

## 2016 Medicines in Development for Diabetes and Related Conditions

<b>Diabetes</b>			
<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AC-201 (caspase 1 inhibitor/ IL-1 beta inhibitor)	TWi Biotechnology Taipei, Taiwan	type 2 diabetes	Phase II completed <a href="http://www.twibiotech.com">www.twibiotech.com</a>
anagliptin (SK-0403) (CD26 antigen antagonist)	Kowa Research Institute Morrisville, NC	type 2 diabetes	Phase II <a href="http://www.kowaus.com">www.kowaus.com</a>
bexagliflozin (SGLT2 inhibitor)	Theracos Marlborough, MA	type 2 diabetes	Phase III <a href="http://www.theracos.com">www.theracos.com</a>
BFKB8488A (RG7992) (anti-FGFR1/KLB mAb)	Genentech South San Francisco, CA	type 2 diabetes	Phase I <a href="http://www.gene.com">www.gene.com</a>
BGP-15 (JNK inhibitor/insulin sensitizer)	N-Gene Research Laboratories New York, NY	type 2 diabetes	Phase II <a href="http://www.n-gene.net">www.n-gene.net</a>
BIOD-123 (RHI-based ultra-rapid-acting insulin)	Biodel Danbury, CT	type 1 diabetes	Phase II <a href="http://www.biodel.com">www.biodel.com</a>
BIOD-531 (concentrated ultra-rapid-acting insulin)	Biodel Danbury, CT	type 2 diabetes	Phase II completed <a href="http://www.biodel.com">www.biodel.com</a>
BKR-013 (glucagon-like peptide 1 stimulant)	BioKier Chapel Hill, NC	type 2 diabetes	Phase I <a href="http://www.biokier.com">www.biokier.com</a>

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BMS-986036 (FGF-21 agonist)	Bristol-Myers Squibb Princeton, NJ	type 2 diabetes	Phase II <a href="http://www.bms.com">www.bms.com</a>
BTI-320 (alpha glucosidase inhibitor-chewable)	Boston Therapeutics Newton, MA	type 2 diabetes	Phase II <a href="http://www.bostonti.com">www.bostonti.com</a>
<b>Bydureon</b> <sup>®</sup> exenatide extended release	AstraZeneca Wilmington, DE	type 2 diabetes (weekly suspension)	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
		type 2 diabetes (pediatric)	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
<b>Byetta</b> <sup>®</sup> exenatide	AstraZeneca Wilmington, DE	type 2 diabetes (pediatric)	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
CLBS03 (Treg cell-based therapy) ORPHAN DRUG	Caladrius Biosciences Basking Ridge, NJ	type 1 diabetes (Fast Track)	Phase II <a href="http://www.caladrius.com">www.caladrius.com</a>
<b>Cycloset</b> <sup>®</sup> bromocriptine	VeroScience Tiverton, RI	type 2 diabetes (pediatric)	Phase I <a href="http://www.veroscience.com">www.veroscience.com</a>
Dance-501 (inhaled recombinant human insulin)	Dance Biopharma Brisbane, CA	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.dancebiopharma.com">www.dancebiopharma.com</a>

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<b>Diamyd®</b> autoimmune diabetes vaccine ORPHAN DRUG	Diamyd Medical Stockholm, Sweden University of Alabama at Birmingham Birmingham, AL	newly-diagnosed type 1 diabetes	Phase I <a href="http://www.diamyd.com">www.diamyd.com</a>
DS-8500 (GPR119 agonist)	Daiichi Sankyo Parsippany, NJ	type 2 diabetes	Phase II <a href="http://www.daiichisankyo.com">www.daiichisankyo.com</a>
DV-100 (autologous dendritic cell immunotherapy) ORPHAN DRUG	DiaVacs Edgewater, NJ	type 1 diabetes	Phase I <a href="http://www.diaavacs.us.com">www.diaavacs.us.com</a>
efpeglenatide (long-acting GLP-1 receptor agonist)	Sanofi US Bridgewater, NJ	type 2 diabetes	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a>
empagliflozin/linagliptin/metformin extended release	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	diabetes	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
empagliflozin/metformin extended release	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	type 2 diabetes	application submitted <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>

