

## 2016 Vaccines in Development

<u>Allergy Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AR 101 (oral immunotherapy)	Aimmune Therapeutics Brisbane, CA	peanut hypersensitivity (FAST TRACK)	Phase III <a href="http://www.aimmune.com">www.aimmune.com</a>
ASP-4070 (immunotherapeutic plasmid-based DNA vaccine)	Astellas Pharma US Northbrook, IL Immunomic Therapeutics Hershey, PA	Japanese red cedar allergy	Phase I <a href="http://www.astellas.com">www.astellas.com</a> <a href="http://www.immunomix.com">www.immunomix.com</a>
ESPI-GAM (subcutaneous bifunctional Fc fusion protein)	Tunitas Therapeutics South San Francisco, CA	cat, dust mite or Bermuda grass hypersensitivity	Phase I <a href="http://www.tunitastherapeutics.com">www.tunitastherapeutics.com</a>
HDM-SPIRE (house dust mite allergy vaccine)	Circassia Oxford, United Kingdom	allergic rhinoconjunctivitis due to dust mite allergy	Phase II <a href="http://www.circassia.com">www.circassia.com</a>
injectable MPL allergy vaccine	Allergy Therapeutics West Sussex, United Kingdom	seasonal allergic rhinitis	Phase II <a href="http://www.allergytherapeutics.com">www.allergytherapeutics.com</a>
MK-8237 (house dust mite allergy vaccine)	Merck Kenilworth, NJ	house dust mite allergen-induced rhinoconjunctivitis/rhinitis	application submitted <a href="http://www.merck.com">www.merck.com</a>
QGE031 (IgE receptor antagonist)	Novartis Pharmaceuticals East Hanover, NJ	allergic asthma, chronic spontaneous urticaria	Phase II <a href="http://www.novartis.com">www.novartis.com</a>
<b>Ragwitek™</b> ragweed allergy vaccine sublingual tablet	Merck Kenilworth, NJ	seasonal allergic rhinitis (pediatric)	Phase III <a href="http://www.merck.com">www.merck.com</a>

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REGN1908-1909 (allergy immunotherapy)	Regeneron Pharmaceuticals Tarrytown, NY	unspecified allergic disease	Phase I <a href="http://www.regeneron.com">www.regeneron.com</a>
STAGR 320 (house dust mite allergy immunotherapy tablet)	Stallergenes Greer Cambridge, MA	allergic rhinitis due to house dust mite allergy	Phase III <a href="http://www.stallergenesgreer.comn">www.stallergenesgreer.comn</a>
		allergic asthma due to house dust mite allergy	Phase II <a href="http://www.stallergenesgreer.comn">www.stallergenesgreer.comn</a>
<b>STAGR SAIL™ SLIT</b> ragweed allergy immunotherapy	Stallergenes Greer Cambridge, MA	seasonal allergic rhinitis	Phase III <a href="http://www.stallergenesgreer.com">www.stallergenesgreer.com</a>
<b>Viaskin® Milk</b> milk allergy immunotherapy	DBV Technologies New York, NY	milk hypersensitivity (pediatric)	Phase II <a href="http://www.dbv-technologies.com">www.dbv-technologies.com</a>
<b>Viaskin® Peanut</b> peanut allergy immunotherapy	DBV Technologies New York, NY	peanut hypersensitivity (pediatric) (FAST TRACK)	Phase III <a href="http://www.dbv-technologies.com">www.dbv-technologies.com</a>
<b>Cancer</b> <b><u>Drug Name</u></b>	<b><u>Sponsor</u></b>	<b><u>Indication</u></b>	<b><u>Development Phase</u></b>
ADU-214 (live attenuated double-deleted [LADD] <i>Listeria monocytogenes</i> immunotherapy)	Aduro Biotech Berkeley, CA Janssen Research & Development Raritan, NJ	non-small cell lung cancer (NSCLC)	Phase I <a href="http://www.adoro.com">www.adoro.com</a> <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>

