2
A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Efficacy of CIM331 in Atopic Dermatitis Patients Who Are Inadequately Controlled or Intolerant to Topical Therapy – CIM003JG
November 2013 to October 2016

Sponsor: Anacor Pharmaceuticals, Inc. PI: Phase:
An Open-Label Study to Determine the Safety, Tolerability, and Pharmacokinetic Profile of AN2728 Ointment in Adolescents with Atopic Dermatitis – AN2728-AD-203
May 2012 to November January 2013

Sponsor: Novartis PI: Phase: 1
A first-in-human Study to evaluate safety and tolerability of repeated topical administrations of BPR277 ointment in healthy volunteers, and safety, tolerability, and preliminary efficacy of multiple topical administrations of BPR277 in patients with atopic dermatitis and Netherton syndrome – CBPR277X2101
October 2011 to February 2013

Sponsor: Astellas Pharma Inc PI: KWD Phase:
APPLES: A Prospective Pediatric Longitudinal Evaluation to Assess the Long-Term Safety of Tacrolimus Ointment for the Treatment of Atopic Dermatitis – FHI-03-0-161/FG-506-06-37
June 2010 to October 2012

Sponsor: Novartis PI: Phase:
A Prospective 10 Year Observational Registry of Pediatric Subjects (Age Greater Than or Equal to Two to Age Less Than or Equal to 17 Years) With Atopic Dermatitis Who Have Used Pimecrolimus 1% Cream (PEER Registry)
March 2010 to December 2012

Sponsor: Taro Pharmaceuticals USA, Inc./Novum PI: Phase:
A Randomized, Double-Blind, Placebo Controlled, Parallel Design, Multiple-Site Clinical Study to Evaluate the Bioequivalence of Two Tacrolimus 0.1% Topical Ointment Formulations in Patients With Moderate to Severe Atopic Dermatitis – TACR-0707
November 2008 to August 2009

Sponsor: Ceragenix ***PI:*** ***Phase:***
A Prospective, Randomized, Investigator-Blind, Controlled, Pilot Study Comparing The Effect of the EpiCeram Device versus Conservative Standard of Care Therapy Utilizing Mid-Strength Topical Steroid XXXXX in the Treatment of Atopic Dermatitis in Pediatric Subjects
November 2006 to May 2007

Sponsor: Cutanea Life Sciences, Inc. ***PI: SAF*** ***Phase: 3***
A Phase III Open-Label Extension Study to Evaluate the Long-Term Safety of Omiganan Topical Gel in Subjects with Rosacea - CLS001-CO-PR-006
December 2015 to March 2018

Sponsor: Cutanea Life Sciences, Inc. ***PI:*** ***Phase: 2***
A Phase II, Randomized, Vehicle-Controlled, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of Three Once-Daily CLS001 Topical Gels Versus Vehicle Administered for 12 Week to Subjects with Papulopustular Rosacea – CLS001-CO-PR-001
March 2013 to April 2014

Sponsor: Galderma Research and Development, Inc. ***PI:*** ***Phase: 3***
A Phase III Randomized, Double-Blind, 12-week Vehicle-Controlled, Parallel-Group Study assessing the efficacy and safety of CD5024 1% cream versus vehicle cream in subjects with papulopustular rosacea, followed by a 40-week investigator-blinding extension comparing the long-term safety of CD5024 1% cream versus azelaic acid 15% gel – RD.06.SPR-18171
March 2012 to September 2013

Sponsor: Galderma ***PI:*** ***Phase: 4***
A Phase IV, Open-Label, Multicenter, Community-Based, 12-Week Trial Assessment of Effectiveness, Safety, and Subject Satisfaction With Oracea® [Doxycycline, USP] Capsules 40 mg (30 mg Immediate Release & 10 mg Delayed Release Beads) When Used as Monotherapy or as Add-On Therapy to Existing Topical Regimens for the Treatment of Rosacea – GLI.04.SPR.US10120
June 2009 to November 2009

Sponsor: Medicis ***PI:*** ***Phase: 4***
R# Trial, Phase IV Evaluation of the Effectiveness of XXXXX in Patients with Rosacea
December 2000

Sponsor: Symbio ***PI: KWD*** ***Phase: 2***
A Multicenter, Randomized, Double-Blind, Parallel-Group, Vehicle-Controlled Study of the Safety and Efficacy of DFD-03 Lotion in the Treatment of Acne Vulgaris for 12 Weeks DFD-03-CD-006
August 2017- July 2018

