

2018 Medicines in Development for Skin Diseases

Acne

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ADPS topical	Taro Pharmaceuticals USA Hawthorne, NY	acne vulgaris	Phase II completed www.taro.com
AOB101 (topical ammonia oxidizing bacteria)	AOBiome Cambridge, MA	acne vulgaris	Phase II www.aobiome.com
ASC-J9 (androgen receptor degradation enhancer)	AndroScience Solana Beach, CA	acne vulgaris	Phase II www.androscience.com
BLI1100	Braintree Laboratories Braintree, MA	acne vulgaris	Phase II completed www.braintreelabs.com
BPX-01 (minocycline topical)	BioPharmX Menlo Park, CA	acne vulgaris	Phase II www.biopharmx.com
BTX1503 (cannabidiol)	Botanix Pharmaceuticals Plymouth Meeting, PA	moderate to severe acne vulgaris	Phase II www.botanixpharma.com
CJM112 (IL-17A protein inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	acne vulgaris	Phase II www.novartis.com
clascoterone (androgen receptor antagonist)	Cassiopea Lainate, Italy	acne vulgaris	Phase III www.cassiopea.com

Acne <u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CLS001 (omiganan)	Cutanea Wayne, PA	acne vulgaris	Phase II www.cutanea.com
DFD-03 (tazarotene topical)	Promius Pharma Princeton, NJ	acne vulgaris	Phase III www.promiuspharma.com
DMT310 (freshwater sponge-derived)	Dermata Therapeutics San Diego, CA	moderate to severe acne vulgaris	Phase II www.dermatarx.com
finasteride (cholestenone 5-alpha reductase inhibitor)	Elorac Vernon Hills, IL	severe nodulocystic acne	Phase II www.eloracpharma.com
FMX101 (minocycline foam)	Foamix Bridgewater, NJ	moderate to severe acne	Phase III www.foamix.com
IDP-120 gel	Ortho Dermatologics Raleigh, NC	acne vulgaris	Phase II www.ortho-dermatologics.com
IDP-123 lotion	Ortho Dermatologics Raleigh, NC	acne vulgaris	Phase III www.ortho-dermatologics.com
IDP-126 gel	Ortho Dermatologics Raleigh, NC	acne vulgaris	Phase II www.ortho-dermatologics.com

Acne

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
LEO 43204 (ingenol disoxate)	LEO Pharma Madison, NJ	acne vulgaris	Phase II completed www.leo-pharma.us
MABp1 (IL-1 alpha inhibitor)	Xbiotech Austin, TX	acne vulgaris (subcutaneous)	Phase II www.xbiotech.com
radezolid topical (second-generation oxazolidinone)	Melinta Therapeutics New Haven, CT	acne vulgaris	Phase II www.melinta.com
SB204 (topical nitric oxide)	Novan Morrisville, NC	acne vulgaris	Phase III www.novan.com
Seysara™ sarecycline	Allergan Parsippany, NJ	acne vulgaris	application submitted www.allergan.com
SIRS-T (encapsulated tretinoin cream)	Sol-Gel Technologies Ness Ziona, Israel	acne vulgaris	Phase II www.sol-gel.com
SNA-001	Sienna Biopharmaceuticals Westlake Village, CA	acne vulgaris	Phase III www.siennabio.com
trifarotene (retinoic acid receptor gamma agonist)	Galderma Fort Worth, TX	acne vulgaris	Phase III completed www.galdermausa.com
TWIN (benzoyl peroxide/tretinoin)	Sol-Gel Technologies Ness Ziona, Israel	acne vulgaris	Phase II www.sol-gel.com

Actinic Keratosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AM001 (potassium dobesilate topical)	AmDerma Pharmaceuticals Bridgewater, NJ	actinic keratosis	Phase II
DFD-07 (celecoxib topical)	Promius Pharma Princeton, NJ	actinic keratosis	Phase II/III www.promiuspharma.com
GDC 695	Gage Development Rosemont, IL	actinic keratosis	Phase III www.capstonedevservices.com
KX-01 ointment (Src kinase inhibitor)	Athenex Buffalo, NY	actinic keratosis on the face and scalp	Phase III www.athenex.com
LEO 43204 (ingenol disoxate)	LEO Pharma Madison, NJ	actinic keratosis	Phase II completed www.leo-pharma.us
LFX453	Novartis Pharmaceuticals East Hanover, NJ	actinic keratosis	Phase II completed www.novartis.com
NanoPac® Ointment paclitaxel nanoformulation (SOR007)	DFB Soria Fort Worth, TX NanOlogy Fort Worth, TX	actinic keratosis	Phase II www.nanolgy.us
SR-T100 gel (<i>Solanum undatum</i> plant extract)	G&E Herbal Biotechnology Tainan City, Taiwan	actinic keratosis	Phase II www.geherbs.com

Actinic Keratosis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VDA-1102 topical ointment (VDAC/HK2 modulator)	Vidac Pharma Jerusalem, Israel	actinic keratosis	Phase II www.vidacpharma.com

Alopecia

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ATI-501 oral (JAK inhibitor)	Aclaris Therapeutics Wayne, PA	alopecia areata	Phase II www.aclaristx.com
ATI-502 topical (JAK inhibitor)	Aclaris Therapeutics Wayne, PA	alopecia areata (Fast Track), androgenetic alopecia	Phase II www.aclaristx.com
BBI-5000 (oral CRTH2 antagonist)	Brickell Biotech Boulder, CO	androgenic alopecia	Phase II www.brickellbio.com
BNZ-1 (IL-2, IL-9, IL-15 receptor antagonist)	Bioniz Irvine, CA	alopecia areata	Phase I www.bioniz.com
BPM 31543 (calcitriol topical)	Berg Framingham, MA	chemotherapy-induced alopecia	Phase I www.berghealth.com
cerdulatinib (RVT-502) (dual Syk/JAK inhibitor)	Dermavant Sciences Phoenix, AZ	alopecia areata	Phase I www.dermavant.com
clascoterone (androgen receptor antagonist)	Cassiopea Lainate, Italy	androgenetic alopecia	Phase II www.cassiopea.com

Alopecia

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CTP-543 (deuterated ruxolitinib)	Concert Pharmaceuticals Lexington, MA	alopecia areata (Fast Track)	Phase II www.concertpharma.com
delgocitinib (JAK inhibitor)	LEO Pharma Madison, NJ	alopecia areata	Phase II www.leo-pharma.us
HSC660 (growth factor receptor agonist)	Histogen San Diego, CA	alopecia (male)	Phase II www.histogeninc.com
		alopecia (female)	Phase I www.histogeninc.com
Olumiant® baricitinib	Eli Lilly Indianapolis, IN Incyte Wilmington, DE	alopecia areata	Phase I/II www.lilly.com www.incyte.com
PF-06651600 (JAK3 inhibitor)	Pfizer New York, NY	alopecia areata (Breakthrough Therapy)	Phase II www.pfizer.com
PF-06700841 (TYK2/JAK1 inhibitor)	Pfizer New York, NY	alopecia areata	Phase II www.pfizer.com
setipiprant (prostaglandin D2 receptor antagonist)	Allergan Parsippany, NJ	androgenic alopecia	Phase II www.allergan.com

Alopecia

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SM04554 (Wnt signalling pathway modulator)	Samumed San Diego, CA	androgenic alopecia	Phase II www.samumed.com

Bullous Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
acebilustat (leukotriene A4 hydrolase inhibitor)	Celtaxsys Atlanta, GA	bullous dermatoses	Phase I completed www.celtaxsys.com
bertilimumab (chemokine CCL11 inhibitor) ORPHAN DRUG	Immune Pharmaceuticals Englewood Cliffs, NJ	bullous pemphigoid	Phase II www.immunepharma.com
BPM 31510 (ubidecarenone topical cream) ORPHAN DRUG	Berg Framingham, MA	epidermolysis bullosa	Phase I www.berghealth.com
CCP-020 (topical diacerein) ORPHAN DRUG	Castle Creek Pharmaceuticals Parsippany, NJ	epidermolysis bullosa simplex (Fast Track)	Phase III www.castlecreekpharma.com
EB-101 (collagen type VII replacement) ORPHAN DRUG	Abeona Therapeutics New York, NY	recessive dystrophic epidermolysis bullosa	Phase I/II completed www.abeonatherapeutics.com