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ADU-623 (live-attenuated double deleted [LADD] <i>Listeria monocytogenes</i> immunotherapy)	Aduro Biotech Berkeley, CA	glioblastoma	Phase I <a href="http://www.adoro.com">www.adoro.com</a>
ADU-741 (live attenuated double-deleted [LADD] <i>Listeria monocytogenes</i> immunotherapy)	Aduro Biotech Berkeley, CA Janssen Research & Development Raritan, NJ	hormone refractory, metastatic prostate cancer	Phase I <a href="http://www.adoro.com">www.adoro.com</a> <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
ADXS11-001 (axalimogene filolisbac) ORPHAN DRUG	Advaxis Princeton, NJ	anal cancer, cervical cancer, head/neck cancer	Phase II <a href="http://www.advaxis.com">www.advaxis.com</a>
ADXS-HER2 ( <i>Listeria monocytogenes</i> listeriolysm immunotherapy) ORPHAN DRUG	Advaxis Princeton, NJ	HER2-positive solid tumors, including sarcoma (FAST TRACK)	Phase I <a href="http://www.advaxis.com">www.advaxis.com</a>
ADXS-PSA (tumor protein inhibitor immunotherapy)	Advaxis Princeton, NJ Merck Kenilworth, NJ	metastatic prostate cancer (in combination with Keytruda®)	Phase I/II <a href="http://www.advaxis.com">www.advaxis.com</a> <a href="http://www.merck.com">www.merck.com</a>
AE37 vaccine (li-key hybrid vaccine - Her2/neu)	Antigen Express Wellesley, MA	breast cancer, prostate cancer	Phase II <a href="http://www.antigenexpress.com">www.antigenexpress.com</a>

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AE-M vaccine (T-helper cell-stimulating peptide vaccine)	Antigen Express Wellesley, MA	malignant melanoma	Phase I <a href="http://www.antigenexpress.com">www.antigenexpress.com</a>
AE-O vaccine (peptide vaccine)	Antigen Express Wellesley, MA	ovarian cancer	Phase I <a href="http://www.antigenexpress.com">www.antigenexpress.com</a>
AGS-003 (autologous dendritic cell vaccine)	Argos Therapeutics Durham, NC	metastatic renal cell carcinoma (FAST TRACK)	Phase III <a href="http://www.argostherapeutics.com">www.argostherapeutics.com</a>
		early stage renal cell carcinoma, NSCLC	Phase II <a href="http://www.argostherapeutics.com">www.argostherapeutics.com</a>
ARB 1598 (immunotherapy)	Checkmate Pharmaceuticals Cambridge, MA	malignant melanoma	Phase I <a href="http://www.checkmatepharma.com">www.checkmatepharma.com</a>
AST-VAC1 (telomerase-based cancer vaccine)	Asterias Biotherapeutics Fremont, CA	acute myeloid leukemia (AML)	Phase II completed <a href="http://www.asteriasbiotherapeutics.com">www.asteriasbiotherapeutics.com</a>
AVX701 (CEA cancer immunotherapy)	AlphaVax Research Triangle Park, NC	colon cancer	Phase I <a href="http://www.alphavax.com">www.alphavax.com</a>
AVX901 (Her2 cancer immunotherapy)	AlphaVax Research Triangle Park, NC	breast cancer	Phase I <a href="http://www.alphavax.com">www.alphavax.com</a>
BB-MPI-03 (multi-peptide immunotherapy)	Benovus Bio Atlanta, GA	AML, myelodysplastic syndromes, multiple myeloma, smoldering multiple myeloma	Phase I <a href="http://www.benovusbio.com">www.benovusbio.com</a>