Sponsor: Foamix ***PI: KWD*** ***Phase: 2***
A Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Efficacy and Safety of Topical Administration of FMX101 for 12 Weeks in the Treatment of Moderate-to-Severe Acne Vulgaris FX2017-22
July 2017- September 2018

Sponsor: Foamix ***PI: SAF*** ***Phase: 3***
A Randomized, Double-Blind Study to compare the efficacy, safety and Long-term safety of topical administration or FMX-101 for 1 year in the treatment of Moderate-to-Severe Acne Vulgaris. FX2014-05
July 2016- April 2017

Sponsor: Valeant ***PI: KWD*** ***Phase: 1B***
A Phase Ib Open-Label, Randomized Study Evaluating the Absorption and Systemic Pharmacokinetics of Topically Applied IDP-123 Lotion in Comparison with Tazorac Cream 0.1% in Subjects with Acne Vulgaris under Maximal Use Conditions. – V01-121A-501

June 2016- March 2017

Sponsor: Dow Pharmaceutical Sciences ***PI: SAF*** ***Phase: 3***
A Phase III, Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, 2-Arm, Parallel Group Comparison Study Comparing the Efficacy and Safety of IDP-121 and IDP-121 Vehicle Lotion in the Treatment of Acne Vulgaris - V01-121A-302
October 2015 to May 2017

Sponsor: Ranbaxy ***PI: KWD*** ***Phase: 4***
A Phase IV Open-Label Study Evaluating the Long-term Efficacy, Quality of Life, and Safety of ABSORICA® (isotretinoin) Capsules Administered Without Food in Patients With Severe Recalcitrant Nodular Acne - ABS1517LT
February 2015 to April 2018

Sponsor: Allergan (North America) ***PI:*** ***Phase: 3***
A Safety and Efficacy Study to Compare Dapsone Dermal Gel with Vehicle Control in Patients with Acne Vulgaris – 225678-007
January 2014 to January 2015

Sponsor: Taro Pharmaceuticals ***PI:*** ***Phase:***
A Multicenter, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Taro Pharmaceuticals, Inc.'s Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5% to the Reference Listed Acanya® (Clindamycin Phosphate and Benzoyl Peroxide) Gel, 1.2%/2.5%, and both Active Treatments to a Vehicle Control in the Treatment of Acne Vulgaris - CLBG1210
January 2013 to February 2014

Sponsor: Warner Chilcott ***PI:*** ***Phase:***
A Randomized, Multicenter, Double-Blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of 3 Different doses of a Novel Tetracycline, Compared to Placebo in Treatment of Facial Acne Vulgaris – PR-10411
May 2012 to December 2012

Sponsor: Dow Pharmaceutical Sciences, Inc ***PI:*** ***Phase: 2***
A Phase II, Multicenter, Randomized, Double-Blind, Dose-Ranging Study to Evaluate IDP-107 Versus Placebo in the Treatment of Severe Acne Vulgaris with Nodules – DPSI-IDP-107-P2-02
August 2010 to June 2011

Sponsor: Stiefel, a GSK company ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of Tazarotene Foam, 0.1%, in Subjects With Acne Vulgaris – W0260-301
October 2009 to January 2011

Sponsor: Cipher Pharmaceuticals ***PI:*** ***Phase: 3***
A Double-Blind, Randomized, Phase III, Parallel Group Study Evaluating the Efficacy and Safety of CIP-Isotretinoin in Patients with Severe Recalcitrant Nodular Acne – ISOCT.08.01
October 2009 to October 2011

Sponsor: Stiefel Laboratories ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-blind, Active and Vehicle-Controlled Study of the Safety and Efficacy of Duac Low-Dose Gel Versus Clindamycin Gel versus Benzoyl Peroxide Gel versus Vehicle Gel in Subjects with Acne Vulgaris – W0261-301
October 2008 to 2009

Sponsor: Novum Pharmaceutical Research ***PI:*** ***Phase:***
A Randomized, Double-Blind, Multiple-Site, Placebo-Controlled Study Comparing XXXXX to XXXXX in the Treatment of Moderate to Severe Acne Vulgaris.