Bullous Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
FCX-007 (genetically-modified autologous human dermal fibroblast cells) ORPHAN DRUG	Fibrocell Science Exton, PA Intrexon Germantown, MD	recessive dystrophic epidermolysis bullosa (Fast Track)	Phase I/II www.fibrocell.com www.dna.com
GBT-101 topical gel (thymosin beta-4) ORPHAN DRUG	Gtree Pharmaceuticals Seongnam-si, South Korea	epidermolysis bullosa	Phase II completed www.gtreebnt.com
KB103 (gene transference) ORPHAN DRUG	Krystal Biotech Pittsburgh, PA	dystrophic epidermolysis bullosa (Fast Track)	Phase I/II www.krystalbio.com
PRN1008 (BTK inhibitor)	Principia Biopharma South San Francisco, CA	pemphigus vulgaris	Phase II www.principiabio.com
QR-313 (RNA interference) ORPHAN DRUG	ProQR Therapeutics Leiden, Netherlands	dystrophic epidermolysis bullosa	Phase I/II www.proqr.com
Rituxan® rituximab	Genentech South San Francisco, CA	pemphigus vulgaris	Phase III www.gene.com
SYNT001 (Fc receptor antagonist) ORPHAN DRUG	Syntimmune Boston, MA	pemphigus foliaceus, pemphigus vulgaris	Phase I/II www.syntimmune.com

Bullous Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VAY736 (anti-BAFF antibody)	Novartis Pharmaceuticals East Hanover, NJ	pemphigus vulgaris	Phase II www.novartis.com

Cosmetic Skin Conditions

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
DWP-450 (prabotulinumtoxin A)	Evolus Irvine, CA	glabellar lines	application submitted www.evolus.com
EB-001A (botulinum toxin E)	Bonti Newport Beach, CA	glabellar lines	Phase II www.bonti.com
ET-01 topical (botulinum toxin A)	Eirion Therapeutics Woburn, MA	facial wrinkles	Phase II www.eirionthera.com
letibotulinumtoxina (botulinum toxin type A)	Croma Pharma Leobendorf, Austria	glabellar frown lines	Phase III
mesenchymal stem cell therapy	Stemmedica Cell Technologies San Diego, CA	cutaneous photoaging	Phase I completed www.stemedica.com
RT002 injectable (botulinum toxin A)	Revance Therapeutics Newark, CA	glabellar lines	Phase III www.revance.com
SP160412 (cyclooxygenase inhibitor)	Sephoris Pharmaceuticals San Diego, CA	sunburn photodamage	Phase II www.sephorispharma.com

Dermatitis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALX-101 (liver X receptor agonist)	Ralexar Therapeutics Malvern, PA	atopic dermatitis	Phase II www.ralexar.com
ANB-020 (etokimab) (anti-IL-33)	AnaptysBio San Diego, CA	moderate to severe atopic dermatitis (adult)	Phase II www.anaptysbio.com
AOB102 (topical ammonia oxidizing bacteria)	AOBiome Cambridge, MA	eczema/itch	Phase II www.aobiome.com
asimadoline (opioid kappa receptor agonist)	Tioga Pharmaceuticals San Diego, CA	pruritus associated with atopic dermatitis	Phase II www.tiogapharma.com
ASN002 (dual JAK/Syk inhibitor)	Asana BioSciences Lawrenceville, NJ	chronic hand and foot eczema, atopic dermatitis	Phase II www.asanabiosciences.com
ATI-502 topical (JAK inhibitor)	Aclaris Therapeutics Wayne, PA	atopic dermatitis	Phase II www.aclaristx.com
BBI-2000 (topical anti-inflammatory peptide)	Brickell Biotech Boulder, CO	allergic contact dermatitis	Phase II www.brickellbio.com
BMX-010 (mangano porphyrin antioxidant mimetic)	BioMimetix Greenwood Village, CO	atopic dermatitis	Phase II

Dermatitis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
cerdulatinib (RVT-502) (dual Syk/JAK inhibitor)	Dermavant Sciences Phoenix, AZ	atopic dermatitis	Phase I www.dermavant.com
CLS001 (omiganan)	Cutanea Wayne, PA	atopic dermatitis	Phase II www.cutanea.com
delgocitinib (JAK inhibitor)	LEO Pharma Madison, NJ	chronic hand eczema	Phase II www.leo-pharma.us
DMT210 topical gel (G-protein modulator)	Dermata Therapeutics San Diego, CA	atopic dermatitis	Phase II completed www.dermatarx.com
DS107 (dihomo gamma linolenic acid)	DS Biopharma Dublin, Ireland	atopic dermatitis	Phase II www.dsbiopharma.com
Dupixent [®] dupilumab	Regeneron Tarrytown, NY Sanofi Genzyme Cambridge, MA	atopic dermatitis (pediatric)	Phase III www.regeneron.com www.sanofigenzyme.com
EDP1066 (immunomodulator)	Evelo Biosciences Cambridge, MA	atopic dermatitis	Phase I www.evelobio.com
GBR 830 (OX40 receptor antagonist)	Glenmark Pharmaceuticals Mumbai, India	moderate to severe atopic dermatitis	Phase II www.glenmarkpharma.com

Dermatitis
Drug Name

Sponsor

Indication

Development Phase

IDP-124 lotion	Ortho Dermatologics Raleigh, NC	atopic dermatitis	Phase III www.ortho-dermatologics.com
KPL-716 (IL-31 protein inhibitor/ oncostatin M inhibitor)	Kiniksa Pharmaceuticals Lexington, MA	atopic dermatitis	Phase I www.kiniksa.com
lebrikizumab (IL-13 inhibitor)	Dermira Menlo Park, CA	atopic dermatitis	Phase II www.dermira.com
lotamilast (RVT-501) (PDE4 inhibitor)	Dermavant Sciences Phoenix, AZ	atopic dermatitis	Phase II www.dermavant.com
MABp1 (IL-1 alpha inhibitor)	Xbiotech Austin, TX	atopic dermatitis (subcutaneous)	Phase II www.xbiotech.com
MM36 topical ointment (PDE4 inhibitor)	Medimetriks Pharmaceuticals Fairfield, NJ	atopic dermatitis	Phase II www.medimetriks.com
nemolizumab (IL-31 receptor antagonist mAb)	Galderma Fort Worth, TX	atopic dermatitis	Phase II www.galdermausa.com
Olumiant® baricitinib	Eli Lilly Indianapolis, IN Incyte Wilmington, DE	atopic dermatitis	Phase III www.lilly.com www.incyte.com

Dermatitis
Drug Name

Sponsor

Indication

Development Phase

PDC-APB (immunomodulator)	Hapten Sciences Memphis, TN	contact dermatitis	Phase I www.haptensciences.com
PF-04965842 (JAK inhibitor)	Pfizer New York, NY	atopic dermatitis (Breakthrough Therapy)	Phase III www.pfizer.com
PF-06817024 (cytokine modulator)	Pfizer New York, NY	atopic dermatitis	Phase I www.pfizer.com
prednisone microencapsulated (taste-masked powder for resuspension)	Orbis Biosciences Lenexa, KS	atopic dermatitis, eczema	Phase I www.orbisbio.com
PRO22 topical gel (NF-kappa B inhibitor)	Realm Therapeutics Malvern, PA	atopic dermatitis	Phase II www.realmtx.com
Q301	Qurient Seongnam-si, South Korea	atopic dermatitis	Phase II www.qurient.com
ruxolitinib cream (JAK1/JAK2 inhibitor)	Incyte Wilmington, DE	atopic dermatitis	Phase I/II www.incyte.com
santalum (East Indian sandalwood tree oil)	Santalus Pharmaceuticals San Antonio, TX	atopic dermatitis	Phase II www.santaluspharma.com

