MOORE
CLINICAL RESEARCH, INC.

Clinical Investigators (Past and Present)

Scott E Miller, MD | Board Certified Internal Medicine and Cardiovascular Diseases | Medical Director | 2018-Present

Julian Melamed, MD | Board Certified Internal Medicine and Allergies and Clinical Immunology | 2018-Present

Stanely N Katz, MD | Board Certified Dermatology | 2020-Present

George W Monlux, Jr, MD | Board Certified Family Practice Medicine | 2019-Present

Katherine S Bencze, MD | Board Certified Neurology | 2020-Present

Jennifer L Ksaibati, ARNP | Advanced Registered Nurse Practitioner | 2015-Present

Reginold L Simmons, MD | Internal Medicine | 2015-2019 (retired)

Reinhard Rott, MD | Board Certified Surgery | 2016-2019

Susan M Barker, MD | Board Certified Dermatology | 2003-2017 (retired)

Bill Fulk, MD | Internal Medicine | 2012-2014

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DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

61	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Tretinoin Gel Microsphere, 0.1% (XXXX) to Retin-A Micro (Tretinoin) Gel Microsphere, 0.1% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2020*			
	PI - Miller, Sub-I Melamed, Monlux, Katz	Screened -	Randomized - , Enrollment	Screen Fail -
	Completed - Ongoing	Drop Out -	Goal - 154	MCR - 20-012-0729-BR-ST
60	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Adapalene Gel 0.1% (XXXX) to Differin Gel (Adapalene 0.1% XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2020*			
	PI - Monlux, Sub-I- Miller/Melamed	Screened - 96	Randomized - 96 , Enrollment 3 weeks	Screen Fail - 0
	Completed -89 (93%)	Drop Out - 7 (3%)	Goal - 100 (100%)	MCR - 19-012-1223-ST-BR
59	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Tretinoin Cream 0.025% (XXXX) to Retin-A® (Tretinoin) Cream 0.025% and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2019*			
	PI - Miller, Sub-I- Monlux/Melamed	Screened - 151	Randomized - 150, Enrollment 5 weeks	Screen Fail -1
	Completed - 122 (80%)	Drop Out 30 (20%) During COVID-19	Goal - 150 (100%)	MCR - 19-012-1110-TT-ST
58	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Clindamycin Phosphate Topical Lotion 1% (XXXX) to Clindamycin Phosphate Topical Lotion 1% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2019*			
	PI - Miller, Sub-I- Monlux/Melamed	Screened - 248	Randomized - 244 , Enrollment 8 weeks	Screen Fail - 4
	Completed - 214 (87%)	Drop Out - 30 (13%)	Goal - 264 (92%)	MCR - 19-012-0404-BR-ST-TT
57	*"A Multi-Center, Double-Blind, Randomized, Three-Arm, Placebo Controlled, Parallel-Group Study, Comparing Dapsone Gel, 7.5% (XXXX) to Aczone® (Dapsone) Gel, 7.5% (XXXX) and Both Active Treatments to A Placebo Control in the Treatment of Acne Vulgaris." 2019*			
	PI - Miller, Sub-I- Monlux/Melamed	Screened - 318	Randomized - 306, Enrollment 9 weeks	Screen Fail - 12
	Completed - 276 (90%)	Drop Out - 30 (10%)	Goal - 285 (107%)	MCR - 19-061-0318-BR-ST-TT
56	*"A Phase 3 Multi-Center, Double-Blind, Randomized, Vehicle-Controlled Study of S6G5T-3 in the Treatment of Acne Vulgaris." 2019*			
	PI - Miller, Sub-I- Monlux	Screened - 9	Randomized -9 , Enrollment 10 weeks	Screen Fail - 0
	Completed - 7 (77%)	Drop Out - 2 (22%)	Goal - 9 (100%)	MCR - 19-034-0314-BR
55	*"A Phase 2, Randomized, Multicenter, Double-Blind, Vehicle Controlled, Dose-ranging Study to Evaluate the Efficacy and Safety of VB-1953 Topical Gel When Applied Daily for 12 Weeks in Subjects with Facial Acne Vulgaris for Treatment of Moderate to Severe Inflammatory Acne Vulgaris" 2019*			
	PI - Miller, Sub-I- Monlux	Screened - 13	Randomized - 12 , Enrollment - 16 weeks	Screen Fail - 1

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

	Completed - 9 (75%)	Drop Out - 3 (25%)	Goal - 48 (25%)	MCR - 19-060-0221-BR
54	*"A Phase 3, Multi-Center, Randomized, Double-Blind, Vehicle Controlled, 2 Arm, Parallel Group Study Comparing The Safety And Efficacy Of IDP-120 Gel And IDP-120 Vehicle Gel In the Treatment Of Acne Vulgaris. " 2018*			
	PI - Miller, Sub-I Melamed	Screened - 33	Randomized - 28 , Enrollment 24 weeks	Screen Fail - 5
	Completed - 26 (93%)	Drop Out - 2 (7%)	Goal - 20 (140%)	MCR - 18-029-1210-ST
53	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Clindamycin Phosphate Topical Gel 1% (XXXX) to Cleocin T (Clindamycin Phosphate Topical Gel 1% XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2018*			
	PI - Miller, Sub-I Melamed/Monlux	Screened - 331	Randomized - 320, Enrollment 11 weeks	Screen Fail -11
	Completed - 274 (86%)	Drop Out - 46 (14%)	Goal - 320 (100%)	MCR - 18-012-1012-BR-ST
52	*"A Multi-Center, Double-Blind, Randomized, Three-Arm, Placebo Controlled, Parallel-Group Study Comparing Adapalene Gel 0.3% (XXXX) to Differin ® (Adapalene Gel 0.3% XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2018*			
	PI - Miller, Sub-I Melamed/Rott	Screened - 154	Randomized - 150 , Enrollment - 2 weeks	Screen Fail - 4
	Completed - 139 (93%)	Drop Out - 11 (7%)	Goal - 150	MCR - 18-057-0802
51	*"A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of XXXX and Clindamycin Phosphate Lotion, 1% in Subjects with Acne Vulgaris." 2018*			
	PI - Miller	Screened - 40	Randomized - 35, Enrollment - 30 weeks	Screen Fail - 5
	Completed - 33 (94%)	Drop Out - 2 (6%)	Goal - 35 (100%)	MCR -18-041-0821-ST
50	*"A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of XXXX and Clindamycin Phosphate Lotion, 1% in Subjects with Acne Vulgaris." 2018*			
	PI - Melamed	Screened - 28	Randomized - 25, Enrollment - 50 weeks	Screen Fail - 3
	Completed - 23 (92%)	Drop Out - 2 (8%)	Goal - 25	MCR - 18-041-0530-TT
49	*"A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of XXXX and Clindamycin Phosphate Lotion, 1% in Subjects with Acne Vulgaris." 2018*			
	PI - Monlux	Screened - 41	Randomized - 35 , Enrollment - 32 weeks	Screen Fail - 6
	Completed - 30 (86%)	Drop Out - 5 (14%)	Goal - 35 (100%)	MCR - 18-041-0523-BR

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

48	*"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study, Comparing Clindamycin 1% to Cleocin T (XXXX, Clindamycin 1% Gel) and Both Active Treatments to a Vehicle Control in the Treatment of Acne." 2018*			
	PI - Melamed, Sub-I Miller/Rott	Screened - 334	Randomized - 325, Enrollment 10 weeks	Screen Fail - 9
	Completed - 298 (92%)	Drop Out - 27 (8%)	Goal - 285 (111%)	MCR - 18-052-0125
47	*"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." 2018*			
	PI - Rott, Sub-I - Simmons	Screened - 21	Randomized - 17, Enrollment - 8 weeks rescue site	Screen Fail - 4
	Completed - 17 (100%)	Drop Out - 0	Goal - 20 (85%)	MCR - 18-049-0212-BR
46	*"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." 2018*			
	PI - Simmons, Sub-I - Miller	Screened - 17	Randomized - 16, Enrollment - 8 weeks rescue site	Screen Fail - 1
	Completed - 16 (100%)	Drop Out - 0	Goal - 20 (80%)	MCR - 18-049-0219-ST
45	*"A MultiCenter, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Comparison Study to Evaluate the Safety and Efficacy of UHE-101 Cream 1% When Applied Twice Daily for 12 Weeks in Subjects with Facial Acne Vulgaris." 2017*			
	PI - Rott, Sub-I - Simmons	Screened - 27	Randomized - 20 , Enrollment - 20 wks	Screen Fail - 7
	Completed - 17 (85%)	Drop Out - 3 (15%)	Goal - 24 (83%)	MCR -17-015-0918-BR
44	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled Parallel-Group Study, Comparing Tretinoin Cream, 0.05% (XXXX) to Retin-A® (Tretinoin) Cream, 0.05% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2017*			
	PI - Rott, Sub-I - Simmons	Screened - 401	Randomized - 310, Enrollment - 8 wks	Screen Fail - 91
	Completed - 275 (89%)	Drop Out - 35 (11%)	Goal - 300 (100%)	MCR -17-012-0329
43	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled Parallel-Group Study, Comparing Tretinoin Cream, 0.1% (XXXX) to Retin-A® (Tretinoin) Cream, 0.1% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2017*			
	PI - Rott, Sub-I - Simmons	Screened - 306	Randomized - 246 , Enrollment - 9 wks	Screen Fail - 60
	Completed - 201 (82%)	Drop Out - 45 (18%)	Goal - 215 (114%)	MCR -17-012-0328

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

42 *"An Open-Label Study Assessing Long-Term Safety of Olumacostat Glasaretil Gel in Subjects with Acne Vulgaris." 2017*

PI - Rott, Sub-I - Simmons	Screened - 5	Randomized - 5, Enrollment - short term roll over	Screen Fail - 0
Completed - 2 (40%)	Drop Out - 3 (60%)	Goal - 5 (100%)	MCR -17-026-0119-2-ST