October 2007 to September 2008

Sponsor: Galderma R&D Inc. ***PI:*** ***Phase:***
A Multi-Center, Randomized, Double-Blind, Parallel Group Study to Demonstrate Safety and Efficacy of a Fixed-Combination of a Topical Retinoid and Benzoyl Peroxide 2.5% Gel Compared With the Monads and Corresponding Topical Gel Vehicle.
October 2006 to June 2007

Sponsor: Johnson & Johnson ***PI:*** ***Phase: 4***
A Open-label, Community Based, Phase IV Study to Assess Facial Acne Improvement with Use of RETIN-A MICRO® (Tretinoin Gel) Microsphere, 0.04% or 0.1% in a Pump Dispenser
September 2006 to June 2007

Sponsor: Allergan ***PI:*** ***Phase:***
A Clinical Evaluation of XXXXX Indicated for the Topical Treatment of Patients with Acne Vulgaris, Who Do Not Want To or Are Unable to participate in the iPLEDGE Program.
May 2006 to July 2006

Sponsor: Concordia Clinical Research, Inc. ***PI:*** ***Phase: 4***
A Phase IV, Open-Label, Multicenter, Community-based, 4-Week Trial Assessing Efficacy, Tolerance to Treatment, and Subject Satisfaction with XXXXX.
March 2006 to June 2006

Sponsor: Elorac, Inc ***PI: KWD*** ***Phase: 2***
A Double-Blind, Randomized, Placebo-Controlled Dose-Ranging Study Evaluating the Efficacy and Safety of Once Weekly High Dose Oral Finasteride in the Treatment of Severe Nodulocystic Acne - EL-1006-01-01
September 2015 to June 2017

Sponsor: Novartis ***PI: KWD*** ***Phase: 2/3***
Novartis Pharmaceuticals trial entitled: A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines
December 2018- Present

Sponsor: Novartis Global Clinical Dev. ***PI: KWD*** ***Phase: 2B***
A Multicenter, Randomized, Double-Blind, Placebo and Active-Controlled Phase IIb Dose-Finding Study of QGE031 as add-on therapy to investigate the efficacy and safety in patients with Chronic Spontaneous Urticaria (CSU) – CQGE031C2201
July 2015 to June 2016

Sponsor: Pfizer ***PI: SAF*** ***Phase: 2A***
C2501007: A PHASE 2A, MULTICCENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, 16 WEEK STUDY EVALUATING THE SAFETY AND EFFICACY OF PF-06650833, PF-06700841 AND PF-06700847 IN ADULTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA
December 2019- Present

Sponsor: Novartis ***PI: KWD*** ***Phase: 2/3***
Novartis Pharmaceuticals trial entitled: A randomized, double-blind, multicenter study assessing short (16 week) and long-term efficacy (up to 1 year), safety, and tolerability of 2 subcutaneous secukinumab does regimens in adult patients with moderate to severe hidradenitis suppurative (SUNRISE)
Protocol No.: CAIN457M2302
January 2019- Present

Sponsor: XBiotech ***PI: KWD*** ***Phase: 2***
2019-PT047: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of Bermekimab in Patients with Moderate to Severe Hidradenitis Suppurativa
August 2019- Present

Sponsor: ChemoCentryx ***PI: KWD*** ***Phase2***
CL016_168: A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 2 Study to Evaluate the Safety and Efficacy of Avacopan in Subjects with Moderate to Severe Hidradenitis Suppurativa
May 2019 - Present

Sponsor: Target-Derm ***PI: KWD*** ***Phase: 2***
CL016_168: A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 2 Study to Evaluate the Safety and Efficacy of Avacopan in Subjects with Moderate to Severe Hidradenitis Suppurativa
April 2019- Present

Sponsor: Novartis Institutes for BioMedical ***PI: KWD*** ***Phase: 2***
A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study to evaluate the clinical efficacy, safety, tolerability, dose relation, atopic etics and pharmacodynamics of CJM112 in moderate to severe chronic hidradenitis suppurativa patients – CCJM112X2202
July 2015 to February 2017

Sponsor: AbbVie ***PI:KWD*** ***Phase:***
An Observational, Multicenter Disease Registry to Evaluate Clinical Practice Trends and Outcomes in Adult and Adolescent Patients with Hidradenitis Suppurativa – *UNITE* – H13-147
May 2014 to February 2020

Sponsor: AstraZeneca ***PI:*** ***Phase:2A***
A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability and Preliminary Efficacy of MEDI8968 in Subjects with Moderate to Severe Hidradenitis Suppurativa – D5440C00001
June 2013 to December 2014

Sponsor: Genentech, Inc. ***PI: KWD*** ***Phase: 4***
A Phase IV, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Omalizumab Through 48 Weeks in Patients with Chronic Idiopathic Urticaria – ML29510
July 2015 to June 2017