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BI 1361849 (RNA cancer vaccine)	Boehringer Ingelheim Pharmaceuticals Ridgefield, CT	NSCLC	Phase II <a href="http://www.boehringer-ingelheim.com">www.boehringer-ingelheim.com</a>
<b>BriaVax™</b> SV-BR 1 GM cancer vaccine	BriaCell Therapeutics Berkeley, CA	ovarian cancer	Phase I <a href="http://www.briacell.com">www.briacell.com</a>
cancer immunotherapy (ovarian cancer stem cell therapy)	AiVita Biomedical Irvine, CA	ovarian cancer	Phase II <a href="http://www.aivitabiomedical.com">www.aivitabiomedical.com</a>
CD40L GVAX cancer vaccine (next generation)	Cellular Biomedicine Cupertino, CA	NSCLC	Phase I <a href="http://www.cellbiomedgroup.com">www.cellbiomedgroup.com</a>
CDX-1401 (dendritic cancer vaccine)	CellDex Therapeutics Hampton, NJ	metastatic melanoma	Phase II <a href="http://www.celldex.com">www.celldex.com</a>
		gynecological cancers	Phase I/II <a href="http://www.celldex.com">www.celldex.com</a>
CLBS20 (eltrapuldencel-T)	Caladrius Biosciences Basking Ridge, NJ	advanced melanoma	Phase II completed <a href="http://www.caladrius.com">www.caladrius.com</a>
CMB 305 (LV305 + G305 prime-boost vaccine) ORPHAN DRUG	Immune Design Seattle, WA	myxoid/round-cell liposarcoma, synovial sarcoma	Phase II <a href="http://www.immunedesign.com">www.immunedesign.com</a>
		solid cancers expressing NY-ESO-1	Phase I <a href="http://www.immunedesign.com">www.immunedesign.com</a>

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CRS-207 (immunotherapy) ORPHAN DRUG	Aduro Biotech Berkeley, CA	metastatic pancreatic cancer (GVAX/anti-PD1 combination)	Phase II <a href="http://www.aduro.com">www.aduro.com</a>
		mesothelioma (chemotherapy combination)	Phase I <a href="http://www.aduro.com">www.aduro.com</a>
		ovarian cancer (epacadostat combination)	Phase I <a href="http://www.aduro.com">www.aduro.com</a>
CV-301 (cancer vaccine)	Bavarian Nordic Redwood City, CA	bladder cancer	Phase II <a href="http://www.bavarian-nordic.com">www.bavarian-nordic.com</a>
<b>DCVax®-Direct</b> solid tumor vaccine	Northwest Biotherapeutics Bethesda, MD	solid tumors	Phase I/II <a href="http://www.nwbio.com">www.nwbio.com</a>
<b>DCVax®-L</b> brain cancer vaccine ORPHAN DRUG	Northwest Biotherapeutics Bethesda, MD	glioblastoma	Phase III <a href="http://www.nwbio.com">www.nwbio.com</a>
		metastatic ovarian cancer	Phase I completed <a href="http://www.nwbio.com">www.nwbio.com</a>
DN24-02 (active cellular immunotherapy)	Dendreon Seattle, WA	HER2-positive urothelial cancer	Phase I completed <a href="http://www.dendreon.com">www.dendreon.com</a>
DNX-2401 (oncolytic immunotherapy) ORPHAN DRUG	DNatrix Houston, TX	glioblastoma (FAST TRACK)	Phase I completed <a href="http://www.dnatrix.com">www.dnatrix.com</a>