41 *"A Randomized, Double-Blind, Vehicle-Controlled, Efficacy and Safety Study of Olmuacostat Glasaretil in Subjects with Acne Vulgaris." 2017*

PI - Rott, Sub-I - Simmons	Screened - 42	Randomized - 15 , Enrollment - 8 weeks	Screen Fail - 19
Completed - 14 (93%)	Drop Out - 1 (7%)	Goal - 15 (100%)	MCR -17-026-0119-ST

40 *A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Adapalene Spray, 0.3% in the Treatment of Acne Vulgaris. 2016*

PI -Simmons, Sub-I-Rott	Screened - 157	Randomized - 154, Enrollment - 6 weeks	Screen Fail - 3
Completed - 141 (92%)	Drop Out - 13 (8%)	Goal - 150 (103%)	MCR - 16-012-0728

39 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Dapsone Gel, 7.5% (XXXX) to Aczone (Dapsone) Gel, 7.5%, XXXX, and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2016*

PI –Simmons, Sub-I-Barker	Screened - 305	Randomized – 300, Enrollment – 6 weeks	Screen Fail - 5
Completed – 286 (95%)	Drop Out – 14 (5%)	Goal – 300 (100%)	MCR – 16-012-0418

38 *"A Phase 3 Multi-Center, Randomized, Double-Blinded, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy, Tolerability and Safety of Once Daily SB204 and Vehicle Gel in the Treatment of Acne Vulgaris." 2016*

PI –Simmons, Sub-I-Barker	Screened - 1	Randomized – 1	Screen Fail - 0
Completed – 1	Drop Out – 0	Goal – Roll over/Long term study	MCR – 16-033-0310-ST

37 *"A Phase 2, Randomized, Multicenter, Double-Blind, Active and Vehicle Controlled Parallel-group Study Evaluating the Efficacy, Safety, and Tolerability of Products XXXX and XXXX for the Treatment of Acne Vulgaris for 12 Weeks." 2016*

PI –Simmons, Sub-I-Rott	Screened - 39	Randomized – 36, Enrollment – 25 weeks	Screen Fail - 4
Completed – 34	Drop Out – 2 (5%)	Goal – 24 (146%)	MCR – 16-034-0219-BR

36 *"A Phase 3 Multi-Center, Randomized, Double-Blinded, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy, Tolerability and Safety of Once Daily XXXX and Vehicle Gel in the Treatment of Acne Vulgaris." 2016*

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

PI –Simmons, Sub-I- Barker	Screened - 26	Randomized – 24, Enrollment – 16 weeks	Screen Fail - 2
Completed – 24 (100%)	Drop Out – 0	Goal – 24 (100%)	MCR – 16-033-0112-ST

35 *"A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study Comparing Dapsone 5% Gel, (XXXX) to Aczone® (XXXX Dapson Gel 5%) and Both Active Ingredients Compared to Placebo (Vehicle) in the Treatment of Acne Vulgaris." 2016*

PI –Simmons, Sub-I-Barker	Screened - 422	Randomized – 413, Enrollment – 23 weeks	Screen Fail - 9
Completed – 376 (91%)	Drop Out – 21 (9%)	Goal – 450 (92%)	MCR - 15-032-1118

34 *"A Phase 2, Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group, Clinical Study Comparing the Efficacy and Safety of IDP-120 Gel in the Treatment of Acne Vulgaris." 2016*

PI –Simmons, Sub-I-Barker	Screened - 28	Randomized – 21, Enrollment – 26 weeks	Screen Fail - 7
Completed – 18 (86%)	Drop Out – 3 (14%)	Goal – 20 (105%)	MCR-15-029-1204-NT

33 *"An Open-Label, Long-Term Extension Study to Evaluate the Safety of Cortexolone 17α-Propionate (CB-03-01) Cream, 1% Applied Twice Daily for up to 12 months in Subjects with Facial Acne Vulgaris." 2015*

PI –Simmons, Sub-I-Rott	Screened - 36	Randomized – 34, Enrollment – 49 weeks	Screen Fail - 2
Completed – 33	Drop Out – 1 (3%)	Goal – 20 (170%)	MCR-15-031-1026-2-NT

32 *A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study, Comparing Dapsone Gel, 5% (XXX) to Aczone® (Dapsone) Gel, 5%, (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris. 2015*

PI - Barker, Sub-I Simmons	Screened - 329	Randomized - 319, Enrollment - 18 weeks	Screen Fail - 19
Completed - 285 (89%)	Drop Out - 34 (11%)	Goal - 275 (116%)	MCR - 15-012-0918

31 *"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence and Safety of adapalene and benzoyl peroxide gel, 0.3%/2.5% (XXXX) to Epiduo® Forte (adapalene and benzoyl peroxide) gel 0.3%/2.5% (XXXX) in the treatment of Acne Vulgaris." 2015*

PI – Barker, Sub-I Simmons	Screened - 105	Randomized – 100, Enrollment – 4 weeks	Screen Fail - 5
Completed – 94 (94%)	Drop Out – 6 (6%)	Goal – 100 (100%)	MCR-15-011-0928-BR

30 *"A Phase 2, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Multicenter Study to Evaluate the Safety and Efficacy of CLS001 Topical Gel versus Vehicle Applied Once Daily for 12 Weeks to Female Subjects with Moderate to Severe Acne Vulgaris." 2015*

PI – Barker, Sub-I Simmons	Screened - 19	Randomized – 10, Enrollment – 24 weeks	Screen Fail - 9
Completed – 10 (100%)	Drop Out – 0	Goal – 10 (100%)	MCR-15-023-0901-ST

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

29	*"A Randomized, Controlled Evaluation of the Safety and Efficacy of Topical Treatments for Moderate-Severe Facial Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 23	Randomized – 15, Enrollment – 14 weeks	Screen Fail - 8
	Completed – 12 (80%)	Drop Out – 3 (20%)	Goal – 10 (150%)	MCR-15-030-0917-ST
28	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study, Comparing Clindamycin and Benzoyl Peroxide Gel 1%/5% (XXXX Pharmaceuticals, Inc.) to Benzaclin® (Clindamycin, as Phosphate, 1% and Benzoyl Peroxide 5%) Topical Gel (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 333	Randomized – 321, Enrollment – 11 weeks	Screen Fail - 12
	Completed – 296 (93%)	Drop Out – 25 (7%)	Goal – 275 (117%)	MCR-15-012-0919
27	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Adapalene and Benzoyl Peroxide Gel, 0.35/2.5% (XXXX Pharmaceuticals USA, Inc.) to Epiduo® Forte (Adapalene and Benzoyl Peroxide Gel 0.3%/2.5%, XXXX Laboratories, L.P.) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 177	Randomized – 164, Enrollment – 6 weeks	Screen Fail - 13
	Completed – 159 (97%)	Drop Out – 5 (3%)	Goal – 150 (109%)	MCR-15-012-0920
26	*"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." 2015*			
	PI-Simmons, Sub-I Barker, Rott	Screened - 11	Randomized – 4, Enrollment – 19 months	Screen Fail - 7
	Completed – 3	Drop Out – 1	Goal – 8 (50%)	MCR-15-028-0430-BR
25	*"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multiple-Site Study to Evaluate the Therapeutic Equivalence of a Generic Clindamycin 1%/Benzoyl Peroxide 5% Topical Gel (XXXX) to the Marketed Product BenzaClin® Topical Gel, Clindamycin 1%/Benzoyl Peroxide 5% (XXXX) in the Treatment of Acne Vulgaris."2015*			
	PI – Barker, Sub-I Simmons	Screened - 122	Randomized – 114, Enrollment – 11 weeks	Screen Fail - 8
	Completed – 104 (92%)	Drop Out – 10 (8%)	Goal – 100 (114%)	MCR-15-020-0202-BR
24	*"A Phase 2, Randomized, Double-Blind, Vehicle Controlled, Dose-Ranging Study of DRM01B Topical Gel in Subjects with Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 29	Randomized – 24, Enrollment – 18 weeks	Screen Fail - 5
	Completed – 22 (92%)	Drop Out – 2 (8%)	Goal – 18 (122%)	MCR-15-026-0328-ST

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

23	*A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Adapelene and Benzoyl Peroxide Gel 0.1%/2.5% (XXXX Pharmaceuticals, Inc.) to Tactupump™ (XXXX Inc., Adapalene and Benzoyl Peroxide Topical Gel, 0.1%/2.5% w/w) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 313	Randomized – 294, Enrollment – 16 weeks	Screen Fail - 19
	Completed – 272 (93%)	Drop Out – 22 (7%)	Goal – 300 (98%)	MCR-15-012-0223
22	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Clindamycin and Benzoyl Peroxide Gel 1.2%/3.75% (XXXX Pharmaceuticals, Inc.) to Onexton™ Gel (Clindamycin and Benzoyl Peroxide Gel 1.2%/3.75% XXXX Pharmaceuticals LLC) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 295	Randomized – 284, Enrollment – 6 weeks	Screen Fail - 13
	Completed – 250 (89%)	Drop Out – 34 (11%)	Goal – 300 (95% - 4 week enrollment)	MCR-15-012-0303
21	*"A Multi-Center Open-Label Evaluation of the Safety of Sarecycline Tablets in the Treatment of Acne Vulgaris." 2015 Long term study*			
	PI – Barker, Sub-I Simmons	Screened - 6	Randomized – 6, Enrollment – 7 weeks	Screen Fail - 0
	Completed – 4 (66%)	Drop Out – 2 (34%)	Goal – Roll over from short term study	MCR -15-011-0218-ST
20	*XXXX Acne Product Study for the Alleviation of Facial Acne and Associated Redness and Inflammation "A Single-site, Randomized, Single-blind, Comparative Therapeutic Clinical Study Against Open-label Proactiv+®" 2015*			
	PI – Barker, Sub-I Simmons	Screened - 95	Randomized – 90, Enrollment – 17 weeks	Screen Fail - 5
	Completed – 88 (98%)	Drop Out – 2 (2%)	Goal – 90 (100%)	MCR-14-024-1218-BR
19	*"A Randomized, Double-Blind, Multiple-Center, Placebo-Controlled Study Comparing Clindamycin and Benzoyl Peroxide Gel 1%/5% (XXXX Pharmaceuticals, Inc.) to BenzaClin® (Clindamycin 1%/Benzoyl Peroxide 5%) Topical Gel (XXXX) in the Treatment of Acne Vulgaris." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 483	Randomized – 461, Enrollment – 21 weeks	Screen Fail - 22
	Completed – 421 (91%)	Drop Out – 40 (9%)	Goal – 461 (100%)	MCR-14-012-1216
18	*"A Randomized, Multicenter, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of 1.5 mg/kg per Day of Sarecycline Compared to Placebo in the Treatment of Acne Vulgaris." 2014*			
	PI – Barker, Sub-I Simmons	Screened - 33	Randomized – 25, Enrollment – 67 weeks	Screen Fail - 8
	Completed – 20 (80%)	Drop Out – 5 (20%)	Goal – 20 (125%)	MCR-14-011-1112-ST