Sponsor: Genentech ***PI:*** ***Phase: 3***
A Phase III, Multicenter, Randomized, Double-Blind, Dose-Ranging, Placebo-Controlled Study to Evaluate the Efficacy, Response, Curation and Safety of Xolair (Omalizumab) in Patients With Chronic Idiopathic Urticaria (CIU) Who Remain Symptomatic Despite Antihistamine Treatment (H1) – Q4882g
April 2011 to September 2012

Sponsor: Athenex ***PI: SAF*** ***Phase: 3***
A Phase III, Double-Blind, Vehicle-Controlled, Randomized, Parallel Group, Multicenter, Efficacy and Safety Study of KX2-391 Ointment 1% in Adult Subjects with Actinic Keratosis on the Face or Scalp KX01-AK-004
October 2017- November 2019

Sponsor: Therapeutics Inc ***PI: KWD*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of a Generic Ingenol Mebutate Gel, 0.015% and Picato Gel,

0.015% in Subjects with Actinic Keratosis on the Face or Scalp 094-8152-301
July 2016 to May 2017

Sponsor: LEO Pharma A/S ***PI: SAF*** ***Phase: 3***
Efficacy and Safety of Ingenol Mebutate Gel in Field Treatment of Actinic Keratosis on Full Face, Balding Scalp or Approximately 250 cm2 on the Chest – LP0105-1032
May 2015 to April 2017

Sponsor: Perrigo UK FINCO Limited Par. ***PI:*** ***Phase: 3***
A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study to Compare Perrigo UK Finco Ingenol Mebutate Topical Gel 0.015% to Leo Pharma Inc. Picato® Topical Gel 0.015% (Ingenol Mebutate Topical Gel 0.015%), and Both Active Treatments to a Vehicle Control in the Treatment of Actinic Keratosis on the Head Region (Face or Scalp) – PRG-NY-14-019
March 2015 to December 2015

Sponsor: LEO Pharma A/S ***PI:*** ***Phase: 3***
Safety of LEO 43204 0.018%, 0.037% and 0.1% for actinic keratosis applied once daily for three consecutive days on face/chest, scalp and trunk/extremities, respectively – LP0084-1148
February 2015 to September 2015

Sponsor: Actavis Mid Atlantic, LLC ***PI:*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of a Generic Ingenol Mebutate Gel, 0.05% and Picato® Gel, 0.05% in Subjects with Actinic Keratosis on the Trunk or Extremities – 094-8151-301
January 2015 to January 2016

Sponsor: LEO Pharma A/S ***PI:*** ***Phase: 2***
Safety and efficacy of escalating doses of ingenol mebutate once daily for two or three consecutive days when used on full face, full balding scalp or approximately 250 cm2 on the chest in subjects with actinic keratosis Part 1: A Phase 1, multicentre, open-label, dose escalation 2-week trial Part 2: A Phase 2, multicentre, randomised, double-blind, parallel group, vehicle-controlled, 8-week trial – LP0105-1012
December 2013 to August 2014

Sponsor: Actavis Elizabeth LLC ***PI:*** ***Phase:***
A Multicenter, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of Generic Imiquimod Cream, 2.5% and Zyclara™ (imiquimod) Cream 2.5% in Subjects with Actinic Keratoses – 094-3153-301
October 2013 to June 2014

Sponsor: Peplin Operations ***PI:*** ***Phase:***
A 12 Month, Long-term Follow-up Study of Patients With Actinic Keratoses on the Head (Face or Scalp) Who Have Completed Day 57 in Studies PEP005-016 or PEP005-025 - PEP005-030
August 2009 to January 2011

Sponsor: Peplin Operations ***PI:*** ***Phase: 2***
A Phase II, Multi-Center, Randomized, Parallel Group, Double-Blind, Vehicle-Controlled Study to Evaluate the Efficacy and Safety of PEP005 (Ingenol Mebutate) Gel, 0.05% in Patients with Actinic Keratoses on Non-Head Locations - PEP005-028
July 2009 to January 2011

Sponsor: Peplin Operations ***PI:*** ***Phase: 3***
A Phase III Multi-Center, Randomized, Parallel Group, Double-Blind, Vehicle-Controlled Study to Evaluate the Efficacy and Safety of PEP005 (Ingenol Mebutate) Gel, 0.15% in Patients with Actinic Keratoses on the Head (Face or Scalp) – PEP005-016
June 2009 to January 2011