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ertugliflozin (SGLT2 inhibitor)	Merck Kenilworth, NJ Pfizer New York, NY	type 2 diabetes	Phase III <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.pfizer.com">www.pfizer.com</a>
<b>Farixga</b> <sup>®</sup> dapagliflozin	AstraZeneca Wilmington, DE	type 1 diabetes	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
		type 2 diabetes (pediatric)	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
GIP/GLP-1 co-agonist peptide	Eli Lilly Indianapolis, IN	diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>
GLWL-01	GLWL Research Montreal, Canada	type 2 diabetes	Phase I
HDV insulin (insulin tregopil)	Diasome Pharmaceuticals Cleveland, OH	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.diasomepharmaceuticals.com">www.diasomepharmaceuticals.com</a>
HIP2B (human proislet peptide)	CureDM Wilmington, DE	type 2 diabetes	Phase I completed <a href="http://www.curedm.com">www.curedm.com</a>
HMS5552 (GKA activator)	Hua Medicine Shanghai, China	type 2 diabetes	Phase I completed <a href="http://www.huamedicine.com">www.huamedicine.com</a>

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imeglimin (glimins)	Poxel Lyon, France	type 2 diabetes	Phase II completed <a href="http://www.poxel.com">www.poxel.com</a>
IN-105 (insulin tregopil)	Biocon Bangalore, India	type 1 diabetes, type 2 diabetes	Phase I completed <a href="http://www.biocon.com">www.biocon.com</a>
insulin glargine biosimilar	Biocon Bangalore, India Mylan Canonsburg, PA	type 1 diabetes, type 2 diabetes	Phase III <a href="http://www.biocon.com">www.biocon.com</a> <a href="http://www.mylan.com">www.mylan.com</a>
insulin glargine biosimilar	Gan&Lee Pharmaceuticals Beijing, China	type 1 diabetes	Phase I <a href="http://www.ganlee.com">www.ganlee.com</a>
insulin/pramlintide combination	AstraZeneca Wilmington, DE Juvenile Diabetes Research Foundation New York, NY	type 1 diabetes	Phase I completed <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
<b>Invokana</b> <sup>®</sup> canagliflozin	Janssen Research & Development Raritan, NJ	type 1 diabetes	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
		type 2 diabetes (pediatric)	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>

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IONIS-GCCR <sub>RX</sub> (glucocorticoid receptor antagonist)	Ionis Pharmaceuticals Carlsbad, CA	type 2 diabetes	Phase II <a href="http://www.ionispharma.com">www.ionispharma.com</a>
IONIS-GCGR <sub>RX</sub> (glucagon receptor antagonist)	Ionis Pharmaceuticals Carlsbad, CA	type 2 diabetes	Phase II <a href="http://www.ionispharma.com">www.ionispharma.com</a>
IONIS-PTP1B <sub>RX</sub> (PTP-1B inhibitor)	Ionis Pharmaceuticals Carlsbad, CA	type 2 diabetes	Phase II <a href="http://www.ionispharma.com">www.ionispharma.com</a>
ITCA 650 (continuous subcutaneous delivery of exenatide)	Intarcia Therapeutics Boston, MA	type 2 diabetes	Phase III <a href="http://www.intarcia.com">www.intarcia.com</a>
<b>Janumet</b> <sup>®</sup> sitagliptin/metformin	Merck Kenilworth, NJ	type 2 diabetes (pediatric)	Phase III <a href="http://www.merck.com">www.merck.com</a>
<b>Janumet</b> <sup>®</sup> XR sitagliptin/metformin extended-release	Merck Kenilworth, NJ	type 2 diabetes (pediatric)	Phase III <a href="http://www.merck.com">www.merck.com</a>
<b>Januvia</b> <sup>®</sup> sitagliptin	Merck Kenilworth, NJ	type 2 diabetes (pediatric)	Phase III <a href="http://www.merck.com">www.merck.com</a>

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<b>Jardiance®</b> empagliflozin	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	type 1 diabetes	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
		type 2 diabetes (pediatric)	Phase I <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
JNJ-54728518 (GLP-1 receptor agonist)	Janssen Research & Development Raritan, NJ	type 2 diabetes	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
JNJ-64565111 (glucagon/GLP-1 dual agonist)	Janssen Research & Development Raritan, NJ	type 2 diabetes	Phase I <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
JTT-251 (PDH kinase inhibitor)	Akros Pharma Princeton, NJ	type 2 diabetes	Phase I <a href="http://www.jt.com">www.jt.com</a>
JTT-851 (G protein-coupled receptor 40)	Akros Pharma Princeton, NJ	type 2 diabetes	Phase II <a href="http://www.jt.com">www.jt.com</a>
KDT501 (GPR120 protein stimulant)	KinDex Pharmaceuticals Seattle, WA	insulin resistance and impaired glucose tolerance in type 2 diabetes	Phase II <a href="http://www.kindexpharmaceuticals.com">www.kindexpharmaceuticals.com</a>
KQ-791 (protein tyrosine phosphatase non receptor type 1 antagonist)	Kaneq Bioscience Montreal, Canada	type 2 diabetes	Phase I <a href="http://www.kaneq.com">www.kaneq.com</a>

