

2019 Medicines in Development for Asthma and Allergy

Respiratory Allergies

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
AR101 (oral immunotherapy)	Aimmune Brisbane, CA	peanut allergy (Fast Track)	application submitted www.aimmune.com
ASP0892 (plasmid-based DNA vaccine)	Astellas Pharma US Northbrook, IL Immunomic Therapeutics Rockville, MD	peanut allergy (Fast Track)	Phase I www.astellas.com
Dupixent® dupilumab	Sanofi Genzyme Cambridge, MA Regeneron Tarrytown, NY	grass immunotherapy, peanut allergy (pediatric)	Phase II www.sanofigenzyme.com www.regeneron.com
HAL-MPE1 (subcutaneous immunotherapy)	HAL Allergy Leiden, Netherlands	peanut allergy (pediatric)	Phase I www.hal-allergy.com
PQ Grass (injectable MPL allergy vaccine)	Allergy Therapeutics West Sussex, United Kingdom	grass pollen hypersensitivity	Phase III www.allergytherapeutics.com
PQ Ragweed (injectable MPL allergy vaccine)	Allergy Therapeutics West Sussex, United Kingdom	grass pollen hypersensitivity	Phase III www.allergytherapeutics.com

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<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
PQ Trees (injectable MPL allergy vaccine)	Allergy Therapeutics West Sussex, United Kingdom	grass pollen hypersensitivity	Phase II www.allergytherapeutics.com
REGN1908-1909 (Fel d 1 antibody)	Regeneron Tarrytown, NY	cat allergy	Phase I www.regeneron.com
SAR439794 (TLR4 agonist)	Sanofi US Bridgewater, NJ	peanut allergy	Phase I www.sanofi.com
UBITh® Allergy anti-IgE allergy immuno- therapeutic vaccine	United Biomedical Hauppauge, NY	desensitization of all IgE/ allergen-mediated allergies	Phase I www.unitedbiomedical.com
Viaskin® Peanut	DBV Technologies New York, NY	peanut allergy (4-11 years old) (Fast Track) (Breakthrough Therapy), peanut allergy (1-3 years old)	Phase III www.dbv-technologies.com
		peanut allergy (adolescents and adults)	Phase I www.dbv-technologies.com
Viaskin® Milk	DBV Technologies New York, NY	cow's milk allergy (2-17 years old) (Fast Track)	Phase II www.dbv-technologies.com