Dermatitis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SB414 (nitric oxide)	Novan Morrisville, NC	atopic dermatitis	Phase I www.novan.com
SNA-125 (JAK3/TrkA inhibitor)	Sienna Biopharmaceuticals Westlake Village, CA	atopic dermatitis with pruritus	Phase I www.siennabio.com
tapinarof (RVT-505) (Aryl hydrocarbon receptor modulator)	Dermavant Sciences Phoenix, AZ	atopic dermatitis	Phase II www.dermavant.com
tradipitant (NK1 receptor antagonist)	Vanda Pharmaceuticals Washington, DC	atopic dermatitis	Phase III www.vandapharma.com
tralokinumab (interleukin-13 inhibitor)	LEO Pharma Madison, NJ	atopic dermatitis	Phase III www.leo-pharma.us
upadacitinib (ABT-494) (JAK1 inhibitor)	AbbVie North Chicago, IL	atopic dermatitis	Phase II www.abbvie.com
VTB-38543 (LXR-B agonist)	Allergan Parsippany, NJ	atopic dermatitis	Phase II www.allergan.com
ZPL389 (histamine H4 receptor antagonist)	Novartis Pharmaceuticals East Hanover, NJ	moderate to severe atopic dermatitis	Phase II www.novartis.com
ZPL521 (cPLA2 inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	atopic dermatitis	Phase I/II completed www.novartis.com

Dermatomyositis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
lenabasum (ajulemic acid) ORPHAN DRUG	Corbus Pharmaceuticals Norwood, MA	dermatomyositis	Phase II www.corbuspharma.com
octagam® 10% immune globulin intravenous (human) 10% liquid preparation ORPHAN DRUG	Octapharma Hoboken, NJ	dermatomyositis	Phase III www.octapharmausa.com
PF-06823859 (interferon-beta-1 fibroblast blocker)	Pfizer New York, NY	dermatomyositis	Phase II www.pfizer.com
VI7734 (plasmacytoid dendritic cell modulator)	Viela Bio Gaithersburg, MD	dermatomyositis	Phase I completed www.vielabio.com

Hidradenitis Suppurativa

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
IFX-1 (complement C5a inhibitor)	InflaRx Planegg, Germany	hidradenitis suppurativa	Phase II www.inflarx.de
INCB54707 (JAK1 inhibitor)	Incyte Wilmington, DE	hidradenitis suppurativa	Phase II www.incyte.com
MABp1 (IL-1 alpha inhibitor)	Xbiotech Austin, TX	hidradenitis suppurativa (intravenous and subcutaneous)	Phase II www.xbiotech.com

Lupus, Cutaneous

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BIIB059 (anti-BDCA2 antibody)	Biogen Cambridge, MA	cutaneous lupus erythematosus	Phase II www.biogen.com
filgotinib (JAK-1 inhibitor)	Galapagos Mechelen, Belgium Gilead Sciences Foster City, CA	cutaneous lupus erythematosus	Phase II www.gilead.com
GS-9876 (Syk kinase inhibitor)	Gilead Sciences Foster City, CA	cutaneous lupus erythematosus	Phase II www.gilead.com
GSK2646264 (Syk kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	cutaneous lupus erythematosus	Phase I completed www.gsk.com

Pruritus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
difelikefalin (opioid kappa receptor agonist)	Cara Therapeutics Stamford, CT	pruritus in patients with chronic kidney disease (CKD) on hemodialysis (injectable) (Breakthrough Therapy)	Phase III www.caratherapeutics.com
		pruritus in patients with CKD stages III-V (oral)	Phase II www.caratherapeutics.com
		pruritus in patients with chronic liver disease	Phase I www.caratherapeutics.com

Pruritus

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK2330672 (bile acid transporter inhibitor)	GlaxoSmithKline Research Triangle Park, NC	pruritus associated with primary biliary cholangitis	Phase II www.gsk.com
nalbuphine extended release (opioid receptor agonist)	Trevi Therapeutics New Haven, CT	prurigo nodularis, uremic pruritus	Phase II/III www.trevitherapeutics.com
naloxone topical ORPHAN DRUG	Elorac Vernon Hills, IL	pruritus in cutaneous T-cell lymphoma (Fast Track)	Phase III www.eloracpharma.com
PA101 (sodium cromoglicate inhalant)	Patara Pharma San Diego, CA	pruritus	Phase II www.patarapharma.com
serlopitant (NK-1 receptor antagonist)	Menlo Therapeutics Redwood City, CA	prurigo nodularis itch	Phase III www.menlotherapeutics.com
SNA-120 (TrkA inhibitor)	Sienna Biopharmaceuticals Westlake Village, CA	pruritis	Phase II www.siennabio.com
SNA-125 (JAK3/TrkA inhibitor)	Sienna Biopharmaceuticals Westlake Village, CA	pruritis	Phase I www.siennabio.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
abacavir (PRINS expression inhibitor)	Innovation Pharmaceuticals Beverly, MA	plaque psoriasis	Phase II www.ipharminc.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ABP-710 (infliximab biosimilar)	Amgen Thousand Oaks, CA	psoriatic arthritis, plaque psoriasis	Phase I www.amgen.com
ANB-019 (anti-IL-36R)	AnaptysBio San Diego, CA	generalized pustular psoriasis	Phase II www.anaptysbio.com
ARQ-151 cream	Arcutis Menlo Park, CA	mild to moderate plaque psoriasis	Phase I/II
AST-005 (tumor necrosis factor inhibitor)	Exicure Skokie, IL Purdue Pharma Stamford, CT	psoriasis	Phase I www.exicuretx.com
AZD0284 (RAR-related receptor agonist)	AstraZeneca Wilmington, DE	plaque psoriasis	Phase I www.astrazeneca.com
BAY1834845 (IRAK4 inhibitor)	Bayer Pharmaceuticals Whippany, NJ	psoriasis	Phase I www.pharma.bayer.com
BBI-6000 (topical ROR gamma inhibitor)	Brickell Biotech Boulder, CO	psoriasis	Phase I www.brickellbio.com
BI655130 (interleukin-36 receptor antagonist)	Boehringer Ingelheim Ridgefield, CT	generalized pustulosis psoriasis	Phase II www.boehringer-ingelheim.com

