

2019 Medicines in Development for Diabetes and Related Conditions

Diabetes

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AB101 (basal insulin injection)	Rezolute Redwood City, CA	type 1 diabetes, type 2 diabetes	Phase I www.rezolutebio.com
Afrezza [®] insulin inhalation powder	MannKind Westlake Village, CA	type 1 diabetes (pediatric)	Phase II www.mannkindcorp.com
AG019 (genetically modified <i>Lactococcus lactis</i>)	Intrexon T1D Partners Germantown, MD ActoBio Therapeutics Ghent, Belgium	type 1 diabetes	Phase I/II www.dna.com www.actobio.com
AID (automated insulin delivery system)	Eli Lilly Indianapolis, IN	diabetes	Phase II www.lilly.com
Aldyxin [®] lixisenatide	Sanofi Bridgewater, NJ	type 2 diabetes (pediatric)	Phase I www.sanofi.com
anti-IL 21 GLP-1 (anti-interleukin-21 mAb/ liraglutide)	Novo Nordisk Plainsboro, NJ	type 1 diabetes	Phase II www.novonordisk.com
basal insulin acytated	Eli Lilly Indianapolis, IN	diabetes	Phase I www.lilly.com

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bexagliflozin (SGLT2 inhibitor)	Theracos Marlborough, MA	type 2 diabetes	Phase III www.theracos.com
BGP-15 (JNK inhibitor/insulin sensitizer)	N-Gen Research Laboratories New York, NY	type 2 diabetes	Phase II completed www.ngene.us
BI 456906 (dual-acting glucagon/GLP-1 agonist)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Zealand Pharma Copenhagen, Denmark	type 2 diabetes	Phase I www.boehringer-ingelheim.com
bimagrumab (type II-B activin receptor modulator)	Novartis Pharmaceuticals East Hanover, NJ	type 2 diabetes	Phase II www.novartis.com
BKR-013 (oral L-glutamine)	BioKier Chapel Hill, NC	type 2 diabetes	Phase II www.biokier.com
BTI-320 (alpha glucosidase inhibitor)	Boston Therapeutics Lawrence, MA	type 2 diabetes	Phase II www.bostonti.com
BTI-410 (human proislet peptide)	Boston Therapeutics Lawrence, MA	type 1 diabetes, type 2 diabetes	Phase I www.bostonti.com
Bydureon [®] exenatide extended-release	AstraZeneca Wilmington, DE	type 2 diabetes (adolescents)	Phase III www.astrazeneca.com

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Bydureon® BCise exenatide extended-release (autoinjector)	AstraZeneca Wilmington, DE	type 2 diabetes (adolescents)	Phase III www.astrazeneca.com
Byetta® exenatide	AstraZeneca Wilmington, DE	type 2 diabetes (adolescents)	Phase III www.astrazeneca.com
CHS-131 (PPAR γ modulator and partial agonist)	Coherus BioSciences Redwood City, CA	type 2 diabetes	Phase II completed www.coherus.com
CJC-1134-PC (GLP-1 agonist)	ConjuChem Los Angeles, CA	type 2 diabetes	Phase II www.conjuchem.com
CLBS03 (ex-vivo expanded polyclonal regulatory T lymphocyte cell therapy) ORPHAN DRUG	Caladrius Biosciences Basking Ridge, NJ	recent onset type 1 diabetes (Fast Track)	Phase II www.caladrius.com
CS02 (R-verapamil)	Center Laboratories Taipei, Taiwan	type 2 diabetes with inadequate glycemic control	Phase II www.centerlab.com.tw/en/
CT 868 (dual GLP-1/GIP receptor modulator)	Carmot Therapeutics Berkeley, CA	type 2 diabetes	Phase I www.carmot-therapeutics.us
DA-1241 (GPR119 protein agonist)	Dong-A ST Seoul, South Korea	type 2 diabetes	Phase I www.donga-st.com