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

17 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Adapalene Gel 0.3% (XXXX) to Differin® (XXXX Adapalene Gel 0.3%) and Both Active Ingredients to a Placebo Control in the Treatment of Acne Vulgaris." 2014*

PI - Barker	Screened - 250	Randomized – 235, Enrollment – 14 weeks	Screen Fail - 15
Completed – 211 (91%)	Drop Out – 24 (9%)	Goal – 235 (100%)	MCR-14-012-0815

16 *"A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study, Comparing Tazarontene Cream 0.1% (XXXX) to Tazorac® (XXXX, Tazarotene Cream 0.1%) and Both Active Treatments to a Placebo Control in the Treatment of Acne Vulgaris." 2014*

PI - Barker	Screened - 359	Randomized – 353, Enrollment – 17 weeks	Screen Fail - 6
Completed – 319 (91%)	Drop Out – 34 (9%)	Goal – 300 (118%)	MCR-14-012-0617

15 *"A Multi-Center, Double-Blind, Randomized, Parallel-Group, Vehicle Controlled Study to Evaluate the Safety and Therapeutic Equivalence of a Generic Tazarotene Foam 0.1% (XXXX) and the Reference Listed Fabior™ (Tazarotene Foam, 0.1%) (XXXX) in Treatment of Subjects with Acne Vulgaris." 2014*

PI - Barker	Screened - 332	Randomized – 321, Enrollment – 10 weeks	Screen Fail - 6
Completed – 298 (93%)	Drop Out – 23 (7%)	Goal – 300 (107%)	MCR-14-011-0612

14 *"A Phase 2, Randomized, Vehicle-Controlled, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of Three Once-Daily XXXX Topical Gels Versus Vehicle Administered for 12 Weeks to Subjects with Acne Vulgaris." 2014*

PI - Barker	Screened - 33	Randomized – 25, Enrollment – 15 weeks	Screen Fail - 8
Completed – 24 (96%)	Drop Out – 1 (4%)	Goal – 16 (156%)	MCR-14-023-0421-ST

13 *"A Randomized, Double-Blind, Multiple-Site, Placebo-Controlled, Parallel Design Study Comparing Adapalene and Benzoyl Peroxide Gel 0.1%/2.5% (XXXX Laboratories) to EPIDUO® Topical Gel Adapalene and Benzoyl Peroxide Gel 0.1%/2.5% (XXXX) in the Treatment of Acne Vulgaris." 2014*

PI - Barker	Screened – 57	Randomized – 50, Enrollment – 14 weeks	Screen Fail - 7
Completed – 46 (92%)	Drop Out – 4 (8%)	Goal – 30 (125%)	MCR-13-020-1120-BR

12 *"A Safety and Efficacy Study to Compare Dapsone Dermal Gel with Vehicle Control in Patients with Acne Vulgaris." 2014*

PI - Barker	Screened - 41	Randomized – 42, Enrollment – 26 weeks	Screen Fail - 1
Completed – 42 (100%)	Drop Out – 0	Goal – 20 (200%)	MCR-13-021-1204-BR

11 *"Bioequivalence Study of XXXX Tretinoin Gel 0.05%, Atralin® (tretinoin) Gel 0.05%, and Placebo." 2013*

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

	PI - Barker, Sub-I Fulk	Screened - 624	Randomized – 574, Enrollment – 18 weeks	Screen Fail - 50
	Completed – 517 (90%)	Drop Out – 57 (10%)	Goal – 570 (101%)	MCR-13-001-0510
10	*"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Adapalene and Benzoyl Peroxide Topical Gel 0.1%/2.5% (XXXX Laboratories) to Epiduo® (XXXX Laboratories, L.P., Adapalene and Benzoyl Peroxide Topical Gel 0.1%/2.5%) and Both Active Treatments to a Vehicle Control (Test) in the Treatment of Mild to Moderate Acne Vulgaris." 2013*			
	PI - Barker, Sub-I Fulk	Screened - 481	Randomized – 462, Enrollment – 10 weeks	Screen Fail - 20
	Completed – 423 (91%)	Drop Out – 39 (9%)	Goal – 300 (154%)	MCR-13-012-0812
9	*"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Adapalene and Benzoyl Peroxide Topical Gel 0.1%/2.5% (XXXX Laboratories) to Epiduo® (XXXX Laboratories, L.P., Adapalene and Benzoyl Peroxide Topical Gel 0.1%/2.5%) and Both Active Treatments to a Vehicle Control (Test) in the Treatment of Mild to Moderate Acne Vulgaris." 2013*			
	PI - Barker, Sub-I Fulk	Screened - 493	Randomized – 473, Enrollment – 14 weeks	Screen Fail - 8
	Completed – 434 (90%)	Drop Out – 39 (10%)	Goal – 450 (105%)	MCR-12-012-0320
8	*"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Clincamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5% (Test) and Acanya® (Clindamycin Phosphate and Benzoyl Peroxide) Gel, 1.2%/205% and Both Active Ingredients to Vehicle Control (Test) for the Treatment of Acne Vulgaris." 2012*			
	PI - Barker, Sub-I Fulk	Screened - 298	Randomized – 286, Enrollment – 4 weeks	Screen Fail - 12
	Completed – 248 (87%)	Drop Out – 38 (13%)	Goal – 250 (114%)	MCR-12-011-0412
7	*"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Adapalene and Benzoyl Peroxide Topical Gel 0.1%/2.5% (XXXX Laboratories) to Epiduo® (XXXX Laboratories, L.P., Adapalene and Benzoyl Peroxide Topical Gel 0.1%/2.5%) and Both Active Treatments to a Vehicle Control (Test) in the Treatment of Mild to Moderate Acne Vulgaris." 2011*			
	PI - Barker	Screened - 630	Randomized – 613	Screen Fail - 17
	Completed – 564 (92%)	Drop Out – 49 (8%)	Goal – 600 (102%)	MCR-11-011-0322
6	*"Bioequivalence Study of XXXX Tretinoin 0.1% Microsphere Gel, 0.1% Retin –A Micro® and Placebo." 2010*			
	PI-Patel, Sub-I Barker	Randomized - 455	MCR-10-01-045	
5	*"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study to Compare XXXX Pharmaceuticals, Ltd., Clindamycin1% Topical Gel to BenzaClin® Topical Gel (Clindamycin-Benzoyl Peroxide Gel) and both active Treatments to a Vehicle Control in the Treatment of Acne Vulgaris." 2009*			

DERMATOLOGY CLINICAL STUDIES

ACNE VULGARIS

PI - Patel, Sub-I Barker	Randomized - 30	MCR-09-009-1016

4 *"A Comparative Study of 0.25% Retin-A Cream with 0.25% Tretinoin Cream and Cream Vehicle." 2009*

PI - Patel, Sub-I Barker	Randomized - 45	MCR-09-001-0324

3 *"A Randomized, Double-Blind, Vehicle-Controlled, Multicenter Study, to Compare the Safety and Efficacy of BenzaClin Topical Gel, to XXXX Labs Clindamycin-Benzoyl Peroxide Gel, in the Treatment of Acne Vulgaris." 2004*

PI - Barker

2 *"A Comparative Study of 0.05% Retin-A Cream with 0.05% Tretinoin Cream and Cream Vehicle." 2005*

PI - Barker

1 *"A Randomized, Double-Blind, Vehicle-Controlled, Multicenter Study, to Compare the Safety and Efficacy of Azelex® Cream, to XXXX Laboratories Azelaic Acid 20% cream, in Patients with Acne Vulgaris." 2004*

PI - Barker

DERMATOLOGY CLINICAL STUDIES

ACTINIC KERATOSIS

19 *"A Randomized, Double-Blind, Placebo-controlled, Three-arm, Parallel Assignment, Multi-Center, Therapeutic Equivalence Study of Two Fluorouracil 5% Topical Cream Formulations in Adult Subjects with Multiple Actinic Lesions." 2019*

PI - Monlux	Screened - 15	Randomized - 13 , Enrollment - 3 weeks	Screen Fail - 2
Completed - 13 (100%)	Drop Out - 0	Goal - 18 (72%)	MCR - 19-066-0904-BR

18 *"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel Group Bioequivalence Study To Compare XXXX 5-FU Cream 5%, With Efudex (5-FU) Cream 5%, and Both Active Treatments to a Vehicle Control, in the Treatment of Actinic Keratosis." 2018*

PI - Miller, Sub-I Melamed	Screened - 54	Randomized - 45, Enrollment - 40 weeks	Screen Fail - 9
Completed - 43 (97%)	Drop Out - 2 (4%)	Goal - 36 (125%)	MCR - 18-034-1127-ST

17 *A Randomized, Double-Blind, Placebo-Controlled, Three-Arm, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence of Diclofenac Sodium Gel 3% (XXXX) Compared to Solaraze® (diclofenac sodium) Gel 3% (XXXX) in the Treatment of Actinic Keratosis." 2017*