Psoriasis
Drug Name

Sponsor

Indication

Development Phase

BI730357	Boehringer Ingelheim Ridgefield, CT	plaque psoriasis	Phase I www.boehringer-ingelheim.com
bimekizumab (interleukin-17AF protein inhibitor)	UCB Atlanta, GA	plaque psoriasis	Phase III www.ucb.com
		psoriatic arthritis	Phase II www.ucb.com
BMS-986165 (TYK2 inhibitor)	Bristol-Myers Squibb Princeton, NJ	plaque psoriasis	Phase III www.bms.com
		psoriatic arthritis	Phase I www.bms.com
BMX-010 (mangano porphyrin antioxidant mimetic)	BioMimetix Greenwood Village, CO	plaque psoriasis	Phase II
CC-90006 (PD-1 receptor antagonist)	AnaptysBio San Diego, CA Celgene Summit, NJ	psoriasis	Phase I www.celgene.com
CF101 (piclidenoson)	Can-Fite Biopharma Petah-Tikva, Israel	plaque psoriasis	Phase II/III www.canfite.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CHS-0214 (etanercept biosimilar)	Coherus BioScience Redwood City, CA	plaque psoriasis	Phase III completed www.coherus.com
CHS-1420 (adalimumab biosimilar)	Coherus BioSciences Redwood City, CA	plaque psoriasis	Phase III completed www.coherus.com
CJM112 (IL-17A protein inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	plaque psoriasis	Phase I www.novartis.com
CLS008 (topical pefcalcitol)	Cutanea Wayne, PA	psoriasis vulgaris	application submitted www.cutanea
EDP1066 (immunomodulator)	Evelo Biosciences Cambridge, MA	psoriasis	Phase I www.evelobio.com
Enstilar® calcipotriene and betamethasone dipropionate aerosol foam	LEO Pharma Madison, NJ	plaque psoriasis (adolescents)	Phase II completed www.leo-pharma.us
ESR0114 (ROR-gamma inhibitor)	Escalier Biosciences Encinitas, CA	plaque psoriasis	Phase I/II www.escalierbio.com
GP-2017 (adalimumab biosimilar)	Sandoz Princeton, NJ	plaque psoriasis, psoriatic arthritis	application submitted www.sandoz.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GR-MD-02 (galectin 3 inhibitor)	Galectin Therapeutics Norcross, GA	moderate to severe plaque psoriasis	Phase II completed www.galectintherapeutics.com
GSK2831781 (LAG3 inhibitor)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase I www.gsk.com
GSK2981278 (inverse agonist of retinoic acid eceptor-related orphan receptor gamma)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase II completed www.gsk.com
GSK2982772 (RIP1 kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	plaque psoriasis	Phase II www.gsk.com
IDP-118 (tazarotene/ulobetasol lotion)	Ortho Dermatologics Raleigh, NC	plaque psoriasis	application submitted www.ortho-dermatologics.com
IDP-122 topical (ulobetasol lotion)	Ortho Dermatologics Raleigh, NC	plaque psoriasis	application submitted www.ortho-dermatologics.com
Impoyz[®] clobetasol propionate	Promius Pharma Princeton, NJ	plaque psoriasis (pediatric)	Phase II www.promiuspharma.com
Jemdel ulobetasol lotion	Ortho Dermatologics Raleigh, NC	plaque psoriasis	application submitted www.ortho-dermatologics.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JNJ-3534 (RORyt modulator oral)	Janssen Research & Development Raritan, NJ	psoriasis	Phase I www.janssen.com
JTE-051 (IL-2 inducible T-cell kinase inhibitor)	Akros Pharma Princeton, NJ	plaque psoriasis	Phase II www.akrospharma.com
JTE-451 (RORy antagonist)	Akros Pharma Princeton, NJ	plaque psoriasis	Phase I completed www.akrospharma.com
KD025 (ROCK2 inhibitor)	Kadmon Pharmaceuticals New York, NY	moderate to severe psoriasis	Phase II www.kadmon.com
LEO 32731 (LP0058) (oral PDE4 inhibitor)	LEO Pharma Madison, NJ	plaque psoriasis	Phase II www.leo-pharma.us
LY3316531	Eli Lilly Indianapolis, IN	psoriasis	Phase I www.lilly.com
LYC-30937 (enteric-coated ATPase modulator)	Lycera Ann Arbor, MI	plaque psoriasis	Phase II completed www.lycera.com
M923 (adalimumab biosimilar)	Momenta Pharmaceuticals Cambridge, MA	plaque psoriasis	Phase III completed www.momentapharma.com
MABp1 (IL-1 alpha inhibitor)	Xbiotech Austin, TX	plaque psoriasis (subcutaneous)	Phase II www.xbiotech.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MC2-01 PAD cream (betamethasone dipropionate/ calcipotriol)	MC2 Therapeutics Copenhagen, Denmark	mild to moderate plaque psoriasis	Phase III www.mc2therapeutics.com
Mical (1)	Crescita Therapeutics Mississauga, Canada Ferndale Laboratories Ferndale, MI	plaque psoriasis	Phase II www.crescitatherapeutics.com
mirikizumab (IL-12 inhibitor)	Eli Lilly Indianapolis, IN	moderate to severe psoriasis	Phase III www.lilly.com
MSB11022 (adalimumab biosimilar)	Fresenius Kabi Bad Homburg, Germany	plaque psoriasis	Phase III completed www.fresenius-kabi.com
Olumiant® baricitinib	Eli Lilly Indianapolis, IN Incyte Wilmington, DE	psoriatic arthritis	Phase I/II www.lilly.com www.incyte.com
ONS-3010 (adalimumab biosimilar)	Oncobiologics Cranbury, NJ	plaque psoriasis	Phase I www.oncobiologics.com

Psoriasis
Drug Name

Sponsor

Indication

Development Phase

Otezla® apremilast	Celgene Summit, NJ	plaque psoriasis of the scalp	Phase III www.celgene.com
		plaque psoriasis (pediatric)	Phase II www.celgene.com
PF-06700841 (TYK2/JAK1 inhibitor)	Pfizer New York, NY	plaque psoriasis	Phase II www.pfizer.com
PF-06763809 (transcription factor inhibitor)	Pfizer New York, NY	mild to moderate plaque psoriasis	Phase I www.pfizer.com
PF-06826647 (TYK2 inhibitor)	Pfizer New York, NY	plaque psoriasis	Phase I www.pfizer.com
PH-10 (rose bengal sodium)	Provectus Biopharmaceuticals Knoxville, TN	psoriasis	Phase II www.provectusbio.com
risankizumab (IL-12 subunit p19 inhibitor)	AbbVie North Chicago, IL Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	plaque psoriasis	application submitted www.abbvie.com www.boehringer-ingelheim.com
		psoriatic arthritis	Phase II www.abbvie.com www.boehringer-ingelheim.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
santalum (East Indian sandalwood tree oil)	Santalis Pharmaceuticals San Antonio, TX	psoriasis	Phase II www.santalispharma.com
SB414 (topical cream)	Novan Morrisville, NC	psoriasis	Phase I www.novan.com
serlopitant (NK-1 receptor antagonist)	Menlo Therapeutics Redwood City, CA	psoriasis itch	Phase II www.menlotherapeutics.com
Sernivo [®] betamethasone dipropionate spray	Promius Pharma Princeton, NJ	plaque psoriasis (adolescents)	Phase III www.promiuspharma.com
SHR-1314 (vunakizumab-IL-17 inhibitor)	Jiangsu HengRui Medicine Shanghai, China	moderate to severe plaque psoriasis	Phase I/II www.hrs.com.cn
SM04755 (Wnt signalling pathway modulator)	Samumed San Diego, CA	plaque psoriasis	Phase I www.samumed.com
SNA-120 (TrkA inhibitor)	Sienna Biopharmaceuticals Westlake Village, CA	plaque psoriasis	Phase II www.siennabio.com
SNA-125 (JAK3/TrkA inhibitor)	Sienna Biopharmaceuticals Westlake Village, CA	psoriasis with pruritus	Phase I www.siennabio.com

Psoriasis

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
tapinarof (RVT-505) (Aryl hydrocarbon receptor modulator)	Dermavant Sciences Phoenix, AZ	psoriasis	Phase II www.dermavant.com
tildrakizumab (interleukin-23 inhibitor)	Sun Pharmaceutical Mumbai, India	psoriatic arthritis	Phase II www.sunpharma.com
Topicort® desoximetasone	Taro Pharmaceuticals USA Hawthorne, NY	plaque psoriasis (pediatric)	Phase III www.taro.com
Tremfya® guselkumab	Janssen Biotech Titusville, NJ	active psoriatic arthritis	Phase III www.janssenbiotech.com
upadacitinib (ABT-494) (JAK1 inhibitor)	AbbVie North Chicago, IL	psoriatic arthritis	Phase III www.abbvie.com
XCUR17 (RNA interference)	Excicure Skokie, IL	psoriasis (in combination with checkpoint inhibitors)	Phase I www.excicuretx.com
XP23829 (tepilamide fumarate)	Promius Pharma Princeton, NJ	plaque psoriasis	Phase II www.promiuspharma.com

Rosacea

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AOB103 (topical ammonia oxidizing bacteria)	AOBiome Cambridge, MA	rosacea	Phase II www.aobiome.com

Rosacea

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BPX-04 (minocycline topical)	BioPharmX Menlo Park, CA	rosacea	Phase II www.biopharmx.com
CLS001 (omiganan)	Cutanea Wayne, PA	rosacea	Phase III www.cutanea.com
DFD-04 (itraconazole ointment)	Promius Pharma Princeton, NJ	rosacea	Phase II www.promiuspharma.com
DFD-09 (oral doxycycline controlled release)	Promius Pharma Princeton, NJ	rosacea	application submitted www.promiuspharma.com
DFD-29 (minocycline oral)	Promius Pharma Princeton, NJ	rosacea	Phase II www.promiuspharma.com
DMT210 topical gel (G-protein modulator)	Dermata Therapeutics San Diego, CA	acne rosacea	Phase II completed www.dermatarx.com
FMX103 (minocycline foam)	Foamix Bridgewater, NJ	moderate to severe rosacea	Phase III www.foamix.com
minocycline topical	Hovione Loures, Portugal	papulopustular rosacea	Phase II www.hovione.com
VERED (benzoyl peroxide)	Sol-Gel Technologies Ness Ziona, Israel	papulopustular rosacea	Phase III www.sol-gel.com