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DACRA 089 (dual amylin calcitonin receptor agonist)	Eli Lilly Indianapolis, IN	diabetes	Phase I www.lilly.com
Dance 501 (mist inhaled insulin)	Dance Biopharm San Francisco, CA	diabetes	Phase II www.dancepharm.com
dasiglucagon (dual hormone pump therapy)	Zealand Pharma Copenhagen, Denmark	type 1 diabetes management	Phase II www.zealandpharma.com
Diamyd®/GABA autoimmune diabetes vaccine ORPHAN DRUG	Diamyd Medical Stockholm, Sweden University of Alabama Birmingham, AL	type 1 diabetes	Phase I www.diamyd.com
donislecel (allogeneic islets of Langerhans for transplant)	CellTrans Chicago, IL	type 1 diabetes	Phase III
dorzagliatin (HMS5552) (glucokinase activator)	Hua Medicine Shanghai, China	type 2 diabetes	Phase I www.huamedicine.com
DV-100 (autologous dendritic cell immunotherapy) ORPHAN DRUG	Diavacs San Diego, CA	type 1 diabetes	Phase I completed www.diavacs.com

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efpeglenatide (long-acting GLP-1 agonist)	Sanofi Bridgewater, NJ	type 2 diabetes	Phase III www.sanofi.com
empagliflozin/linagliptin/metformin fixed-dose combination	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	diabetes	Phase I www.boehringer-ingelheim.com www.lilly.com
Farxiga [®] dapagliflozin	AstraZeneca Wilmington, DE	type 1 diabetes	application submitted www.astrazeneca.com
		type 2 diabetes (pediatric)	Phase III www.astrazeneca.com
Fiasp [®] insulin aspart injection	Novo Nordisk Plainsboro, NJ	type 1 diabetes (pediatric)	application submitted www.novonordisk.com
GDF15 agonist	Eli Lilly Indianapolis, IN	diabetes	Phase I www.lilly.com
HDV insulin (hepatic-directed vesicles containing insulin)	Diasome Pharmaceuticals Cleveland, OH	type 1 diabetes, type 2 diabetes	Phase II completed www.diasome.com
HM12460A (long-acting insulin)	Hanmi Pharmaceutical Seoul, South Korea	type 1 diabetes, type 2 diabetes	Phase I www.hanmipharm.com

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HTI-2088 (GLP-1 peptide)	Hengrui Therapeutics Princeton, NJ	type 2 diabetes	Phase I www.hengruitx.com
imeglimin (glimin)	Poxel Lyon, France Roivant Sciences New York, NY	type 2 diabetes	Phase II www.poxelpharma.com
insulin glargine biosimilar	Gan & Lee Pharmaceuticals Beijing, China	type 1 diabetes, type 2 diabetes	Phase III www.ganlee.com
Invokana [®] canagliflozin	Janssen Raritan, NJ	type 2 diabetes (10-18 years of age)	Phase III www.janssen.com
IONIS-ANGPTL3-LRx (ANGPTL3 protein inhibitor)	Akcea Therapeutics Boston, MA Ionis Pharmaceuticals Carlsbad, CA	type 2 diabetes, hypertriglyceridemia and non-alcoholic fatty liver disease (NAFLD)	Phase II www.akceatx.com www.ionispharma.com
IONIS-DGAT2-Rx (RNA interference)	Ionis Pharmaceuticals Carlsbad, CA	type 2 diabetes and NAFLD	Phase II completed www.ioniapharma.com
IONIS-GCGR-Rx (glucagon receptor antagonist)	Ionis Pharmaceuticals Carlsbad, CA	type 2 diabetes	Phase II www.ioniapharma.com
islet cell replacement therapy	Sernova London, Ontario	type 1 diabetes	Phase I/II www.sernova.com