PI - Simmons, Sub-I Melamed	Screened - 42	Randomized - 31, Enrollment - 14 weeks	Screen Fail - 11
Completed - 30 (93%)	Drop Out -1 (7%)	Goal - 20 (155%)	MCR - 17-051-0831-NT

16 *"A Phase 2 Dose-Rising Study of SOR007 Ointment for Actinic Keratosis." 2017*

PI – Simmons, Sub-I Rott	Screened - 69	Randomized - 33, Enrollment - 22 weeks	Screen Fail - 36
Completed - 32 (97%)	Drop Out - 1 (3%)	Goal – 32 (103%)	MCR- 17-046-0327-ST

15 *"A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Comparison Study to Determine the Therapeutic Equivalence of XXXX and Diclofenac Sodium Gel, 3% in Subjects with Actinic Keratoses." 2016*

PI- Simmons, Sub-I- Rott	Screened- 45	Randomized- 36, Enrollment – 8 weeks	Screen Fail- 9
Completed- 35 (97%)	Drop Out- 1 (3%)	Goal- 27 (133%)	MCR-16-041-0929-ST

14 *"Multi-Center, 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 and Scalp." 2016*

PI – Simmons, Sub-I -Rott	Screened - 19	Randomized - 17 , Enrollment – 14 weeks	Screen Fail - 2
Completed – 17 (100%)	Drop Out – 0	Goal – 24 (71%)	MCR-16-037-0701-NT

13 *"A Phase 2 Study of the Effect of Microneedle Lesion Preparation, Incubation Time and Light Power Density on Photodynamic Therapy with Levulan Kerastick (Aminolevulinic Acid HCL) for Topical Solution, 20% + Blue Light for the Field Treatment of Actinic Keratosis on the Face." 2016*

DERMATOLOGY CLINICAL STUDIES

ACTINIC KERATOSIS

	PI – Barker, Sub-I Simmons	Screened - 22	Randomized – 20, Enrollment – 8 weeks	Screen Fail - 2
	Completed – 20 (100%)	Drop Out – 0	Goal – 20 (100%)	MCR-15-022-1119-ST
12	*"A Randomized, Double-Blind, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence of Diclofenac Sodium Gel 3% (XXXX) Compared to Solaraze 3%, gel (diclofenac sodium 3% w/w; XXXX) in the Treatment of Actinic Keratosis." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 52	Randomized – 35, Enrollment – 23 weeks	Screen Fail - 17
	Completed – 29 (82%)	Drop Out – 6 (18%)	Goal – 35 (100%)	MCR-15-012-0427-NT
11	*"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." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 39	Randomized – 30, Enrollment – 12 weeks	Screen Fail - 9
	Completed – 30 (100%)	Drop Out – 0	Goal – 21 (143%)	MCR-14-011-0923-ST
10	*"Twelve Month Follow-Up Evaluation of Subjects Participating in XXXX CP0108 (A Phase 3 Study of Photodynamic Therapy with Levulan Kerastick Topical Solution + Blue Light Versus Topical Solution Vehicle + Blue Light for the Treatment of Actinic Keratosis on the Upper Extremities." 2014*			
	PI - Barker	Screened - 18	Randomized – 18, Enrollment – 25 weeks	Screen Fail - 0
	Completed – 11 (65%)	Drop Out – 7 (35%)	Goal – 20 (90%)	MCR-14-022-0227-2-ST
9	*"A Phase III Study of Photodynamic Therapy with Levulan® Kerastick® Topical Solution + Blue Light Versus Topical Solution Vehicle + Blue Light for the Treatment of Actinic Keratosis on the Upper Extremities." 2014*			
	PI - Barker	Screened - 34	Randomized – 25, Enrollment – 7 weeks	Screen Fail - 9
	Completed – 22 (88%)	Drop Out – 3 (12%)	Goal – 20 (125%)	MCR-14-022-0227-ST
8	*"A Randomized, Double Blind, Placebo Controlled, Parallel Design, Multiple Site, Clinical Study to Evaluate the Therapeutic Equivalence of Two Imiquimod Cream 5% Formulations in Patients with Actinic Keratosis." 2014*			
	PI - Barker	Screened - 58	Randomized – 40, Enrollment – 17 weeks	Screen Fail - 18
	Completed – 32 (80%)	Drop Out – 8 (20%)	Goal – 38 (105%)	MCR-13-012-1220-ST
7	*"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." 2013*			
	PI - Barker	Screened - 34	Randomized – 17, Enrollment – 7 weeks	Screen Fail - 16

DERMATOLOGY CLINICAL STUDIES

ACTINIC KERATOSIS

	Completed – 17 (100%)	Drop Out – 0	Goal – 20 (90%) 6 wk enrollment	MCR-13-018-1016-ST
6	*"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." 2013*			
	PI - Fulk	Screened - 6	Randomized – 6, Enrollment – 5 weeks	Screen Fail - 0
	Completed – 5 (84%)	Drop Out – 1 (16%)	Goal – 20 (30%) 5 wk enrollment	MCR-13-018-1105-FM
5	*"A Randomized, Double-Blind, Placebo Controlled, Parallel Design, Multiple Site Clinical Study to Evaluate the Bioequivalence of Two Imiquimod Cream 3.75% Formulations in Patients with Actinic Keratosis." 2013*			
	PI - Barker	Screened - 38	Randomized – 30, Enrollment – 7 weeks	Screen Fail - 8
	Completed – 28 (93%)	Drop Out – 2 (7%)	Goal – 21 (143%)	MCR-13-012-0107-ST
4	*"A Randomized, Double-Blind, Multiple-Site, Placebo-Controlled, Parallel Design Study Comparing Diclofenac Sodium Gel 3% (XXXX) to Solaraze® (diclofenac sodium) Gel 3% (XXXX) in the Treatment of Actinic Keratosis." 2013*			
	PI - Fulk	Screened - 21	Randomized – 17, Enrollment – 5 weeks	Screen Fail - 4
	Completed – 15 (88%)	Drop Out – 2 (12%)	Goal – 20 (85%)	MCR-13-011-0301-BR
3	*"A Multi-Center, Double-Blind, Vehicle-Controlled Study Comparing Imiquimod Cream 5% to ALDARA™ Cream5% in the Treatment of Actinic Keratosis." 2008*			
	Sub-I Barker	MCR-08-006-1115		
2	*"A Double-Blind, Randomized, Parallel-Group, Vehicle-Controlled, Multi-Center Study to Evaluate the Safety and Bioequivalence of Diclofenac Sodium Gel, 3% (XXXX, Inc) and Solaraze™ (Diclofenac Sodium) Gel, 3% and Compare Both Active Treatments to a Vehicle Control in the Treatment of Actinic Keratosis." 2008*			
	Sub-I Barker	MCR-08-010-1015		
1	*"A Double-Blind, Randomized, Placebo-Controlled Trial to Evaluate the Clinical Bioequivalence of 5-Flurouracil (XXXX Pharmaceuticals) and Carac for the Treatment of Actinic Keratosis." 2007*			
	PI - Barker	MCR-07-006-1118		

DERMATOLOGY CLINICAL STUDIES

ATOPIC DERMATITIS

11	*"A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis." 2020*			
	PI- Melamed, Sub-I Monlux, Katz	Screened -	Randomized - , Enrollment - weeks	Screen Fail -
	Completed - Ongoing	Drop Out -	Goal - 6	MCR -20-070-0724-BR
10	*"A Randomized, Double-Blind, Placebo-Controlled Phase II Study to Evaluate Efficacy, Pharmacokenetics, and Safety of Multiple Intravenous Doses of FB825 in Adults with Atopic Dermatitis." 2020*			
	PI- Melamed, Sub-I Miller	Screened -	Randomized - , Enrollment - weeks	Screen Fail -
	Completed - Ongoing	Drop Out -	Goal - 8	MCR -20-068-0304-ST
9	*"A Phase II, Randomized, Double-Blind, Vehicle Controlled Study of the Efficacy, Safety, and Tolerability of B244 Topical Spray for the Treatment of Pruritis in Adults with a History of Atopic Dermatitis." 2020*			
	PI- Melamed, Sub-I Miller, Monlux, Katz	Screened -	Randomized -	Screen Fail -
	Completed - Ongoing	Drop Out -	Goal - 10	MCR -20-067-0311-ST-BR
8	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Doxepin Hydrochloride Topical Cream, 5% (XXXX) to Doxepin Hydrochloride topical cream, 5% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Moderate Pruritis in Adults with Atopic Dermatitis." 2019*			
	PI- Melamed, Sub-I Miller, Monlux	Screened - 42	Randomized - 34, Enrollment - 8 weeks	Screen Fail - 8
	Completed - 32 (95%)	Drop Out - 2 (5%)	Goal - 30 (113%)	MCR -19-012-0114-ST/BR
7	*"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study Investigating the Efficacy, Safety, and Pharmacokinetic Profile of XXXX Administered to Adult Subjects with Moderate-to-Severe Atopic Dermatitis." 2018*			
	PI- Rott, Sub-I Miller	Screened - 21	Randomized - 5, Enrollment - 50 weeks	Screen Fail - 16
	Completed - 4 (75%)	Drop Out - 1 (25%)	Goal - 10 (50%)	MCR -18-053-0712-ST
6	*"A Multi-center, Randomized, Double-Blind, Bilateral, Vehicle-Controlled Study of a Topical Gel Administered Twice Daily in Adult and Adolescent Subjects with Moderate to Severe Atopic Dermatitis." 2017*			
	PI - Simmons, Sub-I Melamed	Screened - 63	Randomized - 12, Enrollment - 28 weeks	Screen Fail - 50
	Completed - 10 (83%)	Drop Out - 2 (17%)	Goal - 12 (100%)	MCR -17-047-0123 - NT