Allergic Rhinitis

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
AOB201 (intranasal ammonia oxidizing bacteria-based therapeutic)	AOBiome Cambridge, MA	allergic rhinitis	Phase II www.aobiome.com
budesonide + azelastine fixed-dose combination	Sedor Pharmaceuticals Paoli, PA	seasonal allergic rhinitis	Phase I www.sedorpharmaceuticals.com
Ragwitek™ short ragweed pollen allergen extract	ALK-Bello Round Rock, TX	seasonal allergic rhinitis (adolescents and children)	Phase III completed www.alk.net
Ryaltris™ mometasone/olopatadine	Glenmark Pharmaceuticals Mahwah, NJ	seasonal allergic rhinitis	application submitted www.glenmarkpharma-us.com
		perennial allergic rhinitis, seasonal allergic rhinitis (children)	Phase III www.glenmarkpharma-us.com
STAGR320 (house dust mite allergy immunotherapy tablet)	Stallergenes Greer Boston, MA	allergic rhinitis	Phase III www.stallergenesgreerus.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
A006 (salbutamol dry-powder inhalation)	Amphastar Pharmaceuticals Rancho Cucamonga, CA	asthma	Phase II completed www.amphastar.com
abediterol (LABA agonist)	AstraZeneca Wilmington, DE	asthma	Phase II www.astrazeneca.com
AirDuo RespiClick® salmeterol/fluticasone propionate	Teva Pharmaceuticals North Wales, PA	asthma (4-11 years old)	Phase III www.tevapharm.com
APC-1000 (beclomethasone hydrofluoroalkane)	Adamis Pharmaceuticals San Diego, CA	asthma	Phase III www.adamispharmaceuticals.com
APC-4000 (fluticasone dry powder for inhalation)	Adamis Pharmaceuticals San Diego, CA	asthma	Phase II www.adamispharmaceuticals.com
Arcapta® Neohaler® indacaterol inhalation powder	Novartis Pharmaceuticals East Hanover, NJ	asthma (pediatric)	Phase II www.novartis.com
ArmonAir™ RespiClick® fluticasone propionate inhalation	Teva Pharmaceuticals North Wales, PA	asthma (4-11 years old)	Phase III www.tevapharm.com
AZD0449 (IL13/IL4 signaling inhibitor)	AstraZeneca Wilmington, DE	chronic asthma	Phase I www.astrazeneca.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
AZD1402 (PRS-060) (interleukin 4 receptor antagonist)	AstraZeneca Wilmington, DE Pieris Pharmaceuticals Boston, MA	asthma	Phase I www.astrazeneca.com
AZD1419 (TLR9 agonist)	AstraZeneca Wilmington, DE	asthma	Phase II www.astrazeneca.com
AZD7594 (inhaled SGRN)	AstraZeneca Wilmington, DE	asthma	Phase II www.astrazeneca.com
AZD8154 (PI3K γ δ inhibitor)	AstraZeneca Wilmington, DE	asthma	Phase I www.astrazeneca.com
BI 443651	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	asthma	Phase I completed www.boehringer-ingelheim.com
BI 894416	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	asthma	Phase I www.boehringer-ingelheim.com
CHF 781 (beclomethasone pressurized metered-dose inhaler)	Chiesi Farmaceutici Parma, Italy	asthma	Phase II www.chiesi.com
CINQAIR [®] reslizumab	Teva Pharmaceuticals North Wales, PA	eosinophilic asthma (12 years and older)	Phase III www.tevapharm.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
CJM112 (IL17 protein inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	severe asthma	Phase II www.novartis.com
CSJ117 (inhaled fAb fragment)	Novartis Pharmaceuticals East Hanover, NJ	severe asthma	Phase II www.novartis.com
dexpramipexole (selective dopamine receptor agonist)	Knopp Biosciences Pittsburgh, PA	eosinophilic asthma	Phase II www.knoppbio.com
Dulera [®] mometasone/formoterol	Merck Kenilworth, NJ	asthma (5-11 years old)	Phase III completed www.merck.com
Dupixent [®] dupilumab	Sanofi Genzyme Cambridge, MA Regeneron Tarrytown, NY	asthma (6-11 years old)	Phase II www.sanofigenzyme.com www.regeneron.com
EmphyClear [®] drug free COPD/asthma spray	EmphyCorp Danville, NJ	asthma	Phase II completed www.emphycorp.com
EmphyClear [®] 70% 70% lower steroid oral spray	EmphyCorp Danville, NJ	asthma	Phase III www.emphycorp.com
etokimab (anti-IL33 mAb)	AnaptysBio San Diego, CA	eosinophilic asthma	Phase II www.anaptysbio.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
FP-025 (MMP-12 inhibitor)	Foresee Pharmaceuticals Newark, DE	asthma	Phase I www.foreseepharma.com
GB001	Gossamer Bio San Diego, CA	asthma	Phase II www.gossamerbio.com
GBR 310 (omalizumab biosimilar)	Glenmark Pharmaceuticals Mahwah, NJ	allergic asthma	Phase II www.glenmarkpharma-us.com
GDC-0214 (RG6151)	Genentech South San Francisco, CA	asthma	Phase I www.gene.com
GSK2245035 (TLR7 agonist)	GlaxoSmithKline Research Triangle Park, NC	asthma	Phase II completed www.gsk.com
GSK3511294 (IL5 long-acting mAb)	GlaxoSmithKline Research Triangle Park, NC	asthma	Phase I www.gsk.com
GSK3772847 (IL33r mAb)	GlaxoSmithKline Research Triangle Park, NC	severe asthma	Phase II www.gsk.com
ifetroban (thromboxane A2 receptor antagonist)	Cumberland Pharmaceuticals Nashville, TN	aspirin-induced asthma	Phase II www.cumberlandpharma.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
JNJ-38518168 (histamine H4 receptor antagonist)	Janssen Raritan, NJ	asthma	Phase II completed www.janssen.com
MN-221 (beta 2 adrenergic receptor agonist)	MediciNova La Jolla, CA	acute exacerbations of asthma	Phase II completed www.medicinova.com
NOV-14 (mAb)	MorphoSys Planegg, Germany Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase I www.morphosys.com www.novartis.com
Nucala [®] mepolizumab	GlaxoSmithKline Research Triangle Park, INC	asthma (6-11 years old)	application submitted www.gsk.com
PT001 (glycopyrrolate inhaled)	AstraZeneca (Pearl Therapeutics) Wilmington, DE	asthma	Phase II/III www.astrazeneca.com
PT007 (salmeterol metered-dose inhalation)	AstraZeneca (Pearl Therapeutics) Wilmington, DE	asthma	Phase II completed www.astrazeneca.com
PT010 (budesonide/formoterol/ glycopyrrolate)	AstraZeneca (Pearl Therapeutics) Wilmington, DE	asthma	Phase II www.astrazeneca.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
QAW039 (fevipirant) (prostaglandin D2 receptor antagonist)	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase III www.novartis.com
QMF149 (indacaterol/mometasone fixed-dose combination)	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase III www.novartis.com
QVM149 (glycopyrrolate/indacaterol/mometasone)	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase III www.novartis.com
RG6149 (anti-ST2 mAb)	Genentech South San Francisco, CA	asthma	Phase II www.gene.com
RG6173	Genentech South San Francisco, CA	asthma	Phase I www.gene.com
SAR440340 (REGN3500) (anti-IL33 mAb)	Regeneron Pharmaceuticals Tarrytown, NY Sanofi US Bridgewater, NJ	asthma	Phase II www.regeneron.com www.sanofi.com
Seebri® Neohaler® glycopyrrolate inhalation	Novartis Pharmaceuticals East Hanover, NJ	asthma	Phase II completed www.novartis.com