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DPV-001 (tumor-derived autophagosome enriched vaccine)	UbiVac Portland, OR	stage III NSCLC	Phase II <a href="http://www.ubivac.com">www.ubivac.com</a>
		prostate cancer	Phase I <a href="http://www.ubivac.com">www.ubivac.com</a>
DPX-Survivac (peptide cancer vaccine) ORPHAN DRUG	Immunovaccine Halifax, Canada	ovarian cancer	Phase I/II <a href="http://www.imvaccine.com">www.imvaccine.com</a>
ERC1671 (therapeutic cancer vaccine) ORPHAN DRUG	Epitopoietic Research Pasadena, CA	glioblastoma	Phase II <a href="http://www.erc-usa.com">www.erc-usa.com</a>
ETBX-011 (cancer immunotherapy)	Etubics Seattle, WA	solid tumors	Phase I/II <a href="http://www.etubics.com">www.etubics.com</a>
G305 (GLA-SE+NY-ESO-1 protein) ORPHAN DRUG	Immune Design Seattle, WA	solid tumors	Phase I completed <a href="http://www.immunedesign.com">www.immunedesign.com</a>
GALE-301 (cancer immunotherapy) ORPHAN DRUG	Galena Biopharma San Ramon, CA	endometrial cancer, ovarian cancer	Phase II <a href="http://www.galenabiopharma.com">www.galenabiopharma.com</a>
GALE-301 + GALE-302 (cancer immunotherapy) ORPHAN DRUG	Galena Biopharma San Ramon, CA	breast cancer, ovarian cancer	Phase I/II <a href="http://www.galenabiopharma.com">www.galenabiopharma.com</a>

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galinpepimut-S (WT1 peptide vaccine) ORPHAN DRUG	SELLAS Life Sciences New York, NY	AML (FAST TRACK), mesothelioma, multiple myeloma	Phase II <a href="http://www.sellaslifesciences.com">www.sellaslifesciences.com</a>
		ovarian cancer	Phase I <a href="http://www.sellaslifesciences.com">www.sellaslifesciences.com</a>
GI-6207 (targeted molecular immunogen T cell stimulator)	GlobeImmune Louisville, CO	medullary thyroid cancer	Phase II <a href="http://www.globeimmune.com">www.globeimmune.com</a>
GI-6301 (brachyury peptide vaccine)	GlobeImmune Louisville, CO	chordomas	Phase II <a href="http://www.globeimmune.com">www.globeimmune.com</a>
		advanced cancers	Phase I <a href="http://www.globeimmune.com">www.globeimmune.com</a>
GL-0817 (MAGEA 3 immunotherapy) ORPHAN DRUG	Gliknik Baltimore, MD	MAGE-A3-positive squamous cell cancer of the oral cavity	Phase II <a href="http://www.gliknik.com">www.gliknik.com</a>
GRN-1201 (cancer immunotherapy)	GreenPeptide Fukuoka, Japan	malignant melanoma	Phase I <a href="http://www.green-peptide.com">www.green-peptide.com</a>
GTL001 (bivalent vaccine)	Genticel Labège-Innopole, France	high-grade lesions and cervical cancer associated with human papillomavirus (HPV) 16/18 infection (prevention)	Phase I <a href="http://www.genticel.com">www.genticel.com</a>



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<b>HyperAcute®-Melanoma</b> dorgenmeltucel-L	NewLink Genetics Ames, IA	malignant melanoma (combination therapy)	Phase II <a href="http://www.newlinkgenetics.com">www.newlinkgenetics.com</a>
<b>HyperAcute™ Renal</b> renal cancer vaccine	NewLink Genetics Ames, IA	renal cancer	Phase I <a href="http://www.newlinkgenetics.com">www.newlinkgenetics.com</a>
ICT-107 (dendritic cell vaccine)	ImmunoCellular Therapeutics Calabasas, CA	newly-diagnosed glioblastoma	Phase III <a href="http://www.imuc.com">www.imuc.com</a>
ICT-121 (dendritic cell vaccine)	ImmunoCellular Therapeutics Calabasas, CA	recurrent glioblastoma	Phase I <a href="http://www.imuc.com">www.imuc.com</a>
IMA901 (peptide vaccine) ORPHAN DRUG	immatics US Houston, TX	renal cancer	Phase II completed <a href="http://www.immatics.com">www.immatics.com</a>
IMCgp100 (CD3 antigen inhibitor) ORPHAN DRUG	Immunocore Conshohocken, PA	malignant melanoma	Phase I/II <a href="http://www.immunocore.com">www.immunocore.com</a>
		uveal melanoma	Phase I <a href="http://www.immunocore.com">www.immunocore.com</a>
IMT-1012 immunotherapy vaccine	Immunotope Doylestown, PA	cancer	Phase I completed <a href="http://www.immunotope.com">www.immunotope.com</a>
INO-1400 (hTERT vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	breast cancer, lung cancer, pancreatic cancer	Phase I <a href="http://www.inovio.com">www.inovio.com</a>