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ITCA 650 (exenatide implant)	Intarcia Therapeutics Boston, MA	type 2 diabetes	application submitted www.intarcia.com
Janumet® sitagliptin and metformin	Merck Kenilworth, NJ	type 2 diabetes (pediatric)	Phase III www.merck.com
Janumet® XR sitagliptin and metformin controlled-release	Merck Kenilworth, NJ	type 2 diabetes (pediatric)	Phase III www.merck.com
Januvia® sitagliptin	Merck Kenilworth, NJ	type 2 diabetes (pediatric)	Phase III www.merck.com
Jardiance® empagliflozin	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	type 1 diabetes	Phase III www.boehringer-ingelheim.com www.lilly.com
		type 2 diabetes (pediatric)	Phase III www.boehringer-ingelheim.com www.lilly.com
LAI287 (long-acting basal insulin analogue)	Novo Nordisk Plainsboro, NJ	type 1 diabetes, type 2 diabetes	Phase II www.novonordisk.com
LAIsema (insulin LAI287/semaglutide)	Novo Nordisk Plainsboro, NJ	type 2 diabetes	Phase I www.novonordisk.com

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leucine/metformin fixed-dose combination	NuSirt Biopharma Nashville, TN	type 2 diabetes	Phase II www.nusirt.com
LIK066 (SGLT 1/2 inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	type 2 diabetes	Phase II completed www.novartis.com
LX2761 (SGLT1 inhibitor)	Lexicon Pharmaceuticals The Woodlands, TX	type 2 diabetes	Phase I www.lexpharma.com
LY900014 (ultra-rapid insulin lispro)	Eli Lilly Indianapolis, IN	type 1 diabetes, type 2 diabetes	Phase III www.lilly.com
LY3209590 (basal insulin-Fc)	Eli Lilly Indianapolis, IN	diabetes	Phase II www.lilly.com
MABp1 (bermekimab) (anti-interleukin-1-alpha human IgG1 mAb)	XBioTech Austin, TX	type 2 diabetes	Phase II www.xbiotech.com
MEDI0382 (cotadutide) (GLP-1/glucagon receptor dual agonist)	MedImmune Gaithersburg, MD	type 2 diabetes	Phase II www.medimmune.com
MEDI7219	MedImmune Gaithersburg, MD	type 2 diabetes	Phase I www.medimmune.com

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MER3001 (regulatory T-lymphocyte stimulant)	Mercia Pharma New York, NY	type 1 diabetes	Phase II www.merciapharma.com
metformin DR (metformin delayed-release)	Elcelyx Therapeutics San Diego, CA	type 2 diabetes	Phase II www.elcelyx.com
MK-1092 (PGD2 receptor antagonist)	Merck Kenilworth, NJ	type 1 diabetes	Phase I completed www.merck.com
MK-5160	Merck Kenilworth, NJ	diabetes	Phase I completed www.merck.com
MK-8521 (GLP-1/glucagon receptor co-agonist)	Merck Kenilworth, NJ	type 2 diabetes	Phase II completed www.merck.com
MYL-1501D (insulin glargine biosimilar)	Mylan Canonsburg, PA	type 1 diabetes, type 2 diabetes	application submitted www.mylan.com
MYL-1601D (insulin aspart biosimilar)	Mylan Canonsburg, PA	type 1 diabetes	Phase III www.mylan.com
Nesina [®] alogliptin	Takeda Pharmaceuticals Deerfield, IL	type 2 diabetes (pediatric)	Phase III www.takeda.com

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NGM217	NGM Biopharmaceuticals South San Francisco, CA	diabetes	Phase I www.ngmbio.com
OG2023SC (NNC0113) (oral GLP-1)	Novo Nordisk Plainsboro, NJ	type 2 diabetes	Phase I www.novonordisk.com
Onglyza [®] saxagliptin	AstraZeneca Wilmington, DE	type 2 diabetes (pediatric)	Phase III www.astrazeneca.com
OPK88003 (pegapamidultide)	OPKO Health Miami, FL	type 2 diabetes	Phase II www.opko.com
ORMD-0801 (oral insulin)	Oramed Pharmaceuticals New York, NY	type 1 diabetes, type 2 diabetes	Phase II www.oramed.com
ORMD-0901 (exenatide oral)	Oramed Pharmaceuticals New York, NY	type 2 diabetes	Phase I www.oramed.com
oxyntomodulin	Eli Lilly Indianapolis, IN	diabetes	Phase I www.lilly.com
Ozempic [®] semaglutide	Novo Nordisk Plainsboro, NJ	type 2 diabetes (adjunctive therapy)	Phase III www.novonordisk.com