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KU-5039 (AMP kinase stimulant)	Kareus Therapeutics La Chaux-de-Fonds, Switzerland	insulin resistance, type 2 diabetes	Phase I <a href="http://www.kareustherapeutics.com">www.kareustherapeutics.com</a>
LC15-0444 (DPP-4 inhibitor)	LG Life Sciences Seoul, South Korea	type 2 diabetes	Phase III completed <a href="http://www.lgls.com">www.lgls.com</a>
leucine/metformin fixed-dose combination	NuSirt Biopharma Nashville, TN	type 2 diabetes	Phase II <a href="http://www.nusirt.com">www.nusirt.com</a>
LGD-6972 (glucagon receptor antagonist)	Ligand Pharmaceuticals San Diego, CA	type 2 diabetes	Phase II <a href="http://www.ligand.com">www.ligand.com</a>
LIK066 (SGLT 1/2 inhibitor)	Novartis Pharmaceuticals East Hanover, NJ	type 2 diabetes	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
lingliptin/pioglitazone fixed-dose combination	Boehringer-Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	type 2 diabetes	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
<b>LixiLan</b> lixisenatide/insulin glargine fixed-ratio (new delivery system)	Sanofi US Bridgewater, NJ	type 2 diabetes	application submitted <a href="http://www.sanofi.com">www.sanofi.com</a>
LY900014 (glucose lowering drug)	Eli Lilly Indianapolis, IN	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.lilly.com">www.lilly.com</a>



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Lyxumia® lixisenatide	Sanofi US Bridgewater, NJ	type 2 diabetes (pediatric)	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
MABp1 (IL-1 Alpha mAb)	Xbiotech Austin, TX	type 2 diabetes	Phase II completed <a href="http://www.xbiotech.com">www.xbiotech.com</a>
MEDI0382 (GLP-1/glucagon dual agonist)	MedImmune Gaithersburg, MD	type 2 diabetes	Phase I/II <a href="http://www.medimmune.com">www.medimmune.com</a>
MEDI4166 (PCSK9/GLP-1 mAb + peptide fusion)	MedImmune Gaithersburg, MD	type 2 diabetes	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
MER3001 (regulatory T-lymphocyte stimulant)	Mercia Pharma New York, NY	type 1 diabetes	Phase II <a href="http://www.merciapharma.com">www.merciapharma.com</a>
metformin DR (metformin delayed release)	Elcelyx Therapeutics San Diego, CA	type 2 diabetes	Phase II <a href="http://www.elcelyx.com">www.elcelyx.com</a>
MK-1293 (insulin glargine biosimilar)	Merck Kenilworth, NJ Samsung Bioepis Seoul, South Korea	type 1 diabetes, type 2 diabetes	application submitted <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.samsungbioepis.com">www.samsungbioepis.com</a>
MK-2640	Merck Kenilworth, NJ	type 1 diabetes	Phase I <a href="http://www.merck.com">www.merck.com</a>

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MK-8521 (GLP-1/glucagon receptor co-agonist)	Merck Kenilworth, NJ	type 2 diabetes	Phase II <a href="http://www.merck.com">www.merck.com</a>
MK-8835A (ertugliflozin + sitagliptin)	Merck Kenilworth, NJ Pfizer New York, NY	type 2 diabetes	Phase III <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.pfizer.com">www.pfizer.com</a>
MK-8835B (ertugliflozin + metformin)	Merck Kenilworth, NJ Pfizer New York, NY	type 2 diabetes	Phase III <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.pfizer.com">www.pfizer.com</a>
MLR-1023 (lyn protein-tyrosine kinase stimulant)	Melior Pharmaceuticals Exton, PA	type 2 diabetes	Phase II <a href="http://www.meliorpharmaceuticals.com">www.meliorpharmaceuticals.com</a>
<b>Nesina</b> <sup>®</sup> alogliptin	Takeda Pharmaceuticals Deerfield, IL	type 2 diabetes (pediatric)	Phase II completed <a href="http://www.takeda.com">www.takeda.com</a>
NGM313 (KLB-FGFR1c modulator)	NGM Biopharmaceuticals South San Francisco, CA	type 2 diabetes	Phase I <a href="http://www.ngmbio.com">www.ngmbio.com</a>
NM504 (metagenome modulator)	MicroBiome Therapeutics New Orleans, LA	metformin intolerant type 2 diabetes	Phase 0 <a href="http://www.mbiome.com">www.mbiome.com</a>
NN1218 (faster-acting insulin aspart)	Novo Nordisk Plainsboro, NJ	type 1 diabetes, type 2 diabetes	application submitted <a href="http://www.novonordisk.com">www.novonordisk.com</a>