Scleroderma

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Actemra® tocilizumab	Genentech South San Francisco, CA	systemic sclerosis	Phase III www.gene.com
Adempas® riociguat ORPHAN DRUG	Bayer Pharmaceuticals Whippany, NJ	systemic scleroderma	Phase II www.pharma.bayer.com
ARG201 (extracellular matrix protein) ORPHAN DRUG	arGentis Pharmaceuticals Collierville, TN	diffuse systemic scleroderma	Phase II www.argentisrx.com
FCX-013 (genetically-modified autologous fibroblast cells) ORPHAN DRUG	Fibrocell Exton, PA Intrexon Germantown, MD	moderate to severe localized scleroderma (Fast Track)	Phase I www.fibrocell.com www.dna.com
GSK2330811 (oncostatin M inhibitor)	GlaxoSmithKline Research Triangle Park, NC	diffuse cutaneous systemic scleroderma	Phase II www.gsk.com
Habeo™ autologous cell therapy ORPHAN DRUG	Cytori Therapeutics San Diego, CA	hand scleroderma	Phase III www.cytori.com
lenabasum (ajulemic acid) ORPHAN DRUG	Corbus Pharmaceuticals Norwood, MA	diffuse cutaneous systemic sclerosis (Fast Track)	Phase III www.corbuspharma.com

Scleroderma

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
romilkimab (SAR156597) (IL4/II13 br-specific mAb)	Sanofi Bridgewater, NJ	systemic scleroderma	Phase II www.sanofi.com
Vasculan [®] ifetroban	Cumberland Pharmaceuticals Nashville, TN	systemic scleroderma	Phase II www.cumberlandpharma.com
VI7734 (plasmacytoid dendritic cell modulator)	Viela Bio Gaithersburg, MD	systemic scleroderma	Phase I completed www.vielabio.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Adcetris [®] brentuximab vedotin	Takeda Oncology Cambridge, MA	cutaneous T-cell lymphoma	Phase III www.takedaoncology.com
APX005M (CD40 agonistic antibody)	Apexigen San Carlos, CA Bristol-Myers Squibb Princeton, NJ	malignant melanoma (combination with cabiralizumab and nivolumab)	Phase I/II www.apexigen.com
Bavencio [®] avelumab	EMD Serono Rockland, MA Pfizer New York, NY	melanoma (+4-1BB), merkel cell carcinoma	Phase II www.emdserono.com www.pfizer.com
BBI-3000 (oral rexinoid)	Brickell Biotech Boulder, CO	cutaneous T-cell lymphoma	Phase I www.brickellbio.com