Sponsor: Peplin Operations ***PI:*** ***Phase: 3***

A Phase III, Multi-Center, Open-Label Study to Evaluate the Safety and Efficacy of PEP005 (Ingenol Mebutate) Gel, 0.05% in Patients With Actinic Keratoses on Non-head Locations (Trunk and Extremities) – PEP005-028
June 2009 to January 2011

Sponsor: Graceway Pharmaceuticals, LLC PI: Phase: 4
A Phase IV, Open-Label Safety and Pharmacokinetic Study of Aldara(Imiquimod) Cream, 5% for One, Two, or Three Treatment Cycles to Surface Areas Greater Than 25 cm^2 With Actinic Keratosis
September 2005 to June 2007

Sponsor: 3M PI: Phase: 3B
A Phase IIIb, Open-Label Effectiveness and Safety Study of Imiquimod 5% Topical Cream in the Treatment of Actinic Keratosis.
April 2004 to August 2004

Sponsor: XOMA (US) LLC PI: Phase:
An Open-label Safety Extension Study of Gevokizumab in Active Inflammatory, Erosive Osteoarthritis of the Hand - X052161
September 2013 to February 2015

Sponsor: XOMA (US) LLC PI: Phase: 2
A Phase II Proof-of-Concept Study of Gevokizumab in Subjects with Inflammatory Erosive Osteoarthritis of the Hand - X052162
July 2013 to March 2014

Sponsor: XOMA (US) LLC PI: Phase: 2
A Phase II Proof-of-Concept Study of gevokizumab in active inflammatory, erosive osteoarthritis of the hand – X052160
May 2013 to March 2014

Sponsor: Fairbanks Institute for Health PI: Phase:
Multicenter Research Study to Build a Repository that will allow Researchers to Study Chronic Diseases in the Population of Central Indiana
July 2013 to May 2014

Sponsor: Eli Lilly and Company PI: Phase:
A Randomized, Double-Blind, Placebo-Controlled Parallel Study with an Open-Label Extension to Assess the Impact of Testosterone Solution on Total Testosterone, Sex Drive and Energy in Hypogonadal Men – I5E-MC-TSAT
June 2013 to June 2015

Sponsor: Biogen PI: SAF Phase: 2
A 2-Part Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of BIIB059 in Subjects with Systemic Lupus Erythematosus and Active Skin Manifestations and in Subjects with Active Cutaneous Lupus Erythematosus with or without Systemic Manifestations. 230LE201
August 2016- Present

Sponsor: Janssen Research and Develop PI: Phase:
A Cross-Sectional Study in Subjects With Active Cutaneous Lupus Erythematosus – NOCOMPOUNDLUN0001
June 2013 to October 2014

Sponsor: Pfizer PI: Phase:
A Randomized, Subject and Investigator-Blinded, (Sponsor-Open), Placebo-Controlled dose Escalation Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of Multiple Doses of PD 0360324 in Subjects with Active Cutaneous Lupus Erythematosus – A6261008

January 2012 to July 2014

Sponsor: Celgene Corporation ***PI:*** ***Phase: 2***
A Phase II, Pilot, Multicenter, Sequential, Ascending Dose Study to Evaluate the Preliminary Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of CC-11050 in Subjects With Discoid Lupus Erythematosus and Subacute Cutaneous Lupus Erythematosus – CC-11050-CLE-002
June 2011 to December 2012

Sponsor: Takeda Global Research and Dev ***PI:*** ***Phase: 3***
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study to Evaluate Cardiovascular Outcomes of TAK-875, 50 mg in Addition to Standard of Care in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events – TAK-875_306
February 2013 to February 2014

Sponsor: Merck & Co., Inc. ***PI:*** ***Phase: 3***
A Phase III, Randomized Double-Blind, Active-Comparator Controlled, Clinical Trial to Study the Efficacy and Safety of XXXXX for the Treatment of Patients With Type 2 Diabetes Mellitus
September 2007 to October 2008

Sponsor: GlaxoSmithKline ***PI:*** ***Phase: 2B***
A Phase IIb, 16-week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Study to evaluate the efficacy, safety and tolerability of multiple doses and multiple treatment regimens of Albiglutide (GSK716155) with Byetta as an open-label active reference, in subjects with Type 2 Diabetes Mellitus
April 2007 to February 2008

Sponsor: Eli Lilly and Company ***PI:*** ***Phase:***
The DURABLE Trial: Assessing the Durability of Basal vs. Lispro Mix 25 Insulin Efficacy.
March 2006 to October 2008