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NN1406 (liver-preferential prandal insulin analogue)	Novo Nordisk Plainsboro, NJ	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN1436 (long-acting basal insulin analogue)	Novo Nordisk Plainsboro, NJ	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN1953 (long-acting basal insulin analogue)	Novo Nordisk Plainsboro, NJ	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9748 (appetite-regulating hormone peptide tyrosine)	Novo Nordisk Plainsboro, NJ	type 2 diabetes	Phase I <a href="http://www.novonordisk.com">www.novonordisk.com</a>
NN9828 (anti-IL-21 mAb)	Novo Nordisk Plainsboro, NJ	newly-diagnosed type 1 diabetes (basal cell preservation)	Phase II <a href="http://www.novonordisk.com">www.novonordisk.com</a>
<b>Onglyza</b> <sup>®</sup> saxagliptin	AstraZeneca Wilmington, DE	type 2 diabetes (pediatric)	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
ORMD-0801 (insulin oral)	Oramed Pharmaceuticals Jerusalem, Israel	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.ored.com">www.ored.com</a>
otelixizumab (cluster of differentiation 3) ORPHAN DRUG	GlaxoSmithKline Research Triangle Park, NC	new onset type 1 diabetes	Phase II <a href="http://www.gsk.com">www.gsk.com</a>

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PB1023 (weekly GLP-1 agonist)	PhaseBio Pharmaceuticals Malvern, PA	type 2 diabetes	Phase II <a href="http://www.phasebio.com">www.phasebio.com</a>
PE0139 (weekly basal insulin)	PhaseBio Pharmaceuticals Malvern, PA	type 2 diabetes	Phase II <a href="http://www.phasebio.com">www.phasebio.com</a>
PF-06291874 (glucagon receptor antagonist)	Pfizer New York, NY	type 2 diabetes	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06293620	Pfizer New York, NY	type 2 diabetes	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06342674 (IL-7 receptor inhibitor)	Pfizer New York, NY	type 1 diabetes	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
<b>Prolastin®-C</b> alpha-1-antitrypsin modified process	Grifols Los Angeles, CA	new-onset type 1 diabetes	Phase II <a href="http://www.grifolsusa.com">www.grifolsusa.com</a>
<b>Qtern</b> saxagliptin/dapagliflozin fixed-dose combination	AstraZeneca Wilmington, DE	type 2 diabetes	application submitted <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
REMD-477 (GPCR antagonist)	REMD Biotherapeutics Camarillo, CA	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.remdbio.com">www.remdbio.com</a>

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remogliflozin etabonate (SGLT2 inhibitor)	Avolynt Research Triangle Park, NC	type 2 diabetes	Phase II <a href="http://www.avolynt.com">www.avolynt.com</a>
<b>Ryzodeg®</b> insulin degludec/insulin aspart	Novo Nordisk Plainsboro, NJ	type 1 diabetes (pediatric)	Phase III completed <a href="http://www.novonordisk.com">www.novonordisk.com</a>
SAR342434 (insulin lispro)	Sanofi US Bridgewater, NJ	type 1 diabetes, type 2 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
SAR425899 (GLP-1/GCGR dual agonist)	Sanofi US Bridgewater, NJ	type 2 diabetes	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
SAR438335 (GLP-1R/GIPR dual agonist)	Sanofi US Bridgewater, NJ	type 2 diabetes	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
SAR440067 (LAPS insulin 115; long acting insulin analog)	Sanofi US Bridgewater, NJ	type 1 diabetes, type 2 diabetes	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
semaglutide (NN9535) (GLP-1 analogue)	Novo Nordisk Plainsboro, NJ	type 2 diabetes	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>
semaglutide oral (NN9924) (GLP-1 analogue)	Novo Nordisk Plainsboro, NJ	type 2 diabetes	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>