Asthma

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
Symbicort® budesonide	AstraZeneca Wilmington, DE	as needed use in mild asthma	Phase III www.astrazeneca.com
TD-8236 (inhaled JAK inhibitor)	Theravance Biopharma South San Francisco, CA	asthma	Phase I www.theravance.com
tezepelumab (TSLP inhibitor)	Amgen Thousand Oaks, CA AstraZeneca Wilmington, DE	severe uncontrolled asthma	Phase III www.amgen.com www.astrazeneca.com
Trelegy Ellipta fluticasone furoate/vilanterol/ umeclidinium	GlaxoSmithKline Research Triangle Park, NC	asthma	Phase III www.gsk.com
TRN-157 (muscarinic M3 receptor antagonist)	Theron Pharmaceuticals Sunnyvale, CA	asthma	Phase II completed www.theronpharma.com
umeclidinium (muscarinic receptor antagonist)	GlaxoSmithKline Research Triangle Park, NC	asthma	Phase II completed www.gsk.com
VR647 (nebulized budesonide)	Vectura Wiltshire, United Kingdom	asthma (pediatric)	Phase II www.vectura.com
XmAb7195 (immune inhibitor)	Xencor Monrovia, CA	allergic asthma	Phase I www.xencor.com

Bronchiectasis

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
ARD-3150 (liposomal ciprofloxacin inhalation) ORPHAN DRUG	Aradigm Hayward, CA	non-cystic fibrosis (CF) bronchiectasis (Fast Track)	application submitted www.aradigm.com
INS1007 (AZD7986) (DPP1 inhibitor)	AstraZeneca Wilmington, DE Insmed Bridgewater, NJ	non-CF bronchiectasis	Phase II www.astrazeneca.com www.insmed.com
nemiralisib (PI3-kinase delta inhibitor)	GlaxoSmithKline Research Triangle Park, NC	bronchiectasis	Phase I www.gsk.com
SNSP114 (glycopolymer-based therapeutic)	Synspira Cambridge, MA	non-CF bronchiectasis	Phase I www.synspira.com
tobramycin dry-powder inhalation	Novartis Pharmaceuticals East Hanover, NJ	non-CF bronchiectasis	Phase II www.novartis.com