DERMATOLOGY CLINICAL STUDIES

ATOPIC DERMATITIS

5	*"A Randomized, Double-Blind, Placebo-Controlled, Study of the Efficacy, Safety and Tolerability of Serlopitant for the Treatment of Puritis in Adults and Adolescents with a History of Atopic Dermatitis."2017*			
	PI - Rott	Screened - 63	Randomized - 19, Enrollment - 50 weeks	Screen Fail - 43
	Completed – 17 (89%)	Drop Out - 2 (11%)	Goal – 15 (127%)	MCR – 16-043-1103-ST
4	*"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multiple-Site Study to Evaluate the Therapeutic Equivalence of a Generic Pimecrolimus Cream, 1% (XXXX) to the Marketed Product ELIDEL® (Pimecrolimus) Cream, 1% (XXXX) in the Treatment of Mild to Moderate Atopic Dermatitis (AD)."2017*			
	PI –Simmons, Sub-I- Rott	Screened - 46	Randomized - 35 , Enrollment – 26 weeks	Screen Fail - 11
	Completed – 34 (97%)	Drop Out – 1 (3%)	Goal – 25 (140%)	MCR-16-038-081-ST
3	*"An open label, safety study to assess the potential for adrenal suppression following treatment with desoximetasone 0.15% topical spray in patients with atopic dermatitis." 2016*			
	PI –Simmons, Sub-I-Rott	Screened - 3	Randomized - 1, Enrollment – 1 yr	Screen Fail - 2
	Completed – 1	Drop Out – 0	Goal – 3 (33%)	MCR-16-012-0526-ST
2	*"A Double-Blind, Randomized, Parallel-Group, Vehicle-Controlled, Multicenter Study to Evaluate the Safety and Bioequivalence of a Generic Pimecrolimus Cream, 1% and Reference Listed Elidel® (Pimecrolimus Cream, 1%) and Compare Both Active Ingredients to a Vehicle Control in the Treatment of Mild to Moderate Atopic Dermatitis." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 45	Randomized – 22, Enrollment – 41 weeks	Screen Fail - 23
	Completed – 21 (91%)	Drop Out – 2 (9%)	Goal – 12 (183%)	MCR-15-011-0518-ST
1	*"A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of XXX7061 Capsules in Adult Subjects With Atopic Dermatitis." 2013*			
	PI - Barker	Screened - 15	Randomized – 8, Enrollment – 8 weeks	Screen Fail - 6
	Completed – 7 (88%)	Drop Out – 1 (12%)	Goal – 12 (67%) Rescue Site	MCR-13-017-0724-ST

DERMATOLOGY CLINICAL STUDIES

HERPES LABIALIS

4 *"A Placebo-Controlled Evaluation of Acyclovir/348U87 Cream and 348U87 Cream for the Treatment of Herpes Simplex Labialis Infection." Study 2, Barker PI, 2008*

3 *"A Placebo-Controlled Evaluation of Acyclovir/348U87 Cream and 348U87 Cream for the Treatment of Herpes Simplex Labialis Infection." Study 1, Barker PI, 2002*

2 *"A Clinic Initiated, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Safety and Efficacy of Topical N-Docosanol 10% Cream 10% Cream (Lidakotm) in Patients with Early-Stage Episodes of Acute, Recurrent Herpes Labialis." Study 2, Fulk PI, 1998*

1 *"A Clinic Initiated, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Safety and Efficacy of Topical N-Docosanol 10% Cream 10% Cream (Lidakotm) in Patients with Early-Stage Episodes of Acute, Recurrent Herpes Labialis." Study 1, Fulk PI, 1998*

HERPES ZOSTER

1 *"A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group, Dose-Ranging Study Assessing the Safety and Efficacy of EPB348 versus Valacyclovir Among Patients with an Acute Episode of Herpes Zoster." Barker PI, 2003*

DERMATOLOGY CLINICAL STUDIES

PSORIASIS

21 *"A Phase 3, Multicenter, Randomized, Double Blind Study Evaluating the Efficacy and Safety of ABP 654 Compared with Ustekinumab in Subjects with Moderate to Severe Plaque Psoriasis" 2020*

PI - Miller, Sub-I Melamed	Screened -	Randomized - Enrollment -	Screen Fail -
Completed - Ongoing	Drop Out -	Goal - 5	MCR -

20 *"An Open-Label, Multi-Center Extension Study to Characterize the Long-Term Safety and Efficacy of XXX-986165 in Subjects with Moderate-to-Severe Plaque Psoriasis." 2020*

PI - Miller, Sub-I Melamed	Screened - 3	Randomized - 3 Enrollment - Long Term Extension	Screen Fail - 0
Completed - Ongoing	Drop Out -	Goal - 3 (100%)	MCR -20-58-0224-ST

19 *"A Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Proof of Concept Comparison Study of the Safety and Efficacy of DUR-928 Topical Solution with Occlusion in Subjects with Mild to Moderate Plaque Psoriasis." 2019*

PI - Miller, Sub-I Melamed	Screened - 11	Randomized - 9, Enrollment 4 weeks	Screen Fail - 2
Completed - 9 (100%)	Drop Out - 0	Goal - 3 (300%)	MCR -19-015-0802-ST

18 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Calciotriol and Betamethasone Dipropionate Topical Gel 0.005%/0.064% (XXXX) Dovobet® Gel (Calcipotriol and Betamethasone Dipropionate Gel) 0.005%/0.064% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Mild to Moderate Body Plaque Psoriasis Vulgaris." 2018*

PI - Miller, Sub-I Monlux, Melamed	Screened - 41	Randomized - 36, Enrollment 16 weeks	Screen Fail - 6
Completed - 34 (95%)	Drop Out - 2 (5%)	Goal - 40 (86%)	MCR -18-012-1018-BR/ST

17 *"A Multi-Center, Randomized, Double-Blind, Placebo- and Active Comparator-Controlled Phase 3 Study with Randomized Withdrawal and Retreatment to Evaluate the Efficacy and Safety of XXXXX in Subjects with Moderate-to-Severe Plaque Psoriasis ." 2018*

PI - Miller, Sub-I Melamed	Screened - 16	Randomized - 4, Enrollment (44 weeks)	Screen Fail - 12
Completed - 4 (100%)	Drop Out - 0	Goal - 4	MCR -18-058-1015-ST

16 *"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." 2018*

PI - Miller, Sub-I Melamed	Screened - 13	Randomized - 9 , Enrollment 20 weeks	Screen Fail - 4
Completed - 7 (77%)	Drop Out - 2 (23%)	Goal - 6 (113%)	MCR -18-055-1928-ST

15 *"A Double-Blind, Randomized, Multicenter, Vehicle Controlled, Parallel Group Comparison Study to Determine the Efficacy and Safety of Halobestasol Propionate Spray, 0.05% Versus Vehicle Spray in Subjects with Plaque Psoriasis Receiving Up to Four Weeks of Twice Daily Treatment." 2018*

PI - Simmons	Screened - 21	Randomized -19, Enrollment 16 weeks	Screen Fail - 2

DERMATOLOGY CLINICAL STUDIES

PSORIASIS

Completed - 18 (95%)	Drop Out - 1 (5%)	Goal - 18	MCR -18-015-0530-BR

14 *"A Randomized, Double-Blind, Placebo-Controlled, Multicenter, 24-Week Study to Assess the Efficacy and Safety of XXXX (Tepilamide Fumarate) Extended Release Tablets in Subjects with Moderate-to-Severe Plaque Psoriasis." 2018*

PI - Miller, Sub-I Simmons	Screened - 31	Randomized - 13 , Enrollment - 24 weeks	Screen Fail - 18
Completed - 8 (62%)	Drop Out - 5 (38%)	Goal - 10 (130%)	MCR - 17-042-1201-ST

13 *"A Randomised, Multi-centre, Investigator Blind, Parallel Group Trial to Evaluate the Efficacy and Safety of XXXX Cream Vehicle Compared to XXXX Cream Vehicle and Active Comparator in Subjects with Mild to Moderate Psoraisis Vulgaris." 2017*

PI - Simmons, Sub-I Melamed	Screened - 35	Randomized - 20, Enrollment - 16 weeks	Screen Fail - 14
Completed - 17 (85%)	Drop Out - 3 (15%)	Goal - 14 (143%)	MCR - 17-050-0809-NT

12 *"A Multi-Center, Open Label, Baseline-Controlled Study of XXXX Lotion in Subjects with Plaque Psoriasis." 2017*

PI – Rott, Sub-I Simmons	Screened - 42	Randomized - 30 , Enrollment - 22 weeks	Screen Fail -
Completed - 28 (93%)	Drop Out - 2 (7%)	Goal - 25 (120%)	MCR- 17-045-0228-NT

11 *"A Multi-Center, Double-Blind, Randomized, Vehicle-Controlled, Parallel-Group Study Comparing Tazarotene Cream 0.05% to TAZORAC® (tazarotene) Cream 0.05% and Both Active Treatments to a Vehicle Control in the Treatment of Plaque Psoriasis." 2016*

PI – Simmons, Sub-I-Rott	Screened - 50	Randomized - 41, Enrollment – 30 weeks	Screen Fail - 9
Completed – 33 (80%)	Drop Out – 8 (20%)	Goal – 35 (117%)	MCR-16-040-0808-NT/BR

10 *"A Multi-Center, Randomized, Double-Blind, Parallel Group Comparison of Halobetasol Propionate Foam, 0.05% Versus Vehicle Foam in Subjects with Plaque Psoriasis." 2016*

PI – Simmons, Sub-I-Rott	Screened - 28	Randomized - 25, Enrollment – 19 weeks	Screen Fail - 3
Completed – 25 (100%)	Drop Out – 0	Goal – 24 (104%)	MCR-16-015-0627-ST

9 *"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." 2016*

PI – Barker, Sub-I Simmons	Screened - 11	Randomized – 5, Enrollment – 10 weeks	Screen Fail - 6
Completed – 5 (100%)	Drop Out – 0	Goal – 16 (31%)	MCR-16-019-0120-BR

8 *"A Phase 2, Multicenter, Evaluator-Blinded, Randomized, Vehicle-Controlled Study to Compare the Safety and Efficacy of IDP-118 Lotion with Tazorac® (tazarotene) Cream, 0.05% in the Treatment of Plaque Psoriasis." 2016*