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<b>Simponi</b> <sup>®</sup> golimumab	Janssen Research & Development Raritan, NJ	type 1 diabetes	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
sotagliflozin (oral SGLT-1/2 inhibitor)	Sanofi US Bridgewater, NJ	type 1 diabetes	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
		type 2 diabetes	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a>
<b>Tanzeum</b> <sup>®</sup> albiglutide	GlaxoSmithKline Research Triangle Park, NC	type 1 diabetes	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
teneligliptin (MP-513) (DPP-4 inhibitor)	Mitsubishi Tanabe Pharma Development America Jersey City, NJ	type 2 diabetes	Phase I <a href="http://www.mt-pharma-development-america.com">www.mt-pharma-development-america.com</a>
teplizumab (CD3 antigen inhibitor) ORPHAN DRUG	MacroGenics Rockville, MD	type 1 diabetes (prevention)	Phase II <a href="http://www.macrogenics.com">www.macrogenics.com</a>
TF0023 (thrombin inhibitor)	Techfields Pharma Dover, DE	type 2 diabetes	Phase II <a href="http://www.tfpharma.com">www.tfpharma.com</a>
<b>Toujeo</b> <sup>®</sup> insulin glargine (U300)	Sanofi US Bridgewater, NJ	type 1 diabetes (pediatric)	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>

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<b>Tradjeta®</b> insulin glargine	Boehringer Ingelheim Pharmaceuticals Bridgewater, NJ Eli Lilly Indianapolis, IN	type 2 diabetes (pediatric)	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
TT401 (glucagon-like peptide-1/glucagon dual receptor agonist)	Transition Therapeutics Toronto, Canada	type 2 diabetes in patients with accompanying obesity	Phase II completed <a href="http://www.transitiontherapeutics.com">www.transitiontherapeutics.com</a>
TTP273 (oral GLP-1R agonist)	vTv Therapeutics High Point, NC	type 2 diabetes	Phase II <a href="http://www.vtvtherapeutics.com">www.vtvtherapeutics.com</a>
TTP399 (glucokinase activator)	vTv Therapeutics High Point, NC	type 2 diabetes	Phase II <a href="http://www.vtvtherapeutics.com">www.vtvtherapeutics.com</a>
ultra-rapid insulin (BioChaperone® insulin lispro)	Adocia Lyon, France Eli Lilly Indianapolis, IN	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.adocia.fr">www.adocia.fr</a> <a href="http://www.lilly.com">www.lilly.com</a>
ultra-rapid insulin (insulin lispro UR formulation)	Eli Lilly Indianapolis, IN	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.lilly.com">www.lilly.com</a>
<b>U-Strip Diabetes</b> insulin transdermal	Transdermal Specialties Broomall, PA	type 1 diabetes, type 2 diabetes	Phase II <a href="http://www.transdermalspecialties.com">www.transdermalspecialties.com</a>
VC-01 (pancreatic beta cell replacement)	ViaCyte San Diego, CA	type 1 diabetes	Phase I/II <a href="http://www.viacyte.com">www.viacyte.com</a>

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<b>Victoza®</b> liraglutide	Novo Nordisk Plainsboro, NJ	type 2 diabetes (pediatric)	Phase III <a href="http://www.novonordisk.com">www.novonordisk.com</a>
VK0612 (FBPase inhibitor)	Viking Therapeutics San Diego, CA	type 2 diabetes	Phase II <a href="http://www.vikingtherapeutics.com">www.vikingtherapeutics.com</a>
<b>Xultophy®</b> insulin degludec/liraglutide	Novo Nordisk Plainsboro, NJ	type 2 diabetes	application submitted <a href="http://www.novonordisk.com">www.novonordisk.com</a>
ZP2929 (glucagon/GLP-1 receptor agonist)	Zealand Pharma Copenhagen, Denmark	type 1 diabetes	Phase I <a href="http://www.zealandpharma.com">www.zealandpharma.com</a>
ZYDPLA 1 (CD26 antigen inhibitor)	Cadila Healthcare Gujarat, India	type 2 diabetes	Phase I completed <a href="http://www.zyducadila.com">www.zyducadila.com</a>

## Diabetes-Related Conditions

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
abicipar pegol (VEGF-A inhibitor)	Allergan Parsippany, NJ Molecular Partners Zurich, Switzerland	diabetic macular edema	Phase II completed <a href="http://www.allergan.com">www.allergan.com</a>
<b>Acthar® Gel</b> corticotropin gel	Mallinckrodt St. Louis, MO	diabetic nephropathy	Phase II <a href="http://www.mallinckrodt.com">www.mallinckrodt.com</a>