Sponsor: Novartis Pharmaceuticals ***PI:*** ***Phase:***
A 12-week Treatment, Multi-Center, Randomized, Double-Blind, Parallel-Group, Placebo and Active Controlled Study to assess the efficacy, safety, and tolerability of QVA149 (indacaterol maleate / glycopyrronium bromide) in COPD patients with moderate to severe airflow limitation – CQVA149A2336
January 2013 to May 2014

Sponsor: Forest Laboratories ***PI:*** ***Phase: 3***
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety, and Tolerability of 2 Doses of Aclidinium Bromide Compared With Placebo for 12 Weeks in Patients With Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease Followed by a 40-Week Evaluation of the 2 Aclidinium Bromide Dose – LAS-MD-38
March 2010 to November 2010

Sponsor: Novartis ***PI:*** ***Phase: 3B***
A Phase IIIb, Randomized, Double-Blind, Controlled, Parallel Group, 12-week Treatment Study to compare the efficacy and safety of the combination of indacaterol 150 µg once daily with open label tiotropium 18 µg once daily vs open label tiotropium 18 µg once daily in patients with moderate-to-severe chronic obstructive pulmonary disease – CQAB149B2341
February 2009 to April 2010

Sponsor: Novartis ***PI:*** ***Phase:***
A 12-week Treatment, Multicenter, Randomized, Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Efficacy and Safety of XXXXX in Patients with Chronic Obstructive Pulmonary Disease
February 2008 to August 2009

Sponsor: Novartis ***PI:*** ***Phase: 2/3***
A Phase II/III, 26-Week Treatment, Multicenter, Randomized, Double-Blind, Double Dummy, Placebo-Controlled, Adaptive, Seamless, Parallel-Group Study to Assess the Efficacy, Safety and Tolerability of Two Doses of Indacaterol (Selected From 75, 150, 300 & 600 µg o.d.) in Patients With Chronic Obstructive Pulmonary Disease Using Blinded Formoterol (12 µg b.i.d) and Open Label Tiotropium (18 µg o.d.) as Active Controls
March 2007 to February 2009

Sponsor: GlaxoSmithKline ***PI:*** ***Phase: 4***
A 6-month Safety and Benefit Study of inhaled fluticasone propionate/salmeterol combination versus inhaled fluticasone propionate in the treatment of 6,200 pediatric subjects 4-11 years old with persistent asthma, Phase IV – SAS115358
September 2012 to October 2013

Sponsor: GlaxoSmithKline ***PI:*** ***Phase:***
A Safety and Efficacy Study of Inhaled Fluticasone Propionate/Salmeterol Combination versus Inhaled Fluticasone Propionate in the Treatment of Adolescent and Adult Subjects with Asthma – SAS115359
January 2012 to May 2014

Sponsor: GlaxoSmithKline **PI:** **Phase: 3**
A Phase III, Long-Term, Randomized, Double-Blind, Parallel Group Study of Fluticasone Furoate/GW642444 Inhalation Powder Once-Daily and Fluticasone Furoate Inhalation Powder Once-Daily in Subjects with Asthma – HZA106837
March 2010 to November 2011

Sponsor: Merck and Co., Inc. ***PI:*** ***Phase:***
Time and Motion Study of Allergen Immunotherapy in the Usual Care Environment in the United States and Canada – A-11107
June 2012 to April 2013

Sponsor: Merck and Co., Inc. ***PI:*** ***Phase: 2***
A Phase II Randomized, Placebo-Controlled Clinical Trail to Study the Safety and Immunogenicity of V212 in Adult Patients with Autoimmune Disease – 009-00
February 2012 to December 2012

Sponsor: Novartis ***PI:*** ***Phase:***
A 6-month, Randomized, Active Comparator, Open-Label, Multi-Center Study to Evaluate Patient Outcomes, Safety and Tolerability of Fingolimod 0.5 mg/day in Patients with Relapsing Forms of Multiple Sclerosis who are candidates for MS therapy change from Previous Disease Modifying Therapy (EPOC) – CFTY720DUS01
July 2011 to April 2012

Sponsor: Hisamitsu Pharmaceutical Co., Inc. PI: ***Phase:***
A Randomized, Double-Blind, Parallel-Group, Multicenter, Placebo-Controlled Study of the Safety and Efficacy of HTU-520 in the Treatment of Mild to Moderate Distal Subungual Onychomycosis of the Toenail – HTU-520-US01
June 2011 to May 2013

Sponsor: Eli Lilly & Co. ***PI:*** ***Phase: 2***
A Phase II study of LY900010 (LY2452473 + Tadalafil) in the Treatment of Men With Erectile Dysfunction – I4K-MC-GPEC
October 2010 to January 2012