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INO-3106 (E6, E7 vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	aerodigestive cancer, HPV type 6	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
INO-3112 (HPV type 16/18 vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	cervical cancer, head & neck cancer	Phase I/II <a href="http://www.inovio.com">www.inovio.com</a>
INO-5150 (PSA, PSMA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prostate cancer	Phase I <a href="http://www.inovio.vom">www.inovio.vom</a>
ISA101 (HPV16 vaccine)	ISA Pharmaceuticals Leiden, Netherlands M.D. Anderson Cancer Center Houston, TX	solid tumors (combination therapy)	Phase II <a href="http://www.isa-pharma.com">www.isa-pharma.com</a>
JCAR014 (cancer immunotherapy)	Juno Therapeutics Seattle, WA	adult B cell malignancies	Phase II <a href="http://www.junotherapeutics.com">www.junotherapeutics.com</a>
JCAR015 (cancer immunotherapy)	Juno Therapeutics Seattle, WA	adult acute lymphocytic leukemia (ALL), adult non-Hodgkin's lymphoma (NHL)	Phase II <a href="http://www.junotherapeutics.com">www.junotherapeutics.com</a>
JCAR017 (cancer immunotherapy)	Juno Therapeutics Seattle, WA	pediatric ALL, adult NHL	Phase I <a href="http://www.junotherapeutics.com">www.junotherapeutics.com</a>
JCAR018 (cancer immunotherapy)	Juno Therapeutics Seattle, WA	B cell malignancies	Phase I <a href="http://www.junotherapeutics.com">www.junotherapeutics.com</a>

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JCAR023 (cancer immunotherapy)	Juno Therapeutics Seattle, WA	neuroblastoma, solid tumors	Phase I <a href="http://www.junotherapeutics.com">www.junotherapeutics.com</a>
JTCR016 (cancer immunotherapy)	Juno Therapeutics Seattle, WA	AML, NSCLC	Phase I/II <a href="http://www.junotherapeutics.com">www.junotherapeutics.com</a>
<b>KiroTac</b> tumor associated peptide antigen pulsed dendritic cell vaccine	Kiromic Houston, TX	hematological malignancies, solid tumors	Phase I/II <a href="http://www.kiromic.com">www.kiromic.com</a>
LV 305 (T cell active immunotherapy) ORPHAN DRUG	Immune Design Seattle, WA	breast cancer, malignant melanoma, NSCLC, ovarian cancer, sarcoma	Phase I <a href="http://www.immunedesign.com">www.immunedesign.com</a>
MUC-1/CD40L vaccine	MicroVax Manassas, VA	solid tumors	Phase I
M-VAX (cancer vaccine)	AVAX Technologies Philadelphia, PA	malignant melanoma	Phase III <a href="http://www.avax-tech.com">www.avax-tech.com</a>
MVA-BN Brachyury (cancer immunotherapy)	Bavarian Nordic Redwood City, CA	solid tumors	Phase I <a href="http://www.bavarian-nordic.com">www.bavarian-nordic.com</a>
MVI-118 (pTVG-AR) (androgen receptor plasmid DNA vaccine)	Madison Vaccines Madison, WI	prostate cancer	Phase I <a href="http://www.madisonvaccinesinc.com">www.madisonvaccinesinc.com</a>