Chronic Obstructive Pulmonary Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
abediterol (LABA agonist)	AstraZeneca Wilmington, DE	chronic obstructive pulmonary disease (COPD)	Phase II www.astrazeneca.com

Chronic Obstructive Pulmonary Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
acumapimod (oral p38 MAP kinase inhibitor)	Mereo BioPharma London, United Kingdom	acute exacerbations of COPD	Phase II www.mereobiopharma.com
APC-1000 (beclomethasone hydrofluoroalkane)	Adamis Pharmaceuticals San Diego, CA	COPD	Phase III www.adamispharmaceuticals.com
APC-4000 (fluticasone dry powder for inhalation)	Adamis Pharmaceuticals San Diego, CA	COPD	Phase II www.adamispharmaceuticals.com
AZD8871 (muscarinic antagonist/ beta 2 agonist)	AstraZeneca Wilmington, DE	COPD	Phase II www.astrazeneca.com
AZD7594 (inhaled SGRM)	AstraZeneca Wilmington, DE	COPD	Phase II www.astrazeneca.com
BI 1026706	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	COPD	Phase I completed www.boehringer-ingelheim.com
BI 1323495	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	COPD	Phase I www.boehringer-ingelheim.com
BI 443651	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	COPD	Phase I completed www.boehringer-ingelheim.com

Chronic Obstructive Pulmonary Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
Bio-11006 (myristoylated alanine rich C kinase substrate inhibitor)	BioMarck Pharmaceuticals Research Triangle Park, NC	COPD	Phase II completed www.biomarck.com
CCI 15106	GlaxoSmithKline Research Triangle Park, NC	COPD	Phase I completed www.gsk.com
CHF 5259 (glycopyrrolate inhalation)	Chiesi Farmaceutici Parma, Italy	COPD	Phase II completed www.chiesi.com
danirixin (CXCR2 antagonist)	GlaxoSmithKline Research Triangle Park, NC	COPD	Phase II www.gsk.com
DS102 (AF102) (15-hydroxyeicosapentaenoic acid)	Afimmune Dublin, Ireland	COPD	Phase II www.afimmune.com
Duaklir® Genuair® aclidinium bromide/formoterol	AstraZeneca Wilmington, DE	COPD	application submitted www.astrazeneca.com
EmphyClear® drug free COPD/asthma spray	EmphyCorp Danville, NJ	COPD	Phase II completed www.emphycorp.com
EmphyClear® 70% 70% lower steroid oral spray	EmphyCorp Danville, NJ	COPD	Phase III www.emphycorp.com

Chronic Obstructive Pulmonary Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
Fasenra® benralizumab	MedImmune Gaithersburg, MD	COPD	Phase III www.medimmune.com
FP-025 (MMP-12 inhibitor)	Foresee Pharmaceuticals Newark, DE	COPD	Phase I www.foreseepharma.com
GSK2292767 (PI3-kinase delta inhibitor)	GlaxoSmithKline Research Triangle Park, NC	COPD	Phase I www.gsk.com
GSK3277511A (recombinant vaccine)	GlaxoSmithKline Research Triangle Park, NC	reduction of acute exacerbations in COPD patients by targeting non-typeable Haemophilus influenza and Moraxella catarrhalis	Phase II www.gsk.com
GSP 304 (tiotropium bromide)	Glenmark Pharmaceuticals Wahwah, NJ	COPD	Phase II www.glenmarkpharma-us.com
INS1007 (AZD7986) (DPP1 inhibitor)	AstraZeneca Wilmington, DE Insmmed Bridgewater, NJ	COPD	Phase II www.astrazeneca.com www.insmed.com
MEDI3506 (IL33 mAb)	MedImmune Gaithersburg, MD	COPD	Phase I www.medimmune.com