Sponsor: *Eli Lilly & Co.* ***PI:*** ***Phase:***
Biomarker Study of the Smoothened Pathway in Healthy Volunteers – I4J-MC-HHBA
April 2010 to June 2010

Kenneth W. Dawes, MD

Sponsor: Eli Lilly and Company ***PI:*** ***Phase: 2***
A Phase II, Weight Loss Efficacy Study in Overweight/Obese Men and Women – I1L-MC-GAEB
October 2009 to September 2010

Sponsor: Inhibitex ***PI:*** ***Phase: 2***
A Phase II, Multicenter, Randomized, Double-Blind, Parallel-Group, Comparative Study of FV-100 vs. Valacyclovir in Patients with Herpes Zoster – INH-FV1-005
June 2009 to December 2010

Sponsor: GlaxoSmithKline ***PI:*** ***Phase:***
A Clinical Outcomes Study of Darapladib Versus Placebo in Subjects With Chronic Coronary Heart Disease to Compare the Incidence of Major Adverse Cardiovascular Events (MACE) – LPL100601
February 2009 to August 2013

Sponsor: Novartis ***PI:*** ***Phase:***
An 8 Week Randomized, Double-Blind, Parallel Group, Multi-Center, Active Controlled Study to Evaluate the Antihypertensive Efficacy and Safety of Aliskiren Administered in Combination With Valsartan Versus Valsartan Alone in Patients With Stage 2 Systolic Hypertension and Type 2 Diabetes Mellitus – CSPP100A2409
November 2008 to June 2010

Sponsor: Pharming Technologies B.V. ***PI:*** ***Phase: 2***
A Phase II, Randomized, Placebo-Controlled, Double-Blind Study of the Safety and Efficacy of XXXXX for the Treatment of Acute Attacks in Patients with Hereditary Angioedema – C1 1205-01
July 2008 to January 2010

Sponsor: Eli Lilly and Company ***PI:*** ***Phase: 1***
A Phase I Study to Quantify the Number of Circulating Endothelial Cells in Patients with Severe Sepsis
October 2007 to November 2009

Sponsor: Pfizer ***PI:*** ***Phase: 4***
A Phase IV, Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety In Osteoarthritis Or Rheumatoid Arthritis Patients With Or At High Risk For Cardiovascular Disease Comparing Celecoxib With Naproxen And Ibuprofen (Precision)
December 2006 to October 2016

Sponsor: Genentech, Inc. ***PI:*** ***Phase: 1***
A Phase I, Double-Blind, Randomized, Placebo Controlled, Multicenter Study Evaluating the Safety and Tolerability of a Multidose Regimen of XXXXX Topically Applied to Superficial or Nodular Basal Cell Carcinoma.
June 2004 to July 2006

Sponsor: CoPharma ***PI:*** ***Phase: 1/2***
A Phase I/II Pilot Study of the Safety and Efficacy of PEN203 in the Treatment of Superficial and Nodular Basal Cell Carcinoma of the Skin.
December 2000 to December 2000

Sponsor: Verrica ***PI: KWD*** ***Phase: 3***
COVE-2: A Phase 3, Double-blind, Randomized, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of VP-102 in Subjects with Common Warts (Verruca Vulgaris)
November 2019- Present

Sponsor: Aclaris ***PI: KWD*** ***Phase: 3***
A PHASE 3 OPEN LABEL SAFTEY STUDY OF A-101 TOPICAL SOLUTION FOR THE TRATMENT OF COMMON WARTS
Dec 2018- March 2019

Kenneth W. Dawes, MD

Aclaris **PI: KWD** **Phase :3**
A PHASE 3 RANDOMIZED, DOUBLE-BLIND, VEHICLE-CONTROLLED, PARALLEL GROUP STUDY OF A-101 TOPICAL SOLUTION APPLIED TWICE A WEEK IN SUBJECTS WITH COMMON WARTS A-101-WART-301
August 2018-November 2019

Cutanea ***PI: SAF*** ***Phase: 3***
A Phase 3, Randomized, Double-Blind, Vehicle-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of CLS006 versus Vehicle in Subjects 2 years of age or older with Cutaneous Common Warts. CLS006-CO-PR-002.
December 2017-January 2019

Aclaris ***PI: KWD*** ***Phase: 2***
A Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Of A-101 Topical Solution Applied Once A Week In Subjects With Common Warts- A-101-Wart-202.
August 2017- April 2018