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MVI-816 (prostatic acid phosphatase plasmid DNA vaccine)	Madison Vaccines Madison, WI	prostate cancer	Phase II <a href="http://www.madisonvaccinesinc.com">www.madisonvaccinesinc.com</a>
NEO-PV-01 (personalized neoantigen vaccine)	Neon Therapeutics Cambridge, MA	glioblastoma, malignant melanoma	Phase I <a href="http://www.neontherapeutics.com">www.neontherapeutics.com</a>
neuroblastoma bivalent vaccine ORPHAN DRUG	MabVax San Diego, CA	neuroblastoma	Phase I <a href="http://www.mabvax.com">www.mabvax.com</a>
<b>NeuVax™</b> nelipepimut S (E75 cancer vaccine)	Galena Biopharma San Ramon, CA	breast cancer (FAST TRACK)	Phase III <a href="http://www.galenabiopharma.com">www.galenabiopharma.com</a>
		breast cancer (combination therapy)	Phase II <a href="http://www.galenabiopharma.com">www.galenabiopharma.com</a>
		ductal carcinoma in situ, gastric cancer	Phase I <a href="http://www.galenabiopharma.com">www.galenabiopharma.com</a>
OBI-822 (cancer immunotherapy)	OBI Pharma Taipei, Taiwan	breast cancer	Phase II/III <a href="http://www.obipharma.com">www.obipharma.com</a>
<b>Oncoquest™-CLL</b> personalized cancer vaccine	XEME Biopharma Monmouth Junction, NJ	chronic lymphocytic leukemia	Phase I <a href="http://www.xemebiopharma.com">www.xemebiopharma.com</a>
<b>Oncoquest™-L</b> non-Hodgkin's lymphoma vaccine	XEME Biopharma Monmouth Junction, NJ	non-Hodgkin's follicular lymphoma	Phase II <a href="http://www.xemebiopharma.com">www.xemebiopharma.com</a>

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<b>OncoVAX®</b> colorectal cancer immunotherapy	Vaccinogen Baltimore, MD	colorectal cancer	Phase III <a href="http://www.vaccinogeninc.com">www.vaccinogeninc.com</a>
oregovomab (anti-idiotypic mAb)	OncoQuest Edmonton, Canada	ovarian cancer	Phase II <a href="http://www.oncoquestinc.com">www.oncoquestinc.com</a>
ovarian pentavalent vaccine	MabVax San Diego, CA	ovarian cancer	Phase II <a href="http://www.mabvax.com">www.mabvax.com</a>
O-VAX (cancer vaccine) ORPHAN DRUG	AVAX Technologies Philadelphia, PA	ovarian cancer	Phase I/II <a href="http://www.avax-tech.com">www.avax-tech.com</a>
p53 MVA vaccine (modified vaccinia ankara)	Tara Immuno-Oncology New York, NY	solid tumors	Phase I
PAS (polyclonal antibody stimulator)	Cancer Advances Durham, NC	gastric cancer, pancreatic cancer	Phase III <a href="http://www.canceradvancesinc.com">www.canceradvancesinc.com</a>
		colorectal cancer	Phase II <a href="http://www.canceradvancesinc.com">www.canceradvancesinc.com</a>
PDS0101 (cancer immunotherapy)	PDS Biotechnology North Brunswick, NJ	cervical intraepithelial neoplasia (HPV16-related)	Phase I <a href="http://www.pdsbiotech.com">www.pdsbiotech.com</a>