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AKB-9778 (Tie-2 activator)	Aerpio Therapeutics Cincinnati, OH	diabetic macular edema	Phase II <a href="http://www.aerpio.com">www.aerpio.com</a>
ALG-1001 (integrin therapy)	Allegro Ophthalmics San Juan Capistrano, CA	diabetic macular edema, non-proliferative diabetic retinopathy	Phase II <a href="http://www.allegroeye.com">www.allegroeye.com</a>
alpha-2c adrenergic receptor antagonist	Bayer HealthCare Pharmaceuticals Whippany, NJ	diabetic foot ulcers	Phase I <a href="http://www.bayer.com">www.bayer.com</a>
<b>AmiKet™</b> amitriptyline/ketamine topical cream	Immune Pharmaceuticals New York, NY	painful diabetic neuropathy	Phase II completed <a href="http://www.immunepharma.com">www.immunepharma.com</a>
ARA 290 (erythropoietin receptor agonist)	Araim Pharmaceuticals Tarrytown, NY	diabetic macular edema	Phase I <a href="http://www.araimpharma.com">www.araimpharma.com</a>
ASP8232 (VAP-1 inhibitor)	Astellas Pharma US Northbrook, IL	diabetes macular edema	Phase II <a href="http://www.astellas.com">www.astellas.com</a>
atrasentan (endothelin A antagonist)	AbbVie North Chicago, IL	diabetic nephropathy in patients with type 2 diabetes	Phase III <a href="http://www.abbvie.com">www.abbvie.com</a>
BI 1026706	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	diabetic macular edema	Phase II <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>

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<b>Brilinta®</b> ticagrelor	AstraZeneca Wilmington, DE	cardiovascular outcomes in patients with type 2 diabetes and coronary artery disease, but without a previous history of myocardial infarction or stroke	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
<b>Bydureon®</b> exenatide extended release	AstraZeneca Wilmington, DE	cardiovascular outcomes in type 2 diabetes	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
camicinal (motilin receptor agonist)	GlaxoSmithKline Research Triangle Park, NC	diabetic gastroparesis	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
clonidine topical gel (alpha 2 adrenergic receptor agonist)	BioDelivery Sciences International Raleigh, NC	painful diabetic neuropathy (Fast Track)	Phase III <a href="http://www.bdsi.com">www.bdsi.com</a>
<b>CureXcell®</b> leukocyte cell therapy	MacroCure Radnor, PA	diabetic foot ulcer	Phase III <a href="http://www.macrocure.com">www.macrocure.com</a>
CVBT-141B (fibroblast growth factor-1)	CardioVascular BioTherapeutics Dallas, TX	diabetic foot ulcers	Phase II <a href="http://www.cvbt.com">www.cvbt.com</a>
DM199 (recombinant tissue kallikrein-1 [rKLK1])	DiaMedica Minneapolis, MN	diabetic nephropathy	Phase I <a href="http://www.diamedica.com">www.diamedica.com</a>
emixustat (retinoid isomerohydrolase inhibitor)	Acucela Seattle, WA	proliferative diabetic retinopathy	Phase II <a href="http://www.acucela.com">www.acucela.com</a>

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ETX-101	ETX Pharma Oakland, MD	diabetic gastroparesis	Phase III <a href="http://www.etxpharma.com">www.etxpharma.com</a>
EVK-001 (dopamine receptor antagonist)	Evoke Pharma Solana Beach, CA	diabetic gastroparesis	Phase III <a href="http://www.evokepharma.com">www.evokepharma.com</a>
<b>ExpressGraft™</b> anti-infective skin replacement therapy	Stratatech Madison, WI	diabetic foot ulcers	Phase I <a href="http://www.stratatechcorp.com">www.stratatechcorp.com</a>
<b>Eylea®</b> aflibercept	Bayer HealthCare Pharmaceuticals Whippany, NJ Regeneron Pharmaceuticals Tarrytown, NY	diabetic retinopathy without macular edema	Phase III <a href="http://www.bayer.com">www.bayer.com</a> <a href="http://www.regeneron.com">www.regeneron.com</a>
<b>Eylea®</b> aflibercept + nesvacumab (Ang2 antibody)	Bayer HealthCare Pharmaceuticals Whippany, NJ Regeneron Pharmaceuticals Tarrytown, NY	diabetic macular edema	Phase II <a href="http://www.bayer.com">www.bayer.com</a> <a href="http://www.regeneron.com">www.regeneron.com</a>
<b>Farixga®</b> dapagliflozin	AstraZeneca Wilmington, DE	cardiovascular outcomes in type 2 diabetes	Phase III <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
finerenone (mineralocorticoid receptor antagonist)	Bayer HealthCare Pharmaceuticals Plainsboro, NJ	diabetic nephropathy	Phase III <a href="http://www.bayer.com">www.bayer.com</a>
<b>Galnobox®</b> beta-1 adrenergic receptor agonist	NovaLead Pharma Shrewsbury, MA	diabetic foot ulcer	Phase I/II <a href="http://www.novaleadpharma.com">www.novaleadpharma.com</a>