Chronic Obstructive Pulmonary Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
nemiralisib (PI3-kinase delta inhibitor)	GlaxoSmithKline Research Triangle Park, NC	acute and chronic COPD	Phase II www.gsk.com
Nucala [®] mepolizumab	GlaxoSmithKline Research Triangle Park, NC	COPD	application submitted www.gsk.com
ProAir RespiClick [®] albuterol sulfate inhalation	Teva Pharmaceuticals North Wales, PA	COPD	Phase III completed www.tevapharm.com
PT001 (glycopyrrolate inhaled)	AstraZeneca (Pearl Therapeutics) Wilmington, DE	COPD	Phase III completed www.astrazeneca.com
PT009 (budesonide/formoterol)	AstraZeneca (Pearl Therapeutics) Wilmington, DE	COPD	Phase III completed www.astrazeneca.com
PT010 (budesonide/formoterol/ glycopyrrolate)	AstraZeneca (Pearl Therapeutics) Wilmington, DE	COPD	Phase III www.astrazeneca.com
PUL-042 (toll-like receptor agonist)	Pulmotect Houston, TX	COPD exacerbations	Phase II www.pulmotect.com
PUR0200 (VR410) (tiotropium bromide inhalation)	Pulmatrix Lexington, MA Vectura Wiltshire, United Kingdom	COPD	Phase II www.pulmatrix.com www.vectura.com

Chronic Obstructive Pulmonary Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
PUR1800 (kinase inhibitor)	Pulmatrix Lexington, MA	COPD	Phase II www.pulmatrix.com
QBW251 (CFTR potentiator)	Novartis Pharmaceuticals East Hanover, NJ	COPD	Phase II www.novartis.com
reldeesemtiv (fast skeletal troponin activator)	Cytokinetics South San Francisco, CA Astellas Pharma US Northbrook, IL	COPD	Phase II www.cytokinetics.com www.astellas.com
RPL554 (ensifentrine) (PDE 3/4 inhibitor)	Verona Pharma London, United Kingdom	COPD (combination therapy)	Phase II www.veronapharma.com
SAR440340 (REGN3500) (anti-IL33 mAb)	Regeneron Pharmaceuticals Tarrytown, NY Sanofi US Bridgewater, NJ	COPD	Phase II www.regeneron.com www.sanofi.com
TRN-157 (muscarinic M3 receptor antagonist)	Theron Pharmaceuticals Sunnyvale, CA	COPD	Phase I completed www.theronpharma.com
YPL-001 (herbal medicine)	Yungjin Pharm Seoul, South Korea	COPD	Phase II www.yungjin.co.kr

Cough

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
BAY1817080 (P2X3 antagonist)	Bayer Pharmaceuticals Whippany, NJ	persistent chronic cough	Phase II www.pharma.bayer.com
BAY1902607 (P2X3 antagonist)	Bayer Pharmaceuticals Whippany, NJ	persistent chronic cough	Phase I/II www.pharma.bayer.com
bradanicline (alpha7 nicotinic acetylcholine receptor agonist)	Attenua San Mateo, CA	chronic cough	Phase II www.attenua.com
gefapixant (P2X3 purinoreceptor antagonist)	Merck Kenilworth, NJ	chronic cough	Phase III www.merck.com
orvepitant (NK1 receptor antagonist)	NeRRe Therapeutics Herts, United Kingdom	chronic refractory cough	Phase II www.nerretherapeutics.com
RVT-1601 (sodium cromolinate inhalant)	Respivant Sciences San Diego, CA	chronic cough associated with idiopathic pulmonary fibrosis	Phase II www.nerretherapeutics.com
TRN-124	Tris Pharma Monmouth Junction, NJ	common cold and cough	application submitted www.trispharma.com