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PB-119 (exenatide pegylated analogue)	PegBio Suzhou, China	type 2 diabetes	Phase II www.pegbio.com
PEC-Direct™ islet cell replacement therapy	ViaCyte San Diego, CA	type 1 diabetes	Phase I/II www.viacyte.com
PEC-Encap™ islet cell replacement therapy	ViaCyte San Diego, CA	type 1 diabetes	Phase I/II www.viacyte.com
PF-06882961 (GLP-1R agonist)	Pfizer New York, NY	type 2 diabetes	Phase I www.pfizer.com
REMD 477 (glucagon receptor)	REMD Biotherapeutics Camarillo, CA	type 1 diabetes, type 2 diabetes	Phase II www.remdbio.com
remogliflozin etabonate (SGLT2 inhibitor)	BHV Pharma (Avolynt) Research Triangle Park, NC	type 2 diabetes	Phase II completed www.avolynt.com
RVT-1502 (glucagon receptor antagonist)	Metavant Sciences San Diego, CA	type 2 diabetes	Phase II completed www.metavant.com
S-707106 (insulin sensitizer)	Shionogi Florham Park, NJ	type 2 diabetes	Phase II www.shionogi.com

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SAR341402 (rapid acting insulin)	Sanofi Bridgewater, NJ	type 1 diabetes, type 2 diabetes	Phase III www.sanofi.com
saxagliptin/dapagliflozin/metformin (DPP-4 inhibitor/SGLT-2 inhibitor/ metformin)	AstraZeneca Wilmington, DE	type 2 diabetes	application submitted www.astrazeneca.com
semaglutide oral (GLP-1 receptor agonist)	Novo Nordisk Plainsboro, NJ	type 2 diabetes	application submitted www.novonordisk.com
Simponi [®] golimumab	Janssen Raritan, NJ	type 1 diabetes	Phase II www.janssen.com
		pre-symptomatic type 1 diabetes (children, adolescents, young adults)	Phase I www.janssen.com
SK-0403 (anagliptin) (DDP-4 inhibitor)	Kowa Pharmaceuticals America Montgomery, AL	type 2 diabetes	Phase II www.kowapharma.com
taurocholic acid controlled-release	Satiogen Pharmaceutical San Diego, CA	type 2 diabetes	Phase II completed www.satiogen.com
TF0023 (thrombin inhibitor)	Techfields Pharma Dover, DE	type 2 diabetes	Phase II www.tfpharma.com

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tirzepatide (GIP/GLP-1 dual receptor agonist)	Eli Lilly Indianapolis, IN	type 2 diabetes	Phase III www.lilly.com
tofogliflozin (CSG452) (SGLT2 inhibitor)	Kowa Pharmaceuticals America Montgomery, AL	type 2 diabetes	Phase II www.kowapharma.com
tolimidone (lyn protein-tyrosine kinase stimulant)	Melior Pharmaceuticals Exton, PA	type 2 diabetes	Phase II www.meliorpharmaceuticals.com
Toujeo® insulin glargine (insulin U300)	Sanofi Bridgewater, NJ	type 1 diabetes (pediatric)	Phase III www.sanofi.com
Tradjenta® linagliptin	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	type 2 diabetes (pediatric)	Phase III www.boehringer-ingelheim.com www.lilly.com
Trulicity® dulaglutide	Eli Lilly Indianapolis, IN	type 2 diabetes (pediatric)	Phase III www.lilly.com
		type 2 diabetes (3.0/4.5 mg)	Phase III www.lilly.com