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<b>Granexin™ Gel</b> ACT 1 peptide wound-healing gel formulation	FirstString Research Mount Pleasant, SC	diabetic foot ulcer	Phase III <a href="http://www.firststringresearch.com">www.firststringresearch.com</a>
GS-4997 (ASK-1 inhibitor)	Gilead Sciences Foster City, CA	diabetic nephropathy	Phase II <a href="http://www.gilead.com">www.gilead.com</a>
GSK1278863 (topical prolyl hydroxylase inhibitor mAb)	GlaxoSmithKline Research Triangle Park, NC	diabetic foot ulcers	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
IBI-20089 (glucocorticoid receptor agonist)	Icon Bioscience Sunnyvale, CA	diabetic macular edema	Phase I <a href="http://www.iconbioscience.com">www.iconbioscience.com</a>
INL-002 (gentamicin collagen topical matrix implant)	Innocoll Newtown Square, PA	diabetic foot ulcers	Phase III <a href="http://www.innocoll.com">www.innocoll.com</a>
<b>Invokana®</b> canagliflozin	Janssen Research & Development Raritan, NJ	diabetic nephropathy in patients with type 2 diabetes	Phase III <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
<b>Jardiance®</b> empagliflozin	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	cardiovascular outcomes in type 2 diabetes	application submitted <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
<b>Jetrea®</b> ocriplasmin	ThromboGenics Iselin, NJ	diabetic retinopathy	Phase II <a href="http://www.thrombogenics.com">www.thrombogenics.com</a>

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KVD001 (plasma kallikrein inhibitor)	KalVista Pharmaceuticals Cambridge, MA	diabetic macular edema	Phase I <a href="http://www.kalvista.com">www.kalvista.com</a>
<b>Locilex</b> <sup>®</sup> pexiganan	Dipexium Pharmaceuticals New York, NY	mild diabetic foot infection	Phase III <a href="http://www.dipexiumpharmaceuticals.com">www.dipexiumpharmaceuticals.com</a>
MPC-300-IV (mesenchymal stem cell therapy)	Mesoblast New York, NY	diabetic nephropathy	Phase II <a href="http://www.mesoblast.com">www.mesoblast.com</a>
MT-3995 (selective mineralocorticoid receptor antagonist)	Mitsubishi Tanabe Pharma Development America Jersey City, NJ	diabetic nephropathy	Phase I <a href="http://www.mt-pharma-development-america.com">www.mt-pharma-development-america.com</a>
nasal glucagon	Eli Lilly Indianapolis, IN	severe hypoglycemia in patients with diabetes treated with insulin	Phase III <a href="http://www.lilly.com">www.lilly.com</a>
nemonoxacin (DNA topoisomerase inhibitor)	TaiGen Biotechnology Taipei, Taiwan	diabetic foot ulcers	Phase II completed <a href="http://www.taigenbiotech.com.tw">www.taigenbiotech.com.tw</a>
nepafenac (cyclooxygenase inhibitor)	Alcon Fort Worth, TX	diabetic retinopathy	Phase III <a href="http://www.alcon.com">www.alcon.com</a>
NM504 (metagenome modulator)	MicroBiome Therapeutics New Orleans, LA	diabetic dysbiosis (microbial imbalance), prediabetes	Phase I <a href="http://www.mbiome.com">www.mbiome.com</a>