DERMATOLOGY CLINICAL STUDIES

PSORIASIS

PI –Simmons	Screened - 14	Randomized – 10, Enrollment – 19 weeks	Screen Fail - 4
Completed – 10 (100%)	Drop Out – 0	Goal – 10 (100%)	MCR-16-029-0128-ST

7 *"A Phase 3, Multicenter, Double-Blind, Randomized, Vehicle Controlled Clinical Study to Assess the Safety and Efficacy of IDP-122 in the Treatment of Plaque Psoriasis." 2015*

PI –Simmons, Sub-I-Rott	Screened - 27	Randomized – 15, Enrollment – 48 weeks	Screen Fail - 12
Completed – 12 (80%)	Drop Out – 3 (20%)	Goal – 15 (100%)	MCR-15-029-0930-NT

DERMATOLOGY CLINICAL STUDIES

PSORIASIS

6 *"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone Topical Spray, 0.15% (XXXX Pharmaceuticals, U.S.A., Inc.) in Patients with Mild to Moderate Plaque Psoriasis." 2015*

PI – Barker, Sub-I Simmons	Screened - 18	Randomized – 9, Enrollment – 62 weeks	Screen Fail - 12
Completed – 9 (100%)	Drop Out – 0	Goal – 12 (75%)	MCR-15-012-0311-BR

5 *"A Phase 3, Multicenter, Double-Blind, Randomized, Vehicle Controlled Clinical Study to Assess the Safety and Efficacy of IDP-118 in the Treatment of Plaque Psoriasis." 2015*

PI – Barker, Sub-I Simmons	Screened - 47	Randomized – 21, Enrollment – 42 weeks	Screen Fail - 26
Completed – 19 (91%)	Drop Out – 2 (9%)	Goal – 15 (140%)	MCR-15-029-0707-ST

4 *"A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study, Comparing Tazarotene Cream 0.05% (XXXX Pharmaceuticals, Inc.) to Tazorac (XXXX), LLC, Tazarotene Cream 0.05% and Both Active Treatments to a Placebo Control in the Treatment of Plaque Psoriasis." 2014*

PI – Barker, Sub-I Simmons	Screened - 97	Randomized – 76, Enrollment – 48 weeks	Screen Fail - 21
Completed – 60 (84%)	Drop Out – 16 (21%)	Goal – 60 (126%)	MCR-14-012-0703

3 *"A Randomized, Double-Blind, Vehicle-Controlled, Multicenter, Parallel Group Study of the Efficacy and Safety of Betamethasone Dipropionate Spray 0.05% in the Treatment of Moderate Plaque Psoriasis." 2013*

PI - Barker	Screened - 33	Randomized – 16, Enrollment – 19 weeks	Screen Fail - 17
Completed – 13 (82%)	Drop Out – 3 (18%)	Goal – 10 (160%)	MCR-13-019-1028-ST

2 *"A Multicenter, Randomized, Double-Blind, Parallel Group Comparison of Halobetasol Propionate Lotion 0.05% versus Vehicle Lotion in Subjects with Plaque Psoriasis." 2013*

PI - Barker	Screened - 29	Randomized – 24, Enrollment – 14 weeks	Screen Fail - 5
Completed – 21 (88%)	Drop Out – 3 (12%)	Goal – 24 (100%)	MCR-13-015-0509-BR/ST

1 *"A Double-Blind, Randomized, Vehicle-Controlled, Multi-Center, Paired Efficacy Trial of XXXX Topical 6% Salicylic Acid Formulation in Subjects with Moderate to Severe Plaque Psoriasis." 2006*

PI - Barker	MCR-06-002-0112-2

DERMATOLOGY CLINICAL STUDIES

SCALP PSORIASIS

5 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Calcipotriene Hydrate and Betamethasone Dipropionate Topical Suspension 0.005%/0.064% (XXXX) to Talconex® (Calcipotriene Hydrate and Betamethasone Dipropionate) Topical Suspension 0.005%.0.064% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Scalp Psoriasis." 2018*

PI -Miller, Sub-I Rott	Screened - 47	Randomized - 40, Enrollment weeks	Screen Fail - 7
Completed - 36 (90%)	Drop Out - 4 (10%)	Goal - 50 (80%)	MCR - 18-012-0912-ST & BR

4 *A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multiple-Site Study to Evaluate the Therapeutic Equivalence of a Generic Calcipotriene and Betamethasone Dipropionate Topical Suspension, 0.005%/0.064% (XXXX) to the Marketed Product Taclonex® Topical Suspension (XXXX) in the Treatment of Scalp Psoriasis." 2017*

PI -Simmons, Sub-I - Miller	Screened - 74	Randomized - 42 , Enrollment 40 weeks	Screen Fail - 32
Completed - 40 (95%)	Drop Out - 2 (5%)	Goal - 21 (200%)	MCR - 17-038-1004-ST

3 *"A Randomized, Double-blind, Parallel-group, Vehicle-controlled, Multicenter Study Comparing XXXX Calcipotriene Hydrate and Betamethasone Dipropionate Topical Suspension 0.005%/0.064% to Reference Listed Drug in the Treatment of Scalp Psoriasis." 2016*

PI –Simmons, Sub-I- Rott	Screened - 90	Randomized – 43	Screen Fail - 46
Completed – 40 (93%)	Drop Out – 3 (7%)	Goal – 45 (96%)	MCR-16-006-1011

2 *"An Open Label, Safety Study to Assess the Potential for Adrenal Suppression Following Maximal Use Treatment with Desoximetasone 0.25% shampoo (XXXX U.S.A., Inc.) in Patients with Scalp Psoriasis." 2016*

PI –Simmons, Sub-I- Rott	Screened - 1	Randomized – 1, Enrollment – 1 yr	Screen Fail - 0
Completed – 0	Drop Out – 1	Goal – 3 (33%)	MCR-16-012-0525-ST

1 *"A Randomized, Double-Blind, Vehicle-Controlled, Parallel-Design, Multiple-Site, Phase III Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone 0.25% Shampoo in Patients with Mild to Severe Scalp Psoriasis." 2016*

PI –Simmons, Sub-I-Barker	Screened - 29	Randomized – 24, Enrollment – 6 weeks	Screen Fail - 5
Completed – 22 (92%)	Drop Out – 2 (8%)	Goal – 12 (200%)	MCR-16-012-0323-ST

DERMATOLOGY CLINICAL STUDIES

ROSACEA

11 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Ivermectin Cream 1% (XXXX) to Soolantra (Ivermectin) Cream 1% and Both Active Treatments to a Placebo Control in the Treatment of Moderate to Severe Facial Rosacea." 2020*

PI - Monlux, Sub-I-Miller, Melamed, Katz	Screened - 46	Randomized - 45, Enrollment - 28 weeks	Screen Fail - 1
Completed - Ongoing	Drop Out -	Goal - 54 (83%)	MCR - 20-012-0214 BR/ST/TT

10 *"A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study, Comparing Ivermectin Cream 1% (XXXX) to Soolantra® (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Moderate to Severe Facial Rosacea." 2019*

PI - Melamed, Sub-I-Miller, Monlux	Screened - 47	Randomized - 40, Enrollment - 12 weeks	Screen Fail - 6
Completed - 36 (90%)	Drop Out - 4 (10%)	Goal - 50 (80%)	MCR - 18-034-0920-BR/ST

9 *"A Multi-Center, Open-Label, Long-Term Safety Study of XXXX to Evaluate the Safety of XXXX in Papulopustular Rosacea Patients." 2018*

PI - Monlux	Screened - 13	Randomized - 13, Enrollment - Long Term Follow-Up	Screen Fail -0
Completed - 12 (97%)	Drop Out - 1 (7%)	Goal - 6 (260%)	MCR - 18-034-0920-BR

8 *"A Phase 3 Multi-Center, Double-Blind, Randomized, Vehicle-Controlled Study of XXXX in the Treatment of Papulopustular Rosacea." 2018*

PI - Rott, Sub-I Simmons	Screened - 18	Randomized - 18 , Enrollment 16 weeks	Screen Fail - 0
Completed - 18 (100%)	Drop Out - 0	Goal - 10 (180%)	MCR - 18-034-0418 - BR

7 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Azelaic Acid Foam 15% (XXXX) to Finaea® (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Moderate Facial Rosacea." 2017*

PI - Simmons, Sub-I Miller/Melamed	Screened - 62	Randomized - 39, Enrollment - 16 weeks	Screen Fail -23
Completed - 38 (97%)	Drop Out - 1 (3%)	Goal - 50 (78%)	MCR-17-012-1107-BR/ST

6 *"A Mult-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Ivermectin Cream 1% (XXXX) to Soolantra® (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Moderate to Severe Rosacea." 2017*

PI – Simmons, Sub-I Rott,Miller, Melamed	Screened - 27	Randomized - 26 ,Enrollment - 20 weeks	Screen Fail -1
Completed- 21 (81%)	Drop Out - 5 (19%)	Goal – 35 (75%)	MCR – 17-012-0606-BR/ST

5 *"A Randomized, Multicenter, Double-blind, Vehicle-controlled Study to Evaluate the Safety and Efficacy of FMX103 1.5% Topical Minocycline Foam Compared to Vehicle in the Treatment of Facial Papulopustular Rosacea." 2017*

PI – Simmons, Sub-I Rott,Miller, Melamed	Screened - 30	Randomized - 15, Enrollment - 24 weeks	Screen Fail - 15
Completed- 11 (73%)	Drop Out - 4 (27%)	Goal - 20 (75%)	MCR – 17-049-0323 -ST

DERMATOLOGY CLINICAL STUDIES

ROSACEA

4 *"A Multicenter, Double-blind, Randomized, Parallel-group, Vehicle-Controlled Study to Evaluate the Safety and Clinical Equivalence of a Generic Azelaic Acid Foam, 15% and the Reference Listed Finacea® (azelaic acid) Foam, 15% in Patients with Moderate Facial Rosacea." 2016*