Skin Cancer
Drug Name

Sponsor

Indication

Development Phase

BMS-986205 (IDO1 inhibitor)	Bristol-Myers Squibb Princeton, NJ	advanced melanoma (+nivolumab)	Phase III www.bms.com
BNZ-1 (IL-2, IL-9, IL-15 receptor antagonist)	Bioniz Irvine, CA	cutaneous T-cell lymphoma	Phase II www.bioniz.com
BPM 31510 (ubidecarenone topical cream)	Berg Framingham, MA	squamous cell carcinoma	Phase II www.berghealth.com
Cavatak® coxsackievirus ORPHAN DRUG	Viralytics Sydney, Australia	advanced melanoma (+ipilimumab)	Phase II www.viralytics.com
	Viralytics Sydney, Australia Merck Kenilworth, NJ	advanced melanoma (+pembrolizumab)	Phase II www.viralytics.com
CD11301 (topical gel)	Galderma Fort Worth, TX	cutaneous T-cell lymphoma	Phase II www.galdermausa.com
cemiplimab (anti-PD-1 mAb)	Regeneron Pharmaceuticals Tarrytown, NY Sanofi Bridgewater, NJ	basal cell carcinoma, cutaneous squamous cell carcinoma	Phase II www.regeneron.com www.sanofi.com
CLL442 topical	Novartis Oncology East Hanover, NJ	cutaneous squamous cell carcinoma in situ	Phase I/II www.novartis.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CMP-001 (TLR9 agonist cancer vaccine)	Checkmate Pharmaceuticals Cambridge, MA	malignant melanoma (+pembrolizumab)	Phase I www.checkmatepharma.com
cobomarsen (microRNA inhibitor) ORPHAN DRUG	miRagen Therapeutics Boulder, CO	cutaneous T-cell lymphoma	Phase I www.miragen.com
Cotellic® cobimetinib ORPHAN DRUG	Genentech South San Francisco, CA	1L BRAF-mutant metastatic melanoma (+atezolizumab +vemurafenib), 1L BRAF wild type metastatic melanoma (+atezolizumab)	Phase III www.gene.com
		2L BRAF wild type metastatic melanoma (+atezolizumab), melanoma (+atezolizumab +vemurafenib)	Phase I www.gene.com
daromun (darleukin/fibromun) (recombinant fusion protein)	Philogen Sovicille, Italy	malignant melanoma	Phase III www.philogen.com
entinostat (HDAC inhibitor)	Syndax Pharmaceuticals Waltham, MA	melanoma (+pembrolizumab)	Phase II www.syndax.com
epacadostat (IDO1 inhibitor)	Incyte Wilmington, DE	melanoma	Phase I www.incyte.com
Erivedge® vismodegib	Genentech South San Francisco, CA	operable basal cell carcinoma	Phase II www.gene.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GR-MD-02 (galectin 3 inhibitor)	Galectin Therapeutics Norcross, GA	melanoma (+ipilimumab), melanoma (+pembrolizumab)	Phase I www.galectintherapeutics.com
GRN-1201 (cancer peptide vaccine)	BrightPath Biotherapeutics Tokyo, Japan	melanoma	Phase I www.brightpathbio.com
GSK3377794 (NY-ESO-autologous engineered T-cell receptor therapy)	GlaxoSmithKline Research Triangle Park, NC	melanoma	Phase II www.gsk.com
HBI-8000 (HDAC inhibitor)	Huya Bioscience San Diego, CA	melanoma (+nivolumab)	Phase I/II www.huyabio.com
HF10 (canerapturev)	Takara Bio USA Mountain View, CA	malignant melanoma	Phase II www.takara-bio.com
IMC-gp100 (CD3 antigen inhibitor)	Immunocore Oxford, United Kingdom MedImmune Gaithersburg, MD	cutaneous melanoma (+durvalumab and/or tremelimumab)	Phase I/II www.immunocore.com
IMCnyeso (immunologic cytotoxicity)	Immunocore Oxford, United Kingdom	melanoma	Phase I/II www.immunocore.com
Imfinzi [®] durvalumab	MedImmune Gaithersburg, MD	melanoma (+dabrafenib +trametinib)	Phase I/II www.medimmune.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Imlygic® talimogene laherparepvec (oncolytic virus therapy)	Amgen Thousand Oaks, CA	mid- to late-stage metastatic melanoma (+pembrolizumab)	Phase III www.amgen.com
Imprime PGG® immunostimulant PGG glucan	Biothera Pharmaceuticals Eagan, MN	metastatic melanoma (+pembrolizumab)	Phase I/II www.biothera.com
indoximod (IDO inhibitor) ORPHAN DRUG	NewLink Genetics Ames, IA	advanced melanoma (+PD-1 inhibitors)	Phase II/III www.newlinkgenetics.com
IPH4102 (KIR3DL2 receptor antagonist) ORPHAN DRUG	Innate Pharma Marseille, France	cutaneous T-cell lymphoma	Phase I www.innate-pharma.com
IPI-549 (PI3K-gamma inhibitor)	Infinity Pharmaceuticals Cambridge, MA	melanoma (+nivolumab)	Phase I www.infi.com
Keytruda® pembrolizumab	Merck Kenilworth, NJ	resected high-risk stage III melanoma, merkel cell carcinoma	application submitted www.merck.com
		cutaneous squamous cell carcinoma	Phase II www.merck.com
LN-144 (tumor-infiltrating lymphocyte) ORPHAN DRUG	Iovance Biotherapeutics San Carlos, CA	malignant melanoma (Fast Track)	Phase II www.iovance.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
LV 305	Immune Design Seattle, WA	malignant melanoma	Phase I www.immunedesign.com
MAGE-A10 TCR (T-cell receptor therapy)	Adaptimmune Philadelphia, PA	melanoma	Phase I/II www.adaptimmune.com
mocetinostat	Mirati Therapeutics San Diego, CA	malignant melanoma	Phase I www.mirati.com
MORAb-004 (ontuxizumab)	Eisai Woodcliff Lake, NJ	melanoma	Phase II www.eisai.com
NanoPac® Ointment paclitaxel nanoformulation (SOR007)	DFB Soria Fort Worth, TX NanOlogy Fort Worth, TX	cutaneous metastases	Phase II www.nanolgy.us
NANT merkel cell cancer vaccine (activated natural killer cells - haNK for infusion) ORPHAN DRUG	NantKwest Culver City, CA	merkel cell carcinoma	Phase II www.nantkwest.com
NANT squamous cell carcinoma vaccine (activated natural killer cells - haNK for infusion)	NantKwest Culver City, CA	squamous cell carcinoma (combination therapy)	Phase I/II www.nantkwest.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NCI-4650 (mRNA-based personalized cancer vaccine)	Moderna Therapeutics Cambridge, MD	malignant melanoma	Phase I/II www.modernatx.com
NEO-PV-01 (personal antigen vaccine)	Neon Therapeutics Cambridge, MA	malignant melanoma	Phase I www.neontherapeutics.com
NKTR-214 (natural killer cell stimulant)	Bristol-Myers Squibb Princeton, NJ Nektar San Francisco, CA	melanoma (+nivolumab or +nivolumab and ipilimumab)	Phase II www.nektar.com
	Nektar San Francisco, CA	melanoma (+pembrolizumab or +atezolizumab)	Phase I www.nektar.com
NKTR-262 (TLR7 agonist)	Nektar San Francisco, CA	melanoma (+NKTR-412 and +NKR-214 and nivolumab)	Phase I www.nektar.com
NM-IL-12 (recombinant interleukin-12)	Neumedicines Pasadena, CA	cutaneous T-cell lymphoma (radio-immunotherapy)	Phase II www.neumedicines.com
omaveloxolone (Nrf2 activator) ORPHAN DRUG	Reata Pharmaceuticals Irving, TX	melanoma (+checkpoint inhibitors)	Phase I/II www.reatapharma.com
ONCOS-102 (oncolytic virus therapy)	Targovax Oslo, Norway	advanced or unresectable melanoma progressing after PD1 blockade	Phase I www.targovax.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
OT-101 (TGF-beta antisense)	Autotelic Costa Mesa, CA Oncotelic Agoura Hills, CA	melanoma	Phase II/III www.oncotelic.com
patidegib (hedgehog signaling inhibitor) ORPHAN DRUG	PellePharm San Francisco, CA	basal cell carcinoma, Gorlin syndrome (basal cell nevus syndrome)	Phase II www.pellepharm.com
PDR001 (PD-1 receptor antagonist)	Novartis Oncology East Hanover, NJ	melanoma (combination therapy)	Phase III www.novartis.com
PV-10 (rose bengal sodium) ORPHAN DRUG	Provectus Biopharmaceuticals Knoxville, TN	locally advanced cutaneous melanoma	Phase III www.provectusbio.com
		metastatic melanoma (+pembrolizumab)	Phase I www.provectusbio.com
relatlimab (anti-LAG3 mAb)	Bristol-Myers Squibb Princeton, NJ	malignant melanoma (+nivolumab)	Phase II/III www.bms.com
REM-001 (rostaporfin) (photosensitizer) ORPHAN DRUG	Adgero Biopharmaceuticals Princeton, NJ	cutaneous metastatic breast cancer (CMBC)	Phase II www.adgerobiopharm.com
		recurrent basal cell carcinoma nevus syndrome, locally advanced basal cell carcinoma, cutaneous metastatic cancer other than CMBC	Phase I www.adgerobiopharm.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
remetinostat (HDAX inhibitor) ORPHAN DRUG	Medivir Huddinge, Sweden	basal cell carcinoma, cutaneous T-cell lymphoma	Phase II www.medivir.se
Resimmune® anti-T-cell immunotoxin	Angimmune Rockville, MD	cutaneous T-cell lymphoma	Phase II completed www.angimmune.com
SD-101 (TLR9 agonist)	Dynavax Technologies Berkeley, CA	malignant melanoma (+pembrolizumab)	Phase I/II www.dynavax.com
seviprotimut-L (POL-103A) (therapeutic vaccine) ORPHAN DRUG	Polynoma San Diego, CA	malignant melanoma	Phase III www.polynoma.com
SGX-301 ointment (hypericin photodynamic therapy) ORPHAN DRUG	Soligenix Princeton, NJ	cutaneous T-cell lymphoma (Fast Track)	Phase III www.soligenix.com
spartalizumab (PDR001) (anti-PD-1 mAb)	Novartis Oncology East Hanover, NJ	malignant melanoma (+dabrafenib +trametinib)	Phase III www.novartis.com
		malignant melanoma	Phase I www.novartis.com
SUBA-itraconazole (hedgehog pathway inhibitor) ORPHAN DRUG	HedgePath Pharmaceuticals Tampa, FL	basal cell carcinoma nevus syndrome	Phase II www.hedgepathpharma.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
tavokinogene telsaplasmid (interleukin-12 gene therapy) ORPHAN DRUG	Oncosec Medical San Diego, CA	metastatic melanoma (Fast Track), advanced metastatic melanoma (+pembrolizumab)	Phase II www.oncosec.com
Tecentriq® atezolizumab	Genentech South San Francisco, CA	metastatic melanoma (combination with Zelboraf, with or without Cotellic)	Phase I www.gene.com
telomelysin (oncolytic virus immunotherapy)	Oncolys Biopharma Tokyo, Japan	metastatic melanoma	Phase II www.oncolys.com
tenalisib (PI3K-delta/gamma inhibitor) ORPHAN DRUG	Rhizen Pharmaceuticals La Chaux-de-Fonds, Switzerland	cutaneous T-cell lymphoma (Fast Track)	Phase I www.rhizen.com
tilsotolimod (IMO-2125) (TLR9 agonist) ORPHAN DRUG	Idera Pharmaceuticals Cambridge, MA	metastatic melanoma (+ipilimumab) (Fast Track)	Phase III www.iderapharma.com
		metastatic melanoma (+ipilimumab or pembrolizumab)	Phase I/II www.iderapharma.com
TLPLDC (tumor lysate particle-loaded dendritic cell vaccine)	Elios Therapeutics Austin, TX	metastatic melanoma	Phase II www.eliotherapeutics.com

Skin Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TTI-621 (CD47 antigen inhibitor/SIRPA protein stimulant) ORPHAN DRUG	Trillium Therapeutics Mississauga, Canada	melanoma, merkel cell carcinoma, mycosis fungoides, squamous cell carcinoma	Phase I www.trilliumtherapeutics.com
UV1/GM-CSF vaccine	Ultimovacs Oslo, Norway	malignant melanoma (+pembrolizumab)	Phase I www.ultimovacs.com
X4P-001-IO (CXCR4 inhibitor)	X4 Pharmaceuticals Cambridge, MA	melanoma	Phase I/II www.x4pharma.com

Skin Infections

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
afabacin (FabI inhibitor)	Debiopharm Lausanne, Switzerland	acute bacterial skin and skin structure infections (ABSSSI) caused by <i>Staphylococci</i> (Fast Track)	Phase II www.debiopharm.com
BC-7013 (bacterial protein inhibitor)	Nabriva Therapeutics King of Prussia, PA	uncomplicated skin and skin structure infections (uSSSI)	Phase II www.nabriva.com
brilacidin	Innovation Pharmaceuticals Beverly, MA	ABSSSI	Phase II www.ipharminc.com
BTL-TML001 (virus replication inhibitor)	Beech Tree Labs Delanson, NY	cold sores	Phase II completed www.beechtreelabs.com