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TS-071 (luseogliflozin)	Taisho Pharmaceutical Tokyo, Japan	type 2 diabetes	Phase II www.taisho.co.jp
TTP273 (oral GLP-1R agonist)	vTv Therapeutics High Point, NC	type 2 diabetes	Phase II www.vtvtherapeutics.com
TTP399 (glucokinase activator)	vTv Therapeutics High Point, NC	type 2 diabetes	Phase II www.vtvtherapeutics.com
		type 1 diabetes	Phase I/II www.vtvtherapeutics.com
Victoza [®] liraglutide	Novo Nordisk Plainsboro, NJ	type 2 diabetes (pediatric)	Phase III completed www.novonordisk.com
VK0612 (FBPase inhibitor)	Viking Therapeutics San Diego, CA	type 2 diabetes	Phase II www.vikingtherapeutics.com
ZGN-1061 (MetAP2 inhibitor)	Zafgen Boston, MA	type 2 diabetes	Phase II www.zafgen.com

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Zynquista™ sotagliflozin (oral SGLT1/2 inhibitor)	Lexicon Pharmaceuticals The Woodlands, TX Sanofi US Bridgewater, NJ	type 1 diabetes	application submitted www.sanofi.com
		type 2 diabetes	Phase III www.sanofi.com

Diabetes-Related Conditions

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
abicipar pegol (VEGF-A inhibitor)	Allergan Madison, NJ	diabetic macular edema	Phase II completed www.allergan.com
AKB-9778 (Tie2 activator)	Aerpio Pharmaceuticals Cincinnati, OH	non-proliferative diabetic retinopathy	Phase II www.aerpio.com
ALLO-ASC-DFU (adipose stem cell therapy)	Anterogen Seoul, South Korea	diabetic foot ulcers	Phase II www.anterogen.com
bardoxolone methyl (Arf2 activator)	Reata Pharmaceuticals Irving, TX	chronic kidney disease in type 1 diabetes	Phase II completed www.reatapharma.com
BAY1142524 (fulacimstat) (chymase inhibitor)	Bayer Pharmaceuticals Whippany, NJ	diabetic nephropathy	Phase II www.pharma.bayer.com

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BI 1026706	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	diabetic macular edema	Phase II www.boehringer-ingelheim.com
BI 1467335 (AOC3 protein inhibitor)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	diabetic retinopathy	Phase II www.boehringer-ingelheim.com
BI 685509	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	diabetic nephropathy	Phase I www.boehringer-ingelheim.com
BI 690517	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	diabetic nephropathy	Phase I www.boehringer-ingelheim.com
BNV-222 (diepalrestat choline)	BioNeva Pharmaceuticals Belmont, MA	diabetic neuropathy	in clinical trials www.new-bionevia.com
Brilinta [®] ticagrelor	AstraZeneca Wilmington, DE	cardiovascular outcomes in patients with coronary artery disease and type 2 diabetes without a history of myocardial infarction or stroke	Phase III www.astrazeneca.com
brolicizumab (anti-VEGF antibody fragment)	Alcon Fort Worth, TX	diabetic macular edema	Phase III www.alcon.com
Bydureon [®] exenatide extended-release	AstraZeneca Wilmington, DE	cardiovascular outcomes in type 2 diabetes	application submitted www.astrazeneca.com

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CCX140 (CCR2 receptor antagonist)	ChemoCentryx Mountain View, CA	diabetic nephropathy	Phase II completed www.chemocentryx.com
cibinetide (erythropoietin receptor agonist)	Araim Pharmaceuticals Tarrytown, NY	diabetic macular edema, diabetic neuropathy	Phase II www.araimpharma.com
CVBT-141B topical (fibroblast growth factor 1)	CardioVascular BioTherapeutics Dallas, TX	diabetic foot ulcers	Phase II www.cvbt.com
dasiglucagon (HypoPal® rescue pen)	Zealand Pharma Copenhagen, Denmark	severe hypoglycemia in type 1 diabetes (pediatric)	Phase III www.zealandpharma.com
DM199 (recombinant tissue kallikrein 1)	DiaMedica Therapeutics Minneapolis, MN	diabetic nephropathy	Phase I www.diamedica.com
EMA401 (olodanrigan) (angiotensin II type 2 receptor antagonist)	Novartis Pharmaceuticals East Hanover, NJ	diabetic neuropathy	Phase II www.novartis.com
emixustat (retinoid isomerohydrolase inhibitor)	Acucela Seattle, WA	diabetic retinopathy	Phase II www.acucela.com
ETX-101 (phenylalanine hydroxylase stimulant)	ETX Pharma West Palm Beach, FL	diabetic gastroparesis	Phase III www.etxpharma.com

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ExpressGraft™ anti-infective skin replacement therapy (C9T1 skin tissue)	Stratatech St. Louis, MO	diabetic foot ulcers	Phase I www.mallinckrodt.com
Eylea® aflibercept	Regeneron Tarrytown, NY	non-proliferative diabetic retinopathy without diabetic macular edema	Phase III www.regeneron.com
Farxiga® dapagliflozin	AstraZeneca Wilmington, DE	cardiovascular outcomes in patients with type 2 diabetes	Phase III www.astrazeneca.com
finerenone (nst MR antagonist)	Bayer Pharmaceuticals Whippany, NJ	diabetic nephropathy	Phase III www.pharma.bayer.com
Galnobax® esmolol	NovoLead Pharma Shrewsbury, MA	diabetic foot ulcers	Phase I/II completed www.novaleadpharma.com
Gimoti® metoclopramide nasal spray	Evoke Pharma Solana Beach, CA	diabetic gastroparesis	application submitted www.evokepharma.com
Granexin® Gel peptide mimetic ACT 1	FirstString Research Mount Pleasant, SC	diabetic foot ulcers	Phase III www.firststringresearch.com
HCB1019 (gap junction inhibitor)	OcuNexus Therapeutics San Diego, CA	diabetic macular edema, diabetic retinopathy	Phase II www.ocunexus.com

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Invokana® canagliflozin	Janssen Raritan, NJ	diabetic nephropathy	application submitted www.janssen.com
JNJ-64565111 (HM12525A) (glucagon/GLP-1 dual agonist)	Janssen Raritan, NJ Hanmi Pharmaceutical Seoul, South Korea	obesity in type 2 diabetes	Phase II www.janssen.com
KSI-301 (VEGF inhibitor)	Kodiak Sciences Palo Alto, CA	diabetic macular edema	Phase I www.kodiak.com
KVD001 (plasma kallikrein inhibitor)	KalVista Pharmaceuticals Cambridge, MA	diabetic macular edema	Phase II www.kalvista.com
KVD824 (plasma kallikrein inhibitor)	KalVista Pharmaceuticals Cambridge, MA	diabetic macular edema	Phase I www.kalvista.com
LKA651 (angiogenesis inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	diabetic macular edema	Phase II www.novartis.com
LMB763 (farnesoid X-activated receptor agonist)	Novartis Pharmaceuticals East Hanover, NJ	diabetic nephropathy	Phase II www.novartis.com

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LY900018 (nasal glucagon)	Eli Lilly Indianapolis, IN	severe hypoglycemia in patients with diabetes treated with insulin	application submitted www.lilly.com
M710 (afibercept biosimilar)	Momenta Pharmaceuticals Cambridge, MA Mylan Canonsburg, PA	diabetic macular edema	Phase III www.momentapharma.com www.mylan.com
MBN-101 (topical antibacterial)	Microbion Bozeman, MT	diabetic foot ulcer infections (Fast Track)	Phase II www.microbioncorp.com
MPC-300-IV (allogeneic autologous mesenchymal precursor cell therapy)	Mesoblast New York, NY	diabetic nephropathy in type 2 diabetes	Phase III www.mesoblast.com
NB-01 (<i>Dioscorea japonica</i> Thunberg and <i>Dioscorea nipponica</i> Makino extracts, phytomedicine)	NeuroBo Pharmaceuticals Boston, MA	diabetic neuropathy	Phase II completed www.neurobopharma.com
nemonoxacin (DNA topoisomerase inhibitor)	TaiGen Biotechnology Taipei, Taiwan	diabetic foot ulcers	Phase II www.taigenbiotech.com.tw
nimacimab (CB1 inverse agonist mAb)	Bird Rock Bio La Jolla, CA	diabetic nephropathy	Phase I www.birdrockbio.com