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NOV-9	MorphoSys Martinsried/Planegg, Germany Novartis Pharmaceuticals East Hanover, NJ	diabetic retinopathy	Phase I <a href="http://www.novartis.com">www.novartis.com</a>
Nu-3 topical (cell membrane structure modulator)	Lakewood Amedex Sarasota, FL	diabetic foot ulcers	Phase I/II <a href="http://www.lakewoodamedex.com">www.lakewoodamedex.com</a>
OC-10X (vascular disrupting agent)	OcuCure Therapeutics Roanoke, VA	proliferative diabetic retinopathy	Phase I completed <a href="http://www.ocucure.com">www.ocucure.com</a>
<b>Optina</b> danazol low-dose	Ampio Pharmaceuticals Englewood, CO	diabetic macular edema	Phase II <a href="http://www.ampiopharma.com">www.ampiopharma.com</a>
PAN-90806 (VEGF inhibitor)	PanOptica Bernardsville, NJ	diabetic retinopathy	Phase I <a href="http://www.panopticaopharma.com">www.panopticaopharma.com</a>
PDA-002 (human placental-derived adherent cell therapy)	Celgene Summit, NJ	diabetic foot ulcers, diabetic neuropathy	Phase II <a href="http://www.celgene.com">www.celgene.com</a>
PF-655 (RNA interference)	Quark Pharmaceuticals Fremont, CA	diabetic macular edema	Phase II <a href="http://www.quarkpharma.com">www.quarkpharma.com</a>
PMZ-2123 (endothelin A receptor antagonist)	Pharmazz Willowbrook, IL	brain edema in diabetic ketoacidosis	Phase I <a href="http://www.pharmazz.com">www.pharmazz.com</a>

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relamorelin (ghrelin peptide agonist)	Allergan Parsippany, NJ Motus Boston, MA	diabetic gastroparesis (Fast Track)	Phase II <a href="http://www.allergan.com">www.allergan.com</a> <a href="http://www.motusrx.com">www.motusrx.com</a>
RG-125/AZD4076 (microRNA therapeutic)	AstraZeneca Wilmington, DE Regulus Therapeutics San Diego, CA	non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes or prediabetes	Phase I <a href="http://www.astrazeneca.com">www.astrazeneca.com</a> <a href="http://www.regulusrx.com">www.regulusrx.com</a>
RG7880 (IL-22 modulator)	Genentech South San Francisco, CA	diabetic foot ulcers	Phase I <a href="http://www.gene.com">www.gene.com</a>
RO6867461	Roche Basel, Switzerland	center-involving diabetic macular edema	Phase II <a href="http://www.roche.com">www.roche.com</a>
SF0166 (integrin alphaVbeta3 antagonist)	SciFluor Life Sciences Cambridge, MA	diabetic macular edema	Phase I/II <a href="http://www.scifluor.com">www.scifluor.com</a>
squalamine (VEGF/PDGF/bFGF inhibitor)	Ohr Pharmaceutical New York, NY	diabetic macular edema, proliferative diabetic retinopathy	Phase II <a href="http://www.ohrpharmaceutical.com">www.ohrpharmaceutical.com</a>
teprotumumab (IGF-IR antagonist)	River Vision Development New York, NY	diabetic macular edema	Phase I completed

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Tradjenta® linagliptin	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT Eli Lilly Indianapolis, IN	cardiovascular outcomes in type 2 diabetes, diabetic nephropathy	Phase III <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a> <a href="http://www.lilly.com">www.lilly.com</a>
TV1001sr (sodium nitrite oral)	TheraVasc Cleveland, OH	diabetic neuropathy	Phase II <a href="http://www.theravasc.com">www.theravasc.com</a>
VM202 (modified hepatocyte growth factor gene therapy)	ViroMed Seoul, South Korea	painful diabetic peripheral neuropathy, chronic non-healing ischemic diabetic foot ulcers	Phase III <a href="http://www.viomed.co.kr">www.viomed.co.kr</a>
VPI-2690B (IGF-1 receptor antagonist)	Vascular Pharmaceuticals Research Triangle Park, NC	diabetic nephropathy	Phase II <a href="http://www.vascularpharma.com">www.vascularpharma.com</a>

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 October 12, 2016.** The medicines in this listing include medicines being developed by U.S.-based companies conducting trials in the United States and 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](http://www.clinicaltrials.gov). The entire series of *Medicines in Development* is available on PhRMA's website, [www.phrma.org](http://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 designation”) 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 0**—First-in-human trials conducted in accordance with FDA's 2006 guidance on exploratory Investigational New Drug (IND) studies designed to speed up development of promising drugs by establishing very early on whether the agent behaves in human subjects as was anticipated from preclinical studies.

**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.