

2016 Medicines in Development for Alzheimer's Disease

Alzheimer's Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
A β antibody Fab PEG	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase I www.lilly.com
ABBV-672	AbbVie <i>North Chicago, IL</i>	Alzheimer's disease	Phase I www.abbvie.com
ABT-957 (calpain inhibitor)	AbbVie <i>North Chicago, IL</i>	Alzheimer's disease	Phase I www.abbvie.com
AC-1204 (glucose stimulant)	Accera <i>Broomfield, CO</i>	mild to moderate Alzheimer's disease	Phase III www.accelerapharma.com
ACI-35 (anti-pTau vaccine)	AC Immune <i>Lausanne, Switzerland</i> Janssen Research & Development <i>Raritan, NJ</i>	Alzheimer's disease	Phase I www.acimmune.com www.janssenrnd.com
aducanumab (BIIB037) (amyloid beta-protein inhibitor)	Biogen <i>Cambridge, MA</i> Neurimmune <i>Zurich, Switzerland</i>	Alzheimer's disease	Phase III www.biogen.com
AGB101 (levetiracetam low-dose)	AgenBio <i>Baltimore, MD</i>	amnesic mild cognitive impairment due to Alzheimer's disease (prodromal Alzheimer's disease)	Phase II completed www.agenebio.com

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ALKS 7119 (CNS modulator)	Alkermes <i>Waltham, MA</i>	agitation in Alzheimer's disease	Phase I www.alkermes.com
ALZ-801 (amyloid beta-protein inhibitor)	Alzheon <i>Framingham, MA</i>	Alzheimer's disease (APOE4-positive variant)	Phase I www.alzheon.com
ALZT OP1 (amyloid beta-protein inhibitor)	AZTherapies <i>Boston, MA</i>	Alzheimer's disease	Phase III www.aztherapies.com
ANAVEX™ 2-73	Anavex Life Sciences <i>New York, NY</i>	Alzheimer's disease	Phase II www.anavex.com
ANAVEX™ Plus (ANAVEX 2-73/donepezil)	Anavex Life Sciences <i>New York, NY</i>	Alzheimer's disease	Phase II www.anavex.com
apabetalone (RVX-208) (BET protein inhibitor)	Resverlogix <i>Calgary, Canada</i>	Alzheimer's disease	Phase I completed www.resverlogix.com
ARC-029 (nilvadipine)	Archer Pharmaceuticals <i>Sarasota, FL</i> NILVAD <i>Dublin, Ireland</i>	Alzheimer's disease	Phase III www.archerpharma.com www.nilvad.eu
ASP3662 (11-beta-HSD1 inhibitor)	Astellas Pharma US <i>Northbrook, IL</i>	Alzheimer's disease	Phase I www.astellas.us

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AVN-101 (serotonin 6 receptor antagonist)	AllaChem <i>Hallandale Beach, FL</i> Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease	Phase II www.allachem.com www.avineuro.com
AVN-322 (serotonin 6 receptor antagonist)	AllaChem <i>Hallandale Beach, FL</i> Avineuro Pharmaceuticals <i>San Diego, CA</i>	Alzheimer's disease	Phase II www.allachem.com www.avineuro.com
AVP-786 (dextromethorphan analogue/quinidine)	Avanir Pharmaceuticals <i>Aliso Viejo, CA</i> Concert Pharmaceuticals <i>Lexington, MA</i>	agitation in Alzheimer's disease (Fast Track)	Phase III www.avanir.com www.concertpharma.com
AVP-923 (dextromethorphan/quinidine fixed-dose combination)	Avanir Pharmaceuticals <i>San Diego, CA</i>	agitation in Alzheimer's disease	Phase II www.avanir.com
AXS-05 (bupropion/dextromethrophan)	Axsome Therapeutics <i>New York, NY</i>	agitation in Alzheimer's disease	Phase I www.axsome.com
AZD3293 (BACE inhibitor)	AstraZeneca <i>Wilmington, DE</i> Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase II www.astrazeneca.com www.lilly.com

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azeliragon (TTP488) (RAGE antagonist)	vTv Therapeutics <i>High Point, NC</i>	Alzheimer's disease (Fast Track)	Phase III www.vtvtherapeutics.com
BACE inhibitor	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase I www.lilly.com
BAN2401 (humanized anti-amyloid beta mAb)	Biogen <i>Cambridge, MA</i> Eisai <i>Woodcliff Lake, NJ</i>	Alzheimer's disease	Phase II www.biogen.com www.eisai.com
bexarotene (RXR-selective retinoid analogue)	ReXceptor <i>Cambridge, MA</i>	Alzheimer's disease	Phase I completed www.rexceptor.com
BI 409306 (phosphodiesterase 9A inhibitor)	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	Alzheimer's disease	Phase II www.boehringer-ingelheim.com
bisnorcymserine (butyrylcholinesterase inhibitor)	QR Pharma <i>Berwyn, PA</i>	advanced Alzheimer's disease	Phase I www.qrpharma.com
BPN14770 (type 4 cyclic nucleotide phosphodiesterase inhibitor)	Tetra Discovery Partners <i>Grand Rapids, MI</i>	Alzheimer's disease	Phase I www.tetradiscovery.com