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PEPIDH1M (dendritic cell vaccine)	Annias Immunotherapeutics Chapel Hill, NC Duke University Durham, NC	glioblastoma	Phase I/II <a href="http://www.anniasimmuno.com">www.anniasimmuno.com</a>
PF-06753512 (cancer immunotherapy)	Pfizer New York, NY	prostate cancer	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>
<b>Prophage</b> <sup>®</sup> heat shocked protein-based vaccine	Agenus Lexington, MA	glioblastoma (newly diagnosed and recurrent)	Phase II <a href="http://www.agenusbio.com">www.agenusbio.com</a>
<b>Proscavax</b> PSA/IL-2/GM-CSF vaccine	Oncbiomune Baton Rouge, LA	prostate cancer	Phase I <a href="http://www.oncbiomune.com">www.oncbiomune.com</a>
<b>PROSTVAC</b> rilimogene galvacirepvec-rilimogene glafolivec	Bavarian Nordic Redwood City, CA	prostate cancer (FAST TRACK)	Phase III <a href="http://www.bavarian-nordic.com">www.bavarian-nordic.com</a>
<b>Provenge</b> <sup>®</sup> sipuleucel-T	Dendreon Seattle, WA	recurrent early-stage prostate cancer	Phase III <a href="http://www.dendreon.com">www.dendreon.com</a>
		recurrent hormone refractory metastatic prostate cancer	Phase II <a href="http://www.dendreon.com">www.dendreon.com</a>
PT 107 (allogeneic transfected tumor cell vaccine)	Pique Therapeutics Durham, NC	NSCLC	Phase II <a href="http://www.piquetherapeutics.com">www.piquetherapeutics.com</a>

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PVX-410 (cancer immunotherapy) ORPHAN DRUG	OncoPep North Andover, MA	multiple myeloma	Phase II <a href="http://www.oncopep.com">www.oncopep.com</a>
REIC gene therapy	Momotaro-Gene Okayama, Japan	localized prostate cancer	Phase I/II <a href="http://www.mt-gene.com">www.mt-gene.com</a>
sarcoma trivalent vaccine	MabVax San Diego, CA	sarcoma	Phase II <a href="http://www.mabvax.com">www.mabvax.com</a>
seviprotimut-L (polyvalent therapeutic vaccine)	Polynoma San Diego, CA	resected stage IIB-III melanoma	Phase III <a href="http://www.polynoma.com">www.polynoma.com</a>
SL-701 (cancer immunotherapy)	Stemline Therapeutics New York, NY	glioblastoma multiforme	Phase II <a href="http://www.stemline.com">www.stemline.com</a>
stapuldencel-T (DCVAC/PCa) (active cellular immunotherapy)	SOTIO Boston, MA	prostate cancer	Phase III <a href="http://www.sotio.com">www.sotio.com</a>
<b>SurVaxM</b> synthetic long peptide mimic vaccine	MimiVax Buffalo, NY	newly diagnosed glioblastoma	Phase II <a href="http://www.mimivax.com">www.mimivax.com</a>
		multiple myeloma, recurrent glioma	Phase I <a href="http://www.mimivax.com">www.mimivax.com</a>
<b>Tedopi</b> <sup>®</sup> cancer immunotherapy ORPHAN DRUG	OSE Immunotherapeutics Paris, France	NSCLC	Phase III <a href="http://www.ose-immuno.com">www.ose-immuno.com</a>

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tergenpumatucl-L (cancer immunotherapy)	NewLink Genetics Ames, IA	NSCLC (combination therapy)	Phase II/III <a href="http://www.newlinkgenetics.com">www.newlinkgenetics.com</a>
TG4010 (MVA-MUC1-IL2 cancer vaccine)	Transgene Cedex, France	NSCLC	Phase II <a href="http://www.transgene.fr">www.transgene.fr</a>
TLPLDC vaccine (tumor lysate particle loaded dendritic cell vaccine)	Cancer Insight San Antonio, TX Elios Therapeutics Austin, TX	metastatic melanoma	Phase II <a href="http://www.orbishealthsolutions.com">www.orbishealthsolutions.com</a>
TPIV 100/110 (cancer immunotherapy)	TapImmune Jacksonville, FL	HER2/neu breast cancer	Phase I completed <a href="http://www.tapimmune.com">www.tapimmune.com</a>
TPIV 200 (dendritic cancer vaccine) ORPHAN DRUG	TapImmune Jacksonville, FL	triple-negative breast cancer, ovarian cancer (FAST TRACK)	Phase II <a href="http://www.tapimmune.com">www.tapimmune.com</a>
TVGV-1 (fusion protein-based vaccine)	TheVax Genetics Vaccine Cape Canaveral, FL	HPV-related anal and cervical high squamous intraepithelial lesions	Phase II <a href="http://www.thevaxgenetics.com">www.thevaxgenetics.com</a>
vesigenurtucl-L (tumor cell vaccine)	Heat Biologics Durham, NC	non-muscle invasive bladder cancer (FAST TRACK)	Phase II <a href="http://www.heatbiologics.com">www.heatbiologics.com</a>
VGX-3100 (HPV type 16/18 vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	HPV-related cervical intraepithelial neoplasia	Phase II <a href="http://www.inovio.com">www.inovio.com</a>