PI – Simmons, Sub-I Rott	Screened - 21	Randomized - 19 , Enrollment - 12 weeks	Screen Fail - 2
Completed – 18 (95%)	Drop Out – 1 (5%)	Goal – 40 (48%)	MCR – 16-011-0128

3 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Azelaic Acid Topical Gel 15% (XXXX Pharmaceuticals USA, Inc) to FInacea Gel (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Moderate Facial Rosacea." 2016*

PI – Simmons, Sub- I - Rott	Screened - 71	Randomized – 67, Enrollment – 23 weeks	Screen Fail - 4
Completed - 60 (90%)	Drop Out – 7 (10%)	Goal – 80 (85%)	MCR-16-012-0524

2 *"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence and Safety of Ivermectin Cream 1% (XXXX) to XXXX (Ivermectin) Cream 1% (XXXX) in the Treatment of Moderate to Severe Papulopustular Rosacea." 2016*

PI – Simmons, Sub-I-Barker	Screened - 17	Randomized – 15, Enrolling – 14 weeks	Screen Fail -2
Completed – 15 (100%)	Drop Out – 0	Goal – 15 (100%)	MCR-16-011-0425-ST

1 *"A Multicenter, Double-blind, Randomized, Parallel-group, Vehicle-Controlled Study to Evaluate the Safety and Clinical Equivalence of a Generic Azelaic Acid Gel, 15% and the Reference Listed Finacea® (azelaic acid) Gel, 15% in Patients with Moderate Facial Rosacea." 2013*

PI - Barker, Sub-I Fulk	Screened - 94	Randomized – 80, Enrollment – 53 weeks	Screen Fail - 14
Completed – 68 (85%)	Drop Out – 12 (15%)	Goal – 80 (100%)	MCR-13-011-0531

DERMATOLOGY CLINICAL STUDIES

TINEA PEDIS

11	*"A Randomized, Double-Blind, Vehicle-Controlled, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutics Equivalence of Ketoconazole Cream 2% (XXXX) to Ketoconazole 2% (XXXX) in the Treatment of Tinea Pedis." 2019*			
	PI - Monlux	Screened - 56	Randomized - 31 , Enrollment - 9 weeks	Screen Fail - 25
	Completed - 24 (77%)	Drop Out - 7 (22% Early Term)	Goal - 25 (124%) /Positive Mycology Rate 97%	MCR - 19-064-0325-BR
10	*"A Randomized, Double-Blind, Vehicle-Controlled, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutics Equivalence of Ketoconazole Cream 2% (XXXX) to Ketoconazole 2% (XXXX) in the Treatment of Tinea Pedis." 2019*			
	PI - Miller, Sub-I Melamed	Screened - 101	Randomized - 77 , Enrollment - 9 weeks	Screen Fail - 24
	Completed - 49 (64%)	Drop Out - 28 (36% Early Term)	Goal - 75 (103%) /Positive Mycology Rate 65%	MCR - 19-064-0315-ST
9	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Clotrimazole and Betamethasone Dipropionate Cream 1%/0.064% (XXXX) to Lotriderm (Clotrimazole and Betamethasone Dipropioniate) Cream 1%/0.064% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Tinea Pedis." 2018*			
	PI - Miller, Sub-I Melamed,Rott	Screened - 47	Randomized - 23, Enrollment - 6 weeks	Screen Fail - 24
	Completed - 15 (65%)	Drop Out - 8 (35%) Early Term	Goal - Rescue Site /Positive Mycology Rate 65%	MCR - 18-051-0626-ST/BR
8	*"A Randomized, Double-Blind, Vehicle-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence of Ketoconazole Cream 2% (XXXX) to Ketoconazole Cream 2% (XXXX)in the Treatment of Tinea Pedis." 2018*			
	PI - Miller	Screened - 102	Randomized -75, Enrollment 8 weeks	Screen Fail - 27
	Completed - 56 (75%)	Drop Out - 26 (25%) Early Term	Goal - 50 (150%) /Positive Mycology Rate 75%	MCR - 18-051-0626-ST
7	*"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study Comparing Naftifine HCL 2% (XXXX) to Naftin (Naftifine NCL) Gel, 2% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Tinea Pedis." 2017*			
	PI - Simmons, Sub-I Rott	Screened - 201	Randomized - 98, Enrollment - 18 weeks	Screen Fail -103
	Completed - 55 (56%)	Drop Out - 5 LTFU / Early Term 38	Goal - 100 (98%) /Positive Mycology Rate 65%	MCR - 17-012-0906
6	*"A Multi-Center, Double-blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Luliconazole Cream 1% (XXXX) to Luzu (Luliconazole Cream, 1% (XXXX) and Both Active Ingredients to Placebo Control in the Treatment of Tinea Pedis." 2017*			
	PI –Simmons, Sub-I Rott	Screened - 241	Randomized - 85, Enrollment – 20 weeks	Screen Fail - 155
	Completed – 41 (49%)	Drop Out – 7 LTFU / Early Term - 36	Goal – 80 (106%)	MCR-16-012-1214

DERMATOLOGY CLINICAL STUDIES

TINEA PEDIS

5	*"A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence and Safety of Econazole Nitrate Cream, 1% (XXXX, Inc.) to Econazole Nitrate Cream, 1% (XXXX.) in the Treatment of Interdigital Tinea Pedis." 2016*			
	PI –Simmons, Sub-I-Barker	Screened - 48	Randomized – 35, Enrollment – 14 weeks	Screen Fail - 13
	Completed – 23 (66%)	Drop Out – 12 (Early Term & LTFU)	Goal – 24	MCR-16-036-0425-ST
3	*"A Randomized, Prospective Multicenter, Double Blind, Parallel Assignment, Placebo Controlled, Bioequivalence Study of Naftifine Hydrochloride Cream, 2% for Topical Use with that of Naftifine (naftifine hydrochloride) Cream 2% for Topical Use in Patients with Tinea Pedis Using Clinical Endpoints." 2015*			
	PI – Barker, Sub-I Simmons	Screened - 173	Randomized – 66, Enrollment – 28 weeks	Screen Fail - 107
	Completed – 64 (97%)	Drop Out – 2 (3%)	Goal – 50 (132%)	MCR-14-025-0620
2	*"A Multi-center, Double-blind, Randomized, Parallel-group, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Naftifine HCl Gel 2% (XXX Pharmaceuticals Inc.) and the Naftin (Naftifine HCl) Gel, 2% (XXX Pharmaceuticals, LLC) in Patients with Tinea Pedis." 2014*			
	PI - Barker	Screened - 98	Randomized – 60, Enrollment – 6 weeks	Screen Fail - 38
	Completed – 35 (59%)	Drop Out – 0 / Early Term - 25	Goal – 60 (100%)	MCR-14-012-0827
1	*"A Multicenter, Double-blind, Randomized, Parallel-group, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Naftifine HCl Cream 2% (XXX) and the Naftin® (Naftifine HCl) Cream, 2% (XXX) in Patients with Tinea Pedis." 2013*			
	PI - Barker, Sub-I Fulk	Screened - 117	Randomized – 84, Enrollment – 19 weeks	Screen Fail - 33
	Completed – 41 (49%)	Drop Out – 6 / Early Term - 37	Goal – 114 (74%)	MCR-13-012-0715

ONYCHOMYCOSIS

1	*"A Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Multi-Site Phase 2b Clinical Study to Assess the Efficacy, Safety and Tolerability of 8-Week Regimens of Novexatin®, 10% Topical Solution (XXXX, USA, Inc.) in Patients with Mild to Moderate Onychomycosis." 2016*			
	PI –Simmons, Sub-I-Rott	Screened - 35	Randomized - 1, Enrollment –10 months	Screen Fail - 34
	Completed - 0	Drop Out – 1	Goal – 12	MCR – 16-012-0401-BR

XEROSIS

1	"A Double-Blind, Randomized, Vehicle-Controlled, Multi-Center, Paired Efficacy Trial of Salitop™ Topical 6% Salicylic Acid Formulation in Subjects with Moderate to Severe Plaque Foot Xerosis." 2007		
	PI - Barker	Randomized - 21	MCR-06-002-0111

INTERNAL MEDICINE CLINICAL STUDIES

ALLERGY & ASTHMA

2 *A Randomized, Blinded, Multiple-Dose, Placebo-Controlled, Multi-Center Study Comparing Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg to QVAR® 40 mcg (beclomethasone dipropionate HFA), Inhalation Aerosol in Treatment of Subjects with Asthma." 2018*

PI - Melamed	Screened - 37	Randomized - 1, Enrollment 20 weeks	Screen Fail - 36
Completed - 1 (100%)	Drop Out - 0	Goal - 4	MCR - 18-062-1214-ST

1 *"A Randomized, Double-Blind, Parallel Group, Multi-Center 24-Week Study Comparing the Efficacy and Safety of Three Doses of PT001 to Placebo and Open-label Spiriva, Respimat in Subjects With Persistent Asthma." 2018*

PI - Melamed	Screened -0	Randomized - 0 , Enrollment 16 weeks	Screen Fail -0
Completed -0	Drop Out - 0	Goal - 4	MCR - 18-056-0904 -NT

INFECTIOUS DISEASES

3 *"A Phase 3, Randomized, Double-Blind, Placebo Controlled Trial to Evaluate the Efficacy and Safety of Nitazoxanide in the Treatment of colds due to Enterovirus/Rhinovirus infection." 2018*

PI - Melamed, Sub-I- Miller	Screened - 36	Randomized - 20 , Enrollment - 6 weeks	Screen Fail - 6
Completed - 19 (95%)	Drop Out - (5%)	Goal - 20 (100%)	MCR - 18-059-0809 - ST

2 *"A Phase III, Randomized, Double-Blind, Placebo Controlled Trial to Evaluate Efficacy and Safety Nitazoxanide in the Treatment of Uncomplicated Influenza."*

PI – Melamed, Sub-I -Miller	Screened - 1	Randomized - 1 , Enrollment – 4 weeks	Screen Fail - 0
Completed– 1	Drop Out – 0	Goal - 20 (5%) - Enrollment Closed after 4 weeks	MCR-18-059-1210 - BR/ST