Skin Infections

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
cefilavancin (TD-1792) (cell wall inhibitor antibiotic)	R-Pharm Moscow, Russia Theravance Biopharma South San Francisco, CA	gram-positive complicated skin and skin structure infections (including MRSA)	Phase III www.theravance.com
CLS001 (omiganan)	Cutanea Wayne, PA	genital warts (HPV)	Phase II www.cutanea.com
CLS003 (virus replication inhibitor)	Cutanea Wayne, PA	HPV-related plantar warts	Phase II www.cutanea.com
Contepo™ fosfomicin for injection	Nabriva Therapeutics King of Prussia, PA	ABSSSI (Fast Track)	Phase II www.nabriva.com
contezolid (protein synthesis inhibitor)	Micurx Pharmaceuticals Hayward, CA	complicated skin and skin structure infections (gram-positive MRSA and VRE infections)	Phase II www.micurx.com
contezolid acefosamil (protein synthesis inhibitor)	Micurx Pharmaceuticals Hayward, CA	ABSSSI	Phase II www.micurx.com
Dalvance® dalbavancin	Allergan Madison, NJ	ABSSSI (pediatric)	Phase III www.allergan.com
DFD-11 (metalloprotease inhibitor lotion)	Promius Pharma Princeton, NJ	head lice (pediculosis)	application submitted www.promiuspharma.com

Skin Infections

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
FMX102 (minocycline foam)	Foamix Bridgewater, NJ	impetigo	Phase II www.foamix.com
fusidic acid (oral)	Melinta Therapeutics New Haven, CT	ABSSSI	application submitted www.melinta.com
gepotidacin (type 2 topoisomerase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	ABSSSI	Phase II completed www.gsk.com
HTS-519 insert (terbinafine subungual)	Hallux Laguna Hills, CA	onychomycosis	Phase II www.halluxinc.com
iclaprim (dihydrofolate reductase inhibitor)	Motif BioSciences New York, NY	ABSSSI (Fast Track)	application submitted www.motifbio.com
lefamulin (bacterial protein synthesis inhibitor)	Nabriva Therapeutics King of Prussia, PA	ABSSSI (Fast Track)	Phase II www.nabriva.com
MOB015B (terbinafine topical)	Moberg Pharma Bromma, Sweden	onychomycosis	Phase III www.mobergpharma.com
N-MCT (N-methanocarbothymidine)	N&N Pharmaceuticals Rockville, MD	herpes zoster (shingles)	Phase I
NVXT topical (cell membrane permeability enhancer)	Taro Pharmaceuticals USA Hawthorne, NY	onychomycosis	Phase II www.taro.com

Skin Infections

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
omadacycline (protein synthesis inhibitor)	Paratek Pharmaceuticals Boston, MA	ABSSSI (Fast Track)	application submitted www.paratekpharma.com
pritelivir (DNA helicase-primase inhibitor)	AiCuris Wuppertal, Germany	acyclovir-resistant mucocutaneous herpes simplex virus (HSV) infections	Phase II www.aicuris.com
reltecimod (AB-103) (CD28 co-stimulatory receptor antagonist) ORPHAN DRUG	Atox Bio Chapel Hill, NC	necrotizing soft tissue infections (Fast Track)	Phase III www.atoxbio.com
santalum (East Indian sandalwood tree oil)	Santalis Pharmaceuticals San Antonio, TX	molluscum contagiosum (pediatric)	Phase II www.santalispharma.com
		HPV-related genital warts, HPV-related skin warts	Phase II www.santalispharma.com
SB206 (topical antiviral gel)	Novan Morrisville, NC	molluscum contagiosum	Phase II www.novan.com
SB208 (antifungal gel)	Novan Morrisville, NC	onychomycosis, tinea pedis	Phase II www.novan.com
Sivextro [®] tedizolid	Merck Kenilworth, NJ	ABSSI (pediatric)	Phase III www.merck.com

Skin Infections

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
V212 (herpes zoster inactivated VZV vaccine)	Merck Kenilworth, NJ	herpes zoster	Phase III www.merck.com
VBP-245 topical gel	Veloce BioPharma Fort Lauderdale, FL	molluscum contagiosum	Phase II
VP-102 (protein phosphatase 1/2A inhibitor)	Verrica Pharmaceuticals West Chester, PA	molluscum contagiosum	Phase III www.verrica.com
VT-1161 (CYP51 inhibitor)	Mycovia Pharmaceuticals Durham, NC	onychomycosis	Phase II www.mycovia.com

Urticaria

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AK002 (mast cell inhibitor)	Allakos San Carlos, CA	chronic urticaria	Phase II www.allakos.com
cidoxepin (oral) (histamine H1 receptor antagonist)	Elorac Vernon Hills, IL	urticaria	Phase II www.eloracpharma.com
fenebrutinib (BTK inhibitor)	Genentech South San Francisco, CA	chronic spontaneous urticaria	Phase II www.gene.com
GBR 310 (omalizumab biosimilar)	Glenmark Pharmaceuticals Mumbai, India	chronic idiopathic urticaria	Phase I www.glenmarkpharma.com

Urticaria

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK2646264 (Syk kinase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	urticaria	Phase I completed www.gsk.com
LOU064 (BTK inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	chronic spontaneous urticaria	Phase II www.novartis.com
QGE031 (high-affinity anti-IgE mAb)	Novartis Pharmaceuticals East Hanover, NJ	chronic idiopathic urticaria, chronic spontaneous urticaria	Phase III www.novartis.com

Vitiligo

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ATI-502 topical (JAK inhibitor)	Aclaris Therapeutics Wayne, PA	vitiligo	Phase II www.aclaristx.com
cerdulatinib (RVT-502) (dual Syk/JAK inhibitor)	Dermavant Sciences Pheonix, AZ	vitiligo	Phase I www.dermavant.com
ruxolitinib cream (JAK1/JAK2 inhibitor)	Incyte Wilmington, DE	vitiligo	Phase I/II www.incyte.com
Scenesse® afamelanotide	Clinuvel Pharmaceuticals Menlo Park, CA	vitiligo	Phase II www.clinuvel.com

Warts

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALC-919 (antiviral therapeutic)	Veloce Therapeutics Fort Lauderdale, FL	warts (verruca vulgaris)	Phase II completed
Candin® <i>Candida albicans</i> skin test antigen for cellular hypersensitivity	Nielson BioSciences San Diego, CA	warts (verruca vulgaris)	Phase II www.nielsonbio.com
CLS006 (virus replication inhibitor)	Cutanea Wayne, PA	warts (verruca vulgaris)	Phase III www.cutanea.com
DFD-05	Promius Pharma Princeton, NJ	common warts	Phase II www.promiuspharma.com
Eskata® hydrogen peroxide topical 45%	Aclaris Therapeutics Wayne, PA	common warts	Phase II completed www.aclaristx.com
LFX453	Novartis Pharmaceuticals East Hanover, NJ	external genital warts	Phase II completed www.novartis.com
Nowarta110 (topical botanical)	Nowarta Biopharma Huntington Beach, CA	plantar warts	Phase I/II completed www.nowarta.com
RXI-SCP (diphenylcyclopropanone)	RXi Pharmaceuticals Marlborough, MA	cutaneous warts (verruca vulgaris)	Phase II www.rxipharma.com

Warts

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SB206 (topical antiviral gel)	Novan Morrisville, NC	external genital warts	Phase II www.novan.com
VP-102 (protein phosphatase 1/2A inhibitor)	Verrica Pharmaceuticals West Chester, PA	common warts	Phase II www.verrica.com

Wounds

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
APD334 (S1P1 receptor modulator)	Arena Pharmaceuticals San Diego, CA	pyoderma gangrenosum	Phase II www.arenapharm.com
CVBT-141B topical (fibroblast growth factor 1)	CardioVascular BioTherapeutics Dallas, TX	chronic diabetic foot ulcers (wound healing)	Phase II www.cvbt.com
EB-001A (botulinum toxin E)	Bonti Newport Beach, CA	post-surgery scarring	Phase II www.bonti.com
ESS (human skin replacement) ORPHAN DRUG	Amarantus Bioscience New York, NY	intractable severe burns	Phase II www.amarantus.com
ExpressGraft™ anti-infective skin replacement therapy (C9T1 skin tissue)	Stratatech St. Louis, MO	diabetic foot ulcer	Phase I www.mallinckrodt.com
Galnobax® esmolol	NovaLead Pharma Shrewsbury, MA	diabetic foot ulcer	Phase I/II completed www.novaleadpharma.com