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brexpiprazole (dopamine partial agonist)	Lundbeck <i>Deerfield, IL</i> Otsuka Pharmaceutical <i>Tokyo, Japan</i>	agitation in Alzheimer's disease	Phase III www.lundbeck.com www.otsuka.com
bryostatin 1 (protein kinase C stimulant)	Neurotrope BioScience <i>Newark, NJ</i>	Alzheimer's disease	Phase II www.neurotropebioscience.com
CAD106 (beta-amyloid protein inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	Alzheimer's disease	Phase II/III www.gsk.com
CNP 520 (BACE1 protein inhibitor)	Amgen <i>Thousand Oaks, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Alzheimer's disease	Phase II/III www.amgen.com www.novartis.com
CPC-201 (donepezil/peripherally acting cholinergic blocker fixed-dose combination)	Chase Pharmaceuticals <i>Washington, DC</i>	Alzheimer's disease	Phase II www.chasepharmaceuticals.com
CPC-212 (next-generation acetylcholinesterase inhibitor)	Chase Pharmaceuticals <i>Washington, DC</i>	Alzheimer's disease	Phase I completed www.chasepharmaceuticals.com

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CPC-250 (next-generation acetylcholinesterase inhibitor)	Chase Pharmaceuticals <i>Washington, DC</i>	Alzheimer's disease	Phase I completed www.chasepharmaceuticals.com
crenezumab (beta-amyloid protein inhibitor)	Genentech <i>South San Francisco, CA</i>	mild to moderate Alzheimer's disease	Phase III www.gene.com
CSP-1103 (amyloid beta-protein inhibitor)	CereSpir <i>New York, NY</i>	mild cognitive impairment in patients at risk of Alzheimer's disease	Phase II www.cerespir.com
donepezil transdermal patch	Corium International <i>Menlo Park, CA</i>	mild, moderate and severe Alzheimer's disease	Phase I www.coriumgroup.com
E2027	Eisai <i>Woodcliff Lake, NJ</i>	Alzheimer's disease	Phase I www.eisai.com
E2609 (BACE1 protein inhibitor)	Biogen <i>Cambridge, MA</i> Eisai <i>Woodcliff Lake, NJ</i>	Alzheimer's disease	Phase II www.biogen.com www.eisai.com
ELND005 (amyloid beta-protein inhibitor)	Transition Therapeutics <i>Toronto, Canada</i>	agitation/aggression in Alzheimer's disease (Fast Track)	Phase II/III www.transitiontherapeutics.com
gantenerumab (amyloid beta-protein inhibitor)	Genentech <i>South San Francisco, CA</i>	early-stage Alzheimer's disease	Phase III www.gene.com

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GC021109 (purinoceptor P2Y6 agonist)	GliaCure <i>Boston, MA</i>	mild to moderate Alzheimer's disease (Fast Track)	Phase I www.gliacure.com
GSK933776 (amyloid beta-protein inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	Alzheimer's disease	Phase II www.gsk.com
idalopirdine (serotonin 6 receptor antagonist)	Lundbeck <i>Deerfield, IL</i> Otsuka Pharmaceutical <i>Tokyo, Japan</i>	Alzheimer's disease	Phase III www.lundbeck.com www.otsuka.co.jp
immune globulin	Grifols USA <i>Los Angeles, CA</i>	Alzheimer's disease	Phase III www.grifols.com
INP-102 intranasal	Impel NeuroPharma <i>Seattle, WA</i>	Alzheimer's disease	Phase II/III www.impelneuropharma.com
JNJ-54861911 (BACE inhibitor)	Janssen Research & Development <i>Raritan, NJ</i> Shionogi <i>Osaka, Japan</i>	Alzheimer's disease	Phase II/III www.janssenrnd.com
LY3002813 (N3pG-amyloid beta mAb)	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease	Phase I www.lilly.com
MEDI1814 (anti-amyloid beta mAb)	MedImmune <i>Gaithersburg, MD</i>	Alzheimer's disease	Phase I www.medimmune.com

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memantine transdermal patch	Corium International <i>Menlo Park, CA</i>	moderate to severe Alzheimer's disease	Phase I www.coriumgroup.com
MER 5101 (vaccine with beta-amyloid protein fragment)	MerciaPharma New York, NY	Alzheimer's disease	Phase I www.merciapharma.com
MK-7622 (muscarinic M1 receptor modulator)	Merck <i>Kenilworth, NJ</i>	Alzheimer's disease (adjunct therapy)	Phase II www.merck.com
MSDC-0160 (mTOT modulator)	Metabolic Solutions Development <i>Kalamazoo, MI</i>	Alzheimer's disease	Phase II completed www.msdrx.com
NGP 555 (amyloid precursor protein secretase modulator)	NeuroGenetic Pharmaceuticals <i>Del Mar, CA</i>	Alzheimer's disease	Phase I www.neurogeneticpharmaceuticals.com
NIC-515 (amyloid precursor protein secretase inhibitor)	Humanetics <i>Minneapolis, MN</i>	Alzheimer's disease	Phase II www.humaneticscorp.com
NTC-942 (serotonin 4 receptor agonist)	Nanotherapeutics <i>Alachua, FL</i>	Alzheimer's disease	Phase II www.nanotherapeutics.com
PF-05251749	Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase I www.pfizer.com

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PF-06648671	Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase I www.pfizer.com
PF-06751979	Pfizer <i>New York, NY</i>	Alzheimer's disease	Phase I www.pfizer.com
pioglitazone (insulin sensitizer)	Takeda Pharmaceuticals <i>Skokie, IL</i>	mild cognitive impairment due to Alzheimer's disease (prodromal Alzheimer's disease)	Phase III www.takeda.com
piromelatine (melatonin agonist)	Neurin Pharmaceuticals <i>Zug, Switzerland</i>	mild Alzheimer's disease	Phase II www.neurin.com
Posiphen [®] R-phenserine	QR Pharma <i>Berwyn, PA</i>	early Alzheimer's disease	Phase II www.qrpharma.com
rilapladib (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Research Triangle Park, NC</i>	Alzheimer's disease	Phase II www.gsk.com
RVT-101 (serotonin 6 receptor antagonist)	Axovant Sciences <i>New York, NY</i>	mild to moderate Alzheimer's disease (adjunctive treatment)	Phase III www.axovant.com
SAR228810 (anti-protofibrillar AB mAb)	Sanofi US <i>Bridgewater, NJ</i>	Alzheimer's disease	Phase I www.sanofi.com

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solanezumab (amyloid beta protein inhibitor)	Eli Lilly <i>Indianapolis, IN</i>	Alzheimer's disease, preclinical Alzheimer's disease	Phase III www.lilly.com
SUVN-502 (serotonin 6 receptor antagonist)	Suven Life Sciences <i>Hyderabad, India</i>	moderate Alzheimer's disease (adjunctive treatment)	Phase II www.suven.com
SUVN-D4010 (serotonin 4 receptor agonist)	Suven Life Sciences <i>Hyderabad, India</i>	Alzheimer's disease	Phase I www.suven.com
T-817MA (amyloid beta-protein inhibitor)	Toyama Chemical <i>Tokyo, Japan</i>	Alzheimer's disease	Phase II www.toyama-chemical.co.jp
T3D-959 (PPAR-delta/gamma agonist)	T3D Therapeutics <i>Research Triangle Park, NC</i>	Alzheimer's disease	Phase I/II www.t3dtherapeutics.com
TGF-beta agonist	Stanford University <i>Stanford, CA</i> SRI Bioscience <i>Menlo Park, CA</i>	Alzheimer's disease	Phase I www.sri.com
TPI 287 (next-generation taxane)	Cortice Biosciences <i>New York, NY</i>	mild to moderate Alzheimer's disease	Phase I www.corticebio.com
TRx0237 (tau protein aggregation inhibitor/ TDP-43 aggregation inhibitor)	TauRx Pharmaceuticals <i>Singapore</i>	mild Alzheimer's disease	Phase III www.taurx.com

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UB-311 (amyloid beta-protein inhibitor vaccine)	United Biomedical <i>Hauppauge, NY</i>	Alzheimer's disease	Phase II www.unitedbiomedical.com
verubecestat (MK-8931) (BACE1 protein inhibitor)	Merck <i>Kenilworth, NJ</i>	Alzheimer's disease, prodromal Alzheimer's disease	Phase III www.merck.com
VX-745 (p38 mitogen-activated protein kinase inhibitor)	EIP Pharma <i>Cambridge, MA</i>	Alzheimer's disease	Phase II www.eippharma.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 February 29, 2016**. 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.

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.