Respiratory Distress Syndrome

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
Aerosurf® sinapultide	Windtree Therapeutics Warrington, PA	neonatal respiratory distress syndrome (Fast Track)	Phase II www.wintreetx.com
BAY1097761 (PEGylated adrenomedullin)	Bayer Pharmaceuticals Whippany, NJ	respiratory distress syndrome	Phase I www.pharma.bayer.com
Bio-11006 (myristoylated alanine rich C kinase substrate inhibitor)	BioMarck Pharmaceuticals Research Triangle Park, NC	adult respiratory distress syndrome	Phase II www.biomarck.com
CHF5633 (synthetic surfactant)	Chiesi Parma, Italy	neonatal respiratory distress syndrome	Phase II completed www.chiesi.com
IC14 (CD14 antigen inhibitor mAb)	Implicit Bioscience Seattle, WA	acute respiratory distress syndrome	Phase II www.implicitbioscience.com
Infasurf® aerosolized calfactant	Ony Biotech Amherst, NY	neonatal respiratory distress syndrome (inhalation/aerosol)	Phase III www.onybiotech.com
MultiStem® allogeneic stem cell therapy	Athersys Cleveland, OH	respiratory distress syndrome	Phase I/II www.athersys.com
sGC activator 3	Bayer Pharmaceuticals Whippany, NJ	acute respiratory distress syndrome	Phase I www.pharma.bayer.com

Sinusitis

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
Dupixent® dupilumab	Sanofi Genzyme Cambridge, MA Regeneron Tarrytown, NY	rhinosinusitis with nasal polyps	Phase III www.sanofigenzyme.com www.regeneron.com
etokimab (anti-IL33 mAb)	AnaptysBio San Diego, CA	chronic rhinosinusitis with nasal polyps	Phase II www.anaptysbio.com
LYR-210 (mometasone-eluting resorbable scaffold)	Lyra Therapeutics Watertown, MA	chronic rhinosinusitis	Phase I www.lyratherapeutics.com
PF-06817024 (cytokine modulator)	Pfizer New York, NY	chronic rhinosinusitis	Phase I www.pfizer.com
XHANCE™ fluticasone propionate intranasal	OptiNose US Yardley, PA	chronic sinusitis	Phase III www.optinose.com
Xolair® omalizumab	Genentech South San Francisco, CA Novartis Pharmaceuticals East Hanover, NJ	chronic rhinosinusitis with nasal polyps	Phase III www.gene.com

Other

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
AQST-108 (epinephrine oral film)	Aquestive Therapeutics Warren, NJ	anaphylaxis	Phase I www.aquestive.com
ATYR1923 (recombinant fusion protein)	ATyr Pharma San Diego, CA	pulmonary sarcoidosis	Phase I/II www.atyrpharma.com
AZD9567 (SGRM)	AstraZeneca Wilmington, DE	respiratory tract disorders	Phase II www.astrazeneca.com
epinephrine nasal spray	INSYS Therapeutics Chandler, AZ	anaphylaxis (Fast Track)	Phase II www.insysrx.com
GSK2586881 (recombinant human angiotensin converting enzyme 2)	GlaxoSmithKline Research Triangle Park, NC	acute hypoxic pulmonary vasoconstriction	Phase I www.gsk.com
Ilaris® canakinumab	Novartis Pharmaceuticals East Hanover, NJ	pulmonary sarcoidosis	Phase II www.novartis.com
inhaled AAT ORPHAN DRUG	Kamada Rehovot, Israel	alpha-1 antitrypsin lung disease	Phase II completed www.kamada.com
intravenous citrulline	Asklepion Pharmaceuticals Baltimore, MD	acute lung injury after bronchopulmonary bypass	Phase III www.asklepionpharm.com

Other

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Status</u>
molgramostim inhalation (inhaled granulocyte-macrophage colony-stimulating factor) ORPHAN DRUG	Savara Pharmaceuticals Austin, TX	pulmonary alveolar proteinosis	Phase III www.savarapharma.com
MPH-966 (alvelestat) (neutrophil elastase inhibitor)	Mereo BioPharma London, United Kingdom	alpha 1-antitrypsin deficiency lung disease	Phase II www.mereobiopharma.com
Pneumostem® mesenchymal stem cell therapy ORPHAN DRUG	Medipost Seoul, South Korea	bronchopulmonary dysplasia (neonates and infants)	Phase I/II www.medi-post.com
SHP607 (mecasermin rinfabate)	Shire Lexington, MA	prevention of chronic lung disease of prematurity (Fast Track)	Phase II www.shire.com
T89 (herbal medicine product)	Tasly Pharmaceuticals Rockville, MD	altitude sickness	Phase II www.taslyus.com

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 January 18, 2019**. 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.

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.