Wounds

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GBT-101 topical gel (thymosin beta-4)	Gtree Pharmaceuticals Seongnam-si, South Korea	pressure ulcers	Phase II completed www.gtreebnt.com
Granexin® Gel (peptide mimetic ACT1)	FirstString Research Mt. Pleasant, SC	diabetic foot and venous leg ulcers	Phase III www.firststringresearch.com
		post-surgical keloids (scar reduction)	Phase II www.firststringresearch.com
Humira® adalimumab	AbbVie North Chicago, IL	pyoderma gangrenosum	Phase III www.abbvie.com
IL22-Fc (RG7880) (recombinant human protein)	Genentech South San Francisco, CA	diabetic foot ulcers	Phase II www.gene.com
MABp1 (IL-1 alpha inhibitor)	Xbiotech Austin, TX	pyoderma gangrenosum (intravenous)	Phase II www.xbiotech.com
MBN-101 (topical antibacterial)	Microbion Bozeman, MT	diabetic foot ulcers (Fast Track)	Phase I/II www.microbiocorp.com
nemonoxacin (DNA topoisomerase inhibitor)	TaiGen Biotechnology Taipei, Taiwan	diabetic foot ulcers	Phase www.taigenbiotech.com.tw
Nu-3 (cell membrane structure modulator)	Lakewood-Amedex Sarasota, FL	diabetic foot ulcers	Phase I/II completed www.lakewoodamedex.com

Wounds

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RXI-109 (RNA interference)	RXi Pharmaceuticals Marlborough, MA	hypertrophic scarring	Phase II www.rxipharma.com
STP705 (siRNA oligonucleotides)	Sirnaomics Gaithersburg, MD	hypertrophic scars	Phase I/II www.sirnaomics.com
VF001 (tissue growth factor)	Factor Therapeutics Dara, Australia	chronic venous leg ulcers	Phase II www.factor-therapeutics.com
VM202 (donaperminogene seltoplasmid)	ViroMed Seoul, South Korea	chronic non-healing diabetic foot ulcers	Phase III www.viomed.co.kr

Other

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
852 (TLR7 agonist)	3M Drug Delivery Systems St. Paul, MN	skin disorders	Phase I www.3m.com
ANB-019 (anti-IL-36R)	AnaptysBio San Diego, CA	palmoplantar pustulosis	Phase I completed www.anaptysbio.com
AR28	Arbor Pharmaceuticals Atlanta, GA	skin disorders	Phase II www.arborpharma.com
BI655130 (interleukin-36 receptor antagonist)	Boehringer Ingelheim Ridgefield, CT	palmoplantar pustulosis	Phase II www.boehringer-ingelheim.com

Other

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
clobetasol propionate oral (steroid receptor agonist)	Dermtreat San Diego, CA	oral lichen planus	Phase II www.dermtreat.com
CLS001 (omiganan)	Cutanea Wayne, PA	vulvar intraepithelial neoplasia	Phase II www.cutanea.com
Crysvita [®] burosumab-twza	Kyowa Hakko Kirin Pharma Tokyo, Japan Ultragenyx Novato, CA	epidermal nevus syndrome	Phase II www.kyowa-kirin.com www.ultragenyx.com
FMX104 (doxycycline foam)	Foamix Bridgewater, NJ	chemotherapy-induced rash	Phase II www.foamix.com
Granexin [®] Gel (peptide mimetic ACT1)	FirstString Research Mt. Pleasant, SC	cutaneous radiation injury	Phase III www.firststringresearch.com
KPL-716 (IL-31 protein inhibitor/ oncostatin M inhibitor)	Kiniksa Pharmaceuticals Lexington, MA	nodular prurigo	Phase I www.kiniksa.com
LM-030 (kallikren-related peptidase inhibitor)	LifeMax Laboratories Palo Alto, CA	congenital ichthyosiform erthroderm (Netherton syndrome)	Phase II www.lifemaxhealthcare.com
LX3305 (S1P inhibitor)	Dermecular Therapeutics Palo Alto, CA	Darier's disease, Hailey-Hailey disease	Phase II www.bridgebio.com

Other

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MT-7117 (immunomodulator)	Mitsubishi Tanabe Pharma Jersey City, NJ	erythropoietic protoporphyria (Fast Track)	Phase II www.mt-pharma-america.com
Natroba™ spinosad	ParaPRO Carmel, IN	scabies	Phase III www.parapro.com
PAT-001 (isotretinoin) ORPHAN DRUG	Patagonia Pharmaceuticals Woodcliff Lake, NJ	congenital ichthyosiform erythroderma	Phase II www.patagoniarx.com
PTX-022 (topical high-strength rapamycin) ORPHAN DRUG	Palvella Therapeutics Wayne, PA	pachyonuchia congenita	Phase II www.palvellatx.com
reproxalap (malondialdehyde inhibitor) ORPHAN DRUG	Aldeyra Therapeutics Lexington, MA	Sjogren-Larsson syndrome	Phase III www.aldeyra.com
Scenesse® afamelanotide ORPHAN DRUG	Clinuvel Pharmaceuticals Menlo Park, CA	erythropoietic protoporphyria (Fast Track)	application submitted www.clinuvel.com
sofpironium bromide (cholinergic receptor antagonist)	Brickell Biotech Boulder, CO	axillary hyperhidrosis	Phase II www.brickellbio.com
TC-5214 (alpha3beta4/alpha4beta2 nicotinic receptor antagonist)	Atacama Therapeutics Wellesley, MA	palmar hyperhidrosis	Phase II www.atacamatherapeutics.com

Other

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VBP 926 topical solution	Velocite BioPharma Fort Lauderdale, FL	chemotherapy-associated paronychia	Phase II

The content of this report has been obtained through public, government and industry sources, and the Springer "Adis Insight" database based on the latest information. Report current as of **September 14, 2018**. The medicines in this listing include medicines being developed by U.S.-based companies conducting trials in the United States abroad, PhRMA-member companies conducting trials in the United States and abroad, and foreign companies conducting clinical trials in the United States. Some products may not be in active clinical trials. The information may not be comprehensive. For more, specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's website: www.phrma.org.

Definitions

Application Submitted—An application for marketing has been submitted by the company to the U.S. Food and Drug Administration (FDA).

Breakthrough Therapy—Upon request by a sponsor, the FDA can grant this designation to expedite the development and review of a drug or biologic intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug or biologic is designated as a Breakthrough Therapy, the FDA will expedite the development and review. With this designation, all Fast Track features convey to the medicine.

Fast Track—Upon request by a sponsor, the FDA can grant this designation to facilitate the development and expedite the review of a drug or biologic to treat a serious condition and fill an unmet medical need. When considering a biopharmaceutical company's request for Fast Track designation for an investigational drug or biologic, the FDA evaluates whether it will affect factors such as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one, and whether a condition can be adequately addressed by available therapy. With Fast Track designation, early and frequent communication between the FDA and the biopharmaceutical company is encouraged throughout the entire drug development and review process to help to quickly resolve any questions or issues that arise, potentially leading to an earlier approval and access by patients.

Orphan Designation—Upon request by a sponsor, the FDA can grant special status ("orphan status") to a drug or biologic to treat a rare disease or condition. In order to receive an orphan designation, a qualifying drug or biologic must be intended for the treatment, diagnosis, or prevention of a rare disease or condition that affects usually fewer than 200,000 people in the United States.

Definitions -- Continued

Phase I—Researchers test the investigational drug or biologic in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

Phase II—The investigational drug or biologic is given to volunteer patients, usually between 100 and 500, to determine whether it is effective, identify an optimal dose, and to further evaluate its short-term safety.

Phase III—The investigational drug or biologic is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more), to generate statistically significant evidence to confirm its safety and effectiveness. Phase III studies are the longest studies and usually take place in multiple sites around the world.