<b>Cancer</b>			
<b><u>Drug Name</u></b>	<b><u>Sponsor</u></b>	<b><u>Indication</u></b>	<b><u>Development Phase</u></b>
viagenpumatucl-L (allogeneic vaccine)	Heat Biologics Durham, NC	advanced NSCLC	Phase II <a href="http://www.heatbiologics.com">www.heatbiologics.com</a>
<b>Vigil</b> <sup>®</sup> autologous tumor cell vaccine	Gardalis Dallas, TX	high risk stage III/IV ovarian cancer	Phase II/III <a href="http://www.gradalisinc.com">www.gradalisinc.com</a>
		Ewing's sarcoma, advanced NSCLC	Phase II <a href="http://www.gradalisinc.com">www.gradalisinc.com</a>
		malignant melanoma	Phase I <a href="http://www.gradalisinc.com">www.gradalisinc.com</a>
WT2725 (peptide vaccine)	Sunovion Pharmaceuticals Marlborough, MA	hematological malignancies, solid tumors	Phase I <a href="http://www.sunovion.com">www.sunovion.com</a>
<b>Infectious Diseases</b>			
<b><u>Drug Name</u></b>	<b><u>Sponsor</u></b>	<b><u>Indication</u></b>	<b><u>Development Phase</u></b>
Ad26 Mos HIV vaccine	Janssen Vaccines & Prevention Leiden, Netherlands	HIV infections (prevention)	Phase II <a href="http://www.janssen.com">www.janssen.com</a>
Ad26.ZEBOV (Ebola monovalent vaccine)	Janssen Vaccines & Prevention Leiden, Netherlands	Ebola virus infections (prevention)	Phase III <a href="http://www.janssen.com">www.janssen.com</a>
AE-AI vaccine (li-key hybrid vaccine)	Antigen Express Wellesley, MA	influenza A virus H5N1 and H1N1 subtypes (prevention)	Phase I <a href="http://www.antigenexpress.com">www.antigenexpress.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AE-H vaccine (HIV vaccine)	Antigen Express Wellesley, MA	HIV infections	Phase I <a href="http://www.antigenexpress.com">www.antigenexpress.com</a>
AGS-004 (autologous dendritic cell vaccine)	Argos Therapeutics Durham, NC	HIV-1 infection (treatment)	Phase II <a href="http://www.argostherapeutics.com">www.argostherapeutics.com</a>
anthrax oral vaccine	PaxVax Redwood City, CA	anthrax (prevention)	Phase I <a href="http://www.paxvax.com">www.paxvax.com</a>
ASP0113 (DNA vaccine) ORPHAN DRUG	Astellas Pharma Northbrook, IL Vical San Diego, CA	cytomegalovirus reactivation in hematopoietic cell transplantation (prevention)	Phase III <a href="http://www.astellas.com">www.astellas.com</a> <a href="http://www.vical.com">www.vical.com</a>
		cytomegalovirus reactivation in solid organ transplantation (prevention)	Phase I <a href="http://www.astellas.com">www.astellas.com</a> <a href="http://www.vical.com">www.vical.com</a>
BPZE1 (live-attenuated pertussis vaccine)	ILiAD Biotechnologies New York, NY	<i>Bordetella pertussis</i> infection (prevention and treