

## 2017 HIV/AIDS Medicines in Development

### Antiretrovirals / Antivirals

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALT-803 (IL-15 super agonist protein complex)	Altor BioScience Miramar, FL	HIV infection (treatment)	Phase I <a href="http://www.altorbioscience.com">www.altorbioscience.com</a>
APH-0812 (PKC modulator/HDAC inhibitor)	Aphios Woburn, MA	HIV latency (combination treatment)	Phase I <a href="http://www.aphios.com">www.aphios.com</a>
bictegravir/F/TAF (non-boosted integrase inhibitor/emtricitabine/tenofovir alafenamide)	Gilead Sciences Foster City, CA	HIV-1 infection (treatment)	Phase III <a href="http://www.gilead.com">www.gilead.com</a>
cabotegravir LA (HIV integrase inhibitor [long-acting intramuscular injection])	ViiV Healthcare Research Triangle Park, NC	HIV infection (PrEP)	Phase III <a href="http://www.viivhealthcare.com">www.viivhealthcare.com</a>
cabotegravir LA/rilpivirine LA combination (HIV integrase inhibitor and NNRTI [long-acting intramuscular injection])	Janssen Research & Development Raritan, NJ ViiV Healthcare Research Triangle Park, NC	HIV infection (treatment)	Phase III <a href="http://www.janssen.com">www.janssen.com</a> <a href="http://www.viivhealthcare.com">www.viivhealthcare.com</a>
cenicriviroc (CCR2/CCR5 receptor antagonist)	Tobira Therapeutics South San Francisco, CA	HIV-1 infection (adjunctive care)	Phase II <a href="http://www.tobiratx.com">www.tobiratx.com</a>
dapivirine vaginal ring (NNRTI)	International Partnership for Microbicides Silver Spring, MD	HIV infection (prevention)	Phase I <a href="http://www.ipmglobal.org">www.ipmglobal.org</a>

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darunavir STR (darunavir/cobicistat/emtricitabine/ tenofovir alafenamide fixed-dose combination)	Janssen Research & Development Raritan, NJ	HIV-1 infection (treatment)	Phase III <a href="http://www.janssen.com">www.janssen.com</a>
		HIV-1 infection (pediatric treatment)	Phase I <a href="http://www.janssen.com">www.janssen.com</a>
<b>Descovy</b> <sup>®</sup> emtricitabine/tenofovir alafenamide	Gilead Sciences Foster City, CA	HIV-1 infection (PrEP)	Phase III <a href="http://www.gilead.com">www.gilead.com</a>
dolutegravir/lamivudine (HIV integrase inhibitor/NRTI fixed-dose combination)	ViiV Healthcare Research Triangle Park, NC	HIV infection (treatment)	Phase III <a href="http://www.viivhealthcare.com">www.viivhealthcare.com</a>
dolutegravir/rilpivirine STR	Janssen Research & Development Raritan, NJ ViiV Healthcare Research Triangle Park, NC	HIV infection (treatment) (treatment experienced)	application submitted <a href="http://www.janssen.com">www.janssen.com</a> <a href="http://www.viivhealthcare.com">www.viivhealthcare.com</a>
doravirine (MK-1439) (NNRTI)	Merck Kenilworth, NJ	HIV-1 infection (treatment) (treatment-naïve)	Phase III <a href="http://www.merck.com">www.merck.com</a>
doravirine/lamivudine/ tenofovir disoproxil fumarate	Merck Kenilworth, NJ	HIV-1 infection (treatment) (treatment-naïve)	Phase III <a href="http://www.merck.com">www.merck.com</a>
<b>Edurant</b> <sup>®</sup> LA rilpivirine long-acting nanosuspension for injection	Janssen Research & Development Raritan, NJ	HIV infection (treatment)	Phase I <a href="http://www.janssen.com">www.janssen.com</a>

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elsulfavirine (NNRTI)	Viriom San Diego, CA	HIV infection (PrEP, PEP & treatment) (sustained-release oral)	Phase II <a href="http://www.viriom.com">www.viriom.com</a>
fostemsavir (attachment inhibitor)	ViiV Healthcare Research Triangle Park, NC	HIV-1 infection (treatment)	Phase III <a href="http://www.viivhealthcare.com">www.viivhealthcare.com</a>
GS-9620 (vesatolimod)	Gilead Sciences Foster City, CA	HIV infection (treatment)	Phase I <a href="http://www.gilead.com">www.gilead.com</a>
GSK2838232 (HIV maturation inhibitor)	GlaxoSmithKline Philadelphia, PA	HIV-1 infection (treatment)	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
ibalizumab (viral entry inhibitor) ORPHAN DRUG	US TaiMed Biologics Irvine, CA	HIV-1 infection (treatment)	application submitted <a href="http://www.taimedbiologics.com">www.taimedbiologics.com</a>
IRT-101 (methionine enkephalin)	Cytocom Orlando, FL	HIV infection (treatment)	Phase II <a href="http://www.cytocom.com">www.cytocom.com</a>
MB66 microbicide (monoclonal antibodies)	Mapp Biopharmaceutical San Diego, CA	HIV infection (prevention)	Phase I <a href="http://www.mappbio.com">www.mappbio.com</a>
MIV 150/zinc acetate (vaginal gel)	Population Council New York, NY	HIV infection (prevention)	Phase I <a href="http://www.popcouncil.org">www.popcouncil.org</a>

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MK-8591 (NRTI)	Merck Kenilworth, NJ	HIV-1 infection (treatment) (ART-treatment-naïve)	Phase I <a href="http://www.merck.com">www.merck.com</a>
<b>Prezcobix</b> <sup>®</sup> cobicistat/darunavir	Janssen Research & Development Raritan, NJ	HIV-1 infection (pediatric treatment)	Phase I <a href="http://www.janssen.com">www.janssen.com</a>
PRO 140 (viral entry inhibitor)	CytoDyn Vancouver, WA	HIV infection (treatment) Fast Track	Phase III <a href="http://www.cytodyn.com">www.cytodyn.com</a>
<b>Reyataz</b> <sup>®</sup> atazanavir	Bristol-Myers Squibb Princeton, NJ	HIV-1 infection (pediatric treatment)	Phase III <a href="http://www.bms.com">www.bms.com</a>
RPI-MN (modified cobratoxin/nicotinic receptor antagonist/interferon gamma stimulant)	ReceptoPharm Plantation, FL	HIV infection (treatment)	Phase I completed <a href="http://www.receptopharm.com">www.receptopharm.com</a>
tenofovir gel (NtRTI)	CONRAD Arlington, VA	HIV infection (prevention)	Phase II <a href="http://www.conrad.org">www.conrad.org</a>
TMB-607 (HIV protease inhibitor)	TaiMed Biologics Taipei City, Taiwan	HIV infection (treatment)	Phase I <a href="http://www.taimedbiologics.com">www.taimedbiologics.com</a>
<b>Vitekta</b> <sup>®</sup> elvitegravir	Gilead Sciences Foster City, CA	HIV-1 infection (pediatric treatment)	Phase II/III <a href="http://www.gilead.com">www.gilead.com</a>

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<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VM1500a (NNRTI)	Viriom San Diego, CA	HIV infection (PrEP, PEP & treatment) (long-acting injectable)	Phase I <a href="http://www.viriom.com">www.viriom.com</a>
VRC01LS (CD4 antigen inhibitor mAb)	National Institute of Allergy and Infectious Diseases Rockville, MD Xencor Monrovia, CA	HIV infection (treatment)	Phase I <a href="http://www.xencor.com">www.xencor.com</a>

## Cell Therapies / Gene Therapies

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CAL-1 (stem cell gene therapy)	Calimmune Los Angeles, CA	HIV-1 infection (one-time treatment)	Phase I/II <a href="http://www.calimmune.com">www.calimmune.com</a>
SB-728-HSPC (ZFN-mediated genome editing T-cells)	Sangamo Therapeutics Richmond, CA	HIV infection (treatment)	Phase I/II <a href="http://www.sangamo.com">www.sangamo.com</a>
SB-728-T (ZFN-mediated genome editing in HSCs)	Sangamo Therapeutics Richmond, CA	HIV infection (treatment)	Phase II <a href="http://www.sangamo.com">www.sangamo.com</a>
<b>StealthVector® HGTV43™</b> (antisense HIV-1 therapy)	Enzo Therapeutics New York, NY	HIV-1 infection (treatment)	Phase II <a href="http://www.enzo.com">www.enzo.com</a>

## Vaccines

### Drug Name

### Sponsor

### Indication

### Development Phase

AGS-004 (autologous dendritic cell vaccine)	Argos Therapeutics Durham, NC University of North Carolina Chapel Hill, NC	HIV-1 infection (treatment) (with vorinostat)	Phase I <a href="http://www.argostherapeutics.com">www.argostherapeutics.com</a>
DNA-C (DNA HIV vaccine)	National Institute of Allergy and Infectious Diseases Rockville, MD	HIV infection (prevention) (combination with other HIV vaccines)	Phase I/II
GOVX-B11 (clade-B DNA HIV vaccine)	GeoVax Labs Smyrna, GA	HIV infection (prevention)	Phase II <a href="http://www.geovax.com">www.geovax.com</a>
		HIV infection (treatment)	Phase I <a href="http://www.geovax.com">www.geovax.com</a>
HIV vaccine (Ad26 Mos HIV trivalent vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	HIV infection (prevention)	Phase II <a href="http://www.janssen.com">www.janssen.com</a>
HIV vaccine (Ad26 Mos4 HIV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	HIV infections (prevention)	Phase II <a href="http://www.janssen.com">www.janssen.com</a>
HIV vaccine (MVA mosaic HIV vaccine)	Janssen Vaccines and Prevention Leiden, Netherlands	HIV infection (prevention)	Phase I/II <a href="http://www.janssen.com">www.janssen.com</a>
HIV vaccine (viral vector prime & rgp 120 boost vaccine)	Sanofi Bridgewater, NJ	HIV infection (prevention)	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a>

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HIV vaccine Ad4-CladeC	PaxVax Redwood City, CA	HIV infection (prevention)	Phase I <a href="http://www.paxvax.com">www.paxvax.com</a>
HIV vaccine Ad4-mGag	PaxVax Redwood City, CA	HIV infection (prevention)	Phase I <a href="http://www.paxvax.com">www.paxvax.com</a>
<b>HIVAX™</b> replication-defective HIV vaccine	GeneCure Biotechnologies Norcross, GA	HIV-1 infection (treatment)	Phase I <a href="http://www.genecure.com">www.genecure.com</a>
IHV001 (subunit HIV vaccine)	Profectus Biosciences Baltimore, MD	HIV infection (prevention)	Phase I <a href="http://www.profectusbiosciences.com">www.profectusbiosciences.com</a>
ITV-1 (inactivated pepsin fraction)	Immunotech Laboratories Monrovia, CA	HIV infection (treatment)	Phase II <a href="http://www.immunotechlab.com">www.immunotechlab.com</a>
<b>PBSVax™</b> HIV-MAG DNA vaccine	Profectus Biosciences Baltimore, MD	HIV infection (treatment)	Phase I <a href="http://www.profectusbiosciences.com">www.profectusbiosciences.com</a>
		HIV infection (prevention)	Phase I <a href="http://www.profectusbiosciences.com">www.profectusbiosciences.com</a>
<b>PENNVAX®-GP</b> Clade A, B, C, D HIV vaccine	Inovio Pharmaceuticals Plymouth Meeting, PA	HIV infection (prevention and treatment)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
<b>Remune®</b> GP120-depleted HIV-1 vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	HIV-1 infection (adult and pediatric treatment)	application submitted <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>

## Vaccines

### Drug Name

### Sponsor

### Indication

### Development Phase

**RemuneX®**  
HIV combination vaccine

Immune Response Biopharma  
Atlantic City, NJ

HIV-1 infection (treatment)

Phase III  
[www.immuneresponsebiopharma.com](http://www.immuneresponsebiopharma.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 June 9, 2017.** 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).

**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.



**PEP**—Post-Exposure Prevention

**PrEP**—Pre-Exposure Prevention

**STR**—Single Tablet Regimen