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Nu-3 (cell membrane structure modulator)	Lakewood-Amedex Sarasota, FL	diabetic foot ulcers	Phase I/II www.lakewoodamedex.com
OPT-302 (VEGF-C/VEGF-D inhibitor)	Opthea Victoria, Australia	diabetic macular edema	Phase I/II www.opthea.com
Optina™ danazol low-dose	Ampio Pharmaceuticals Englewood, CO	diabetic macular edema	Phase III www.ampiopharma.com
PDA-002 (placenta-derived stem cell therapy)	Celularity Warren, NJ	diabetic foot ulcers, diabetic peripheral neuropathy	Phase II www.celularity.com
PF-655 (siRNA, RNA interference)	Quark Pharmaceuticals Newark, CA	diabetic macular edema	Phase II completed www.quarkpharma.com
praliguat (IW-1973) (soluble guanylate cyclase agonist)	Ironwood Pharmaceuticals Cambridge, MA	diabetic nephropathy	Phase II www.ironwoodpharma.com
relamorelin (ghrelin receptor agonist)	Allergan Madison, NJ	diabetic gastroparesis (Fast Track)	Phase III www.allergan.com
RG7716 (faricimab)	Roche Basel, Switzerland	diabetic macular edema	Phase III www.roche.com

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RG7880 (IL-22 receptor agonist)	Genentech South San Francisco, CA	diabetic foot ulcers	Phase II www.gene.com
risuteganib (oligopeptide therapy)	Allegro Ophthalmics San Juan Capistrano, CA	diabetic macular edema	Phase II www.allegroeye.com
RTA 901 (heat shock protein)	Reata Pharmaceuticals Irving, TX	diabetic neuropathy	Phase I completed www.reatapharma.com
selonsertib (ASK-1 inhibitor)	Gilead Sciences Foster City, CA	diabetic nephropathy	Phase II www.gilead.com
SF0166 (integrin antagonist)	SciFluor Life Sciences Cambridge, MA	diabetic macular edema	Phase I/II www.scifluor.com
SP 20202 (mineralocorticoid receptor antagonist)	Sarfez Pharmaceuticals Vienna, VA	diabetic nephropathy	in clinical trials www.sarfezpharma.com
suprachoroidal CLS-TA (triamcinolone acetonide corticosteroid)	Clearside Biomedical Alpharetta, GA	diabetic macular edema	Phase II www.clearsidebio.com
TAK-906 (D2/D3 receptor antagonist)	Takeda Pharmaceuticals Deerfield, IL	diabetic gastroparesis	Phase II www.takeda.com

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TAK-954 (serotonin 4 receptor agonist)	Takeda Pharmaceuticals Deerfield, IL	diabetic gastroparesis	Phase II www.takeda.com
THR-149 (PKal inhibitor)	ThromboGenics (Oxurion) Iselin, NJ	diabetic macular edema	Phase I www.oxurion.com
THR-687 (pan RGD integrin antagonist)	ThromboGenics (Oxurion) Iselin, NJ	diabetic macular edema, diabetic retinopathy	Phase I www.oxurion.com
TMX-049DN (xanthine oxidase inhibitor)	Teijin Pharma Tokyo, Japan	diabetic nephropathy	Phase II www.teijin-pharma.com
TV1001SR (sodium nitrite oral)	Theravasc (Soin Neuroscience) Dayton, OH	diabetic neuropathy	Phase II www.soinneuroscience.com
VM202 (donaperminogene seltoplasmid)	ViroMed Seoul, South Korea	diabetic foot ulcers	Phase III www.viromed.co.kr
VPI-2690B	Vascular Pharmaceuticals Chapel Hill, NC	diabetic nephropathy	Phase II
WST-057 (pirenzepine topical)	WinSanTor San Diego, CA	diabetic neuropathy	Phase I www.winsantor.com

Diabetes-Related Conditions

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Zynquista™ sotagliflozin	Lexicon Pharmaceuticals The Woodlands, TX Sanofi US Bridgewater, NJ	worsening heart failure in diabetes	Phase III www.sanofi.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 **April 4, 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).

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.

Definitions

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.