1 *"A Clinical Study to Demonstrate the Clinical Significance and Effectiveness of a Combination of Tamiflu® (Oseltamivir Phosphate) and XXXX versus Tamiflu® (Oseltamivir Phosphate) Alone as a Treatment for Influenza and the Effectiveness of a Recommended Prevention Dose of Tamiflu® (Oseltamivir Phosphate) Alone versus a Treatment of Tamiflu (Oseltamivir Phosphate) in Combination with XXXX as a Treatment for the Prevention of Influenza." Influenza/Cold Seasons 2015-2016*

PI – Simmons, Sub-I -Rott	Screened - 88	Randomized - 88, Enrollment – 55 weeks	Screen Fail - 5
Completed– Study Closed	Drop Out – 0	Goal - 120	MCR-15-024-0202

GLUCOSE RISK ASSESSMENT DEVICE

1 *"Glucose Risk Assessment in Employer Populations." 2019*

PI – Jennifer Ksaibati, ARNP	Screened - 206	Randomized - 207 , Enrollment – 12 weeks	Screen Fail - 1
Completed– 207 (100%)	Drop Out – 0	Goal - 207 (100%)	MCR-19-063-0307

HYPERHIDROSIS

3 *"A Multicenter, Randomized, Vehicle Controlled Study to Evaluate the Safety and Efficacy of Topically Applied Sofpironium Bromide Gel, 15% in Subjects wth Axillary Hyperhidrosis (the Cardigan II Study)." 2020*

INTERNAL MEDICINE CLINICAL STUDIES

PI - Miller, Sub-I Monlux, Katz	Screened -	Randomized – , Enrollment –	Screen Fail -
Completed – Ongoing	Drop Out –	Goal – 8	MCR – 20-

2 *"A Double-Blind, Randomized, Placebo-Controlled Study to Assess the Efficacy and Safety of AT-5214 in the Treatment of Subjects with Moderate to Severe Palmar Hyperhidrosis." 2020*

PI - Miller, Sub-I Melamed	Screened -	Randomized – , Enrollment –	Screen Fail -
Completed – Ongoing	Drop Out –	Goal – 10	MCR – 20-069-0518-ST

1 *"An Interview Study in Children and Adolescents with Hyperhidrosis and Adults with Mild Hyperhidrosis." 2016*

PI - Mathias	Screened - 37	Randomized – 25, Enrollment – 20 weeks	Screen Fail - 12
Completed – 24 (94%)	Drop Out – 1 (6%)	Goal – 15 (175%)	MCR – 16-035-0212-ST

OSTEOARTHRITIS

2 *"A Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel-Group Study, Comparing Diclofenac Sodium Gel, 1% (XXXX) to Voltaren Gel (Diclofenac Sodium) Gel, 1% (XXXX) and Both Active Treatments to a Placebo Control in the Treatment of Patients with Osteoarthritis of the Knee." 2017*

PI – Rott, Sub-I- Simmons	Screened - 165	Randomized - 32 , Enrollment - 20 wks	Screen Fail - 132
Completed - 27 (84%)	Drop Out - 5 (16%)	Goal – 80 (40%)	MCR – 17-012-0308

1 *"XXXX Product Study for the Alleviation of Pain, Inflammation and Increased Range of Motion in Patients Diagnosed with Mild to Moderate Knee Osteoarthritis; A Single-Site, Randomized, Double-Blind, Placebo-Controlled Comparative Therapeutic Clinical Study Against Osteo Bi-Flex Triple Strength." 2016*

PI - Simmons	Screened - 83	Randomized – 60, Enrollment – 22 weeks	Screen Fail - 23
Completed – 58 (97%)	Drop Out – 2 (3%)	Goal – 60 (100%)	MCR-16-024-0105-BR

HYPERTENSION

3 *"A Randomized, Double-Blind, Parallel Group Study Evaluating the Efficacy and Safety of Co-Administration of a Triple combination Therapy of Olmesartan Medoxomil, Amlodipine Besylate, and Hydrochlorothiazide in Subjects with Hypertension." Barker PI, 2008*

2 *"The Respond Trial, a Multi-National, Prospective, Randomized, Double-Blind, Multi-Center, Placebo-Controlled Study to Evaluate Efficacy and Safety of a Fixed combination Therapy of Amlodipine and Atorvastatin in the Treatment of concurrent Hypertension and Hyperlipidemia." Barker PI, 2007*

1 *"A Double-Blind, Randomized, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of TAK_01 in Black Subjects with Essential Hypertension." Barker PI, 2007*

OTITIS EXTERNA

1 *"A Randomized, Double-Blind, Placebo-Controlled, Parallel Design, Multiple-Site Study to Evaluate the Clinical Equivalence of Ciprofloxacin O.3%lDexamethasone 0.1 % Sterile Otic Suspension (XXX) Compared to CIPRODEX® (ciprofloxacin O.3%/dexamethasone 0.1%) Sterile Otic Suspension (XXX) in the Treatment of Adults with Acute Bacterial Otitis Externa." 2013*

PI - Fulk	Screened - 2	Randomized – 1, Enrollment – 1 week	Screen Fail - 1

INTERNAL MEDICINE CLINICAL STUDIES

Completed – 1 (100%)	Drop Out – 0	Study Discontinued	MCR-13-016-0718-FM

ADHD

2 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Methylphenidate Administered As The Content Of 1 x 40 mg Extended-Release Capsule Mixed With Applesauce in Fasted Normal, Healthy Men and Women ." Barker PI, 2004*

1 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Methylphenidate Administered As The Content of 1 x 40 mg Extended-Release Capsule in Normal Healthy Men and Women Following A standard Meal." Barker PI, 2004*

ANTIDEPRESSANTS

1 *"A Randomized, Single-Dose, Three-Way Crossover Relative Bioavailability Relative Bioavailability Study of Bupropion Sustained Release Tablet in Fasted Normal Healthy Men." Barker PI, 2005*

DECONGESTANTS AND COMBINATION DRUGS

7 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Desloratadine Tablet in Normal, Healthy Men and Women Following a High Calorie and High Fat Breakfast." Barker PI, 2004*

6 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Desloatidine- Pseudoephedrine Extended-Release Tablet in Fasted, Normal, Healthy Men and Women." Barker PI, 2004*

5 *"A Single Center Study to Evaluate the Adhesion of Two Fentanyl Transdermal Systems in Normal, Healthy Men and Women." Barker PI, 2003*

4 *"A Blind, Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Desloratadine Tablet in Fasted Normal, Healthy Men and Women." Barker PI, 2003*

3 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Desloratadine Tablet in Normal, Healthy Men and Women Following a Standard Meal." Barker PI, 2003*

2 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Desloratadine Tablet in Fasted, Normal, Healthy Men and Women Following a Standard Meal." Barker PI, 2003*

1 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Desloratadine Tablet in Fasted, Normal, Healthy Men and Women Following a Standard Meal." Barker PI, 2003*

DIABETES

1 *"A Randomized, Double-Blind, comparator-Controlled Study of Pioglitazone HCl vs Glyburide in the Treatment of Subjects with Type II (Non-Insulin Dependent) Diabetes Mellitus and Mild to Moderate Congestive Heart Failure." Barker PI, 2006*

DIURETICS

1 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Furosemide Tablet in Fasted, Normal, Healthy Men and Women Following a Standard Meal." Barker PI, 2003*

FEMALE HORMONES

1 *"An Open-Label, Randomized, Parallel Group on the Effect of Various Combinations of Esterified Estrogens and Methyltestosterone on Circulating Plasma Levels of Estradiol, Estrone, Testosterone and Sex Hormone Binding Globulin in Postmenopausal Women." Barker PI, 2002*

INTERNAL MEDICINE CLINICAL STUDIES

MALE HORMONES

2 *"The Single and Multiple Dose Pharmacokinetics of Testosterone After Administration of 1.62% Hydro-Alcoholic Gel at Dose Levels of 1.25, 2.50, 3.75, 5.00, 6.25 g in Hypogonadal Males." Barker PI, 2003*

NARCOTIC ANALGESICS – OPIOID AGONISTS

5 *"A Single Center Study to Evaluate the Adhesion of Two Fentanyl Transdermal Systems in Normal, Healthy Men and Women." 2002*

4 *"A Pilot Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Oxycodone Modified-Release Capsules and OxyCotin Controlled – Release Tablets in Fasted, Normal, Healthy Men and Women." 2002*

3 *"A Pilot, Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Oxycodone Modified-Release Capsules and OxyCotin Controlled – Release Tablets in Fasted, Normal, Healthy Men and Women Following a Standard Meal." 2002*

2 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Morphine Sulfate Extended-Release Tablet Formulations in Fasted, Normal, Healthy Men and Women." 2002*

1 *"A Randomized, Single-Dose, Two-Way Crossover Relative Bioavailability Study of Morphine Sulfate Extended-Release Tablet Formulations in Normal, Healthy Men and Women Following a Standard Meal." 2002*

NON-NARCOTIC ANALGESICS

4 *"Gastrointestinal (GI) Randomized Event and Safety Open-Label NSAID Study (GI Reasons): A Randomized, Open-Label, Blinded-Endpoint, Parallel-Group Trial of GI Safety of Celecoxib compared with Non-Selective Nonsteroidal Anti-inflammatory Drugs (NSAIDS) in Osteoarthritis Patients." 2007*

3 *"A Multi-Centre, Parallel Group, Double-Blind, Placebo Controlled, Dose Ranging Study of the Efficacy and Tolerability of Tonabersat In the Prophylaxis of Migraine Headache and Open Label Extension." 2007*

2 *"A Randomized, Single-Dose, Three-Way Crossover Relative Bioavailability Study of Tramadol Modified Release Tablet Formulations in Fasted, Normal, Healthy Men and Women." 2003*

1 *"A Randomized, Single-Dose, Three-Way Crossover Relative Bioavailability Study of Tramadol Modified Release Tablet Formulations in Normal, Healthy Men and Women Following a Standard Meal." 2003*