Sponsor: RXi Pharmaceuticals ***PI: SAF*** ***Phase: 2A***
A Prospective, Phase IIa Study to Evaluate the Effectiveness and Safety of DPCP Ointment (Samcyprone) on the Clearance of Verruca Vulgaris (Common Warts) in Subject Ages 18-65 Years. RX-SCP-1502
July 2016 – September 2018

Sponsor: Soligenix ***PI: KWD*** ***Phase: 3***
A Phase III Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Determine the Efficacy of Topical SGX301 (Synthetic Hypericin) and Fluorescent Bulb-Light Irradiation for the Treatment of Cutaneous T-Cell Lymphoma. HPN-CTCL-01
August 2016- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase: 3***
B7981032: A PHASE OPEN- LABEL, MULTI-CENTER, LONG-TERM STUDY INVESTIGATING THE SAFETY AND EFFICACY OF PF-06651600
August 2019- Present

Sponsor: Lilly ***PI: SAF*** ***Phase: 3***
14v-MC-JAIR
A multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Severe or Very Alopecia Areata
April 2019- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase: 2B/3***
A PHASE 2B/3 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-RANGING STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF PF-06651600 IN ADULT AND ADOLESCENT ALOPECIA AREATA (AA) SUBJECTS WITH 50% OR GREATER SCALP HAIR LOSS
January 2019- Present

Sponsor: Evidera ***PI: KWD*** ***Phase: Registry***
Development of a New Outcome Measure for Alopecia Areata EVA-20417-00
September 2017- Present

Sponsor: Pfizer ***PI: SAF*** ***Phase: 2A***
A Phase IIa, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety Profile of PF-06651600 and PF-0670081 in Subjects with Moderate to Severe Alopecia Areata: B7931005
February 2017- March 2019

Sponsor: Incyte ***PI: KWD*** ***Phase: 2***
A Randomized, Double-Blind, Dose-Ranging Study of INCB018424 Phosphate Cream in Subjects With Vitiligo: 18424-211
October 2017- Present

Sponsor: Novan ***PI: SAF*** ***Phase: 3***
Protocol No: NI-MC301 A Phase 3 Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy, Safety and Tolerability of SB206 and Vehicle Gel Once Daily in the Treatment of Molluscum Contagiosum
April 2019- Present

Sponsor: Novan ***PI: SAF*** ***Phase: 2***
A Phase 2 Multi-Center, Randomize, Double-Blind, Vehicle-Controlled, Ascending Dose Study of SB206 in Subjects with Molluscum Contagiosum. NI-MC201
January 2018- January 2019

Sponsor: Mayne ***PI: KWD*** ***Phase: 2***
A Phase 2 Randomized, Mukti-center, Double-blind, Vehicle-controlled, 12-Week, Safety, Efficacy, and Systemic Exposure Study followed by a 12-Week Open-label Extension of Trifarotene (CD5789) Cream HE1 in Adults and Adolescents with Autosomal Protocol number 18-Ich-001
October 2019- Present

Sponsor: Brickell ***PI: KWD*** ***Phase: 2/3***

BBI-4000-CL-301: A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Topical Applied Sofpironium Bromide Gel, 15% in Subjects with Axillary Hyperhidrosis (the "Cardigan I Study")
November 2019- Present

Sponsor: CastleBio Science ***PI: SAF*** ***Phase:***
Prospective Development and Validation of a Gene Expression Assay to Predict the Risk of Recurrence Disease in Cutaneous Squamous Cell Carcinoma
August 2019- Present

Articles and Publications

Fretzin S., Dawes K. *J Am Acad Dermatol* 2005; 52:P182. Abstract P2745.
Dermatofibrosarcoma Protuberans Treated with Mohs Micrographic Surgery: Cure Rates and Surgical Margins, Journal of Dermatologic Surgery and Oncology, June 1996.

License/Certifications

Board Certified in Dermatology, October 22, 1995
Board Certified in Internal Medicine, September 16, 1992, Certificate #146725
National Board of Medical Examiners, July 1, 1990, Certificate #374396
Indiana State License #01038446
ACLS Certified

Kenneth W. Dawes, MD

CITI Certification, May 2010, May 2012, June 2014, May 2015, May 2016, March 2017, March 2018, March 2022

Professional Societies

American Academy of Dermatology
Indiana State Medical Association
Indiana Academy of Dermatology, Secretary/Treasurer, 2010-2012
Indiana Academy of Dermatology, President, 2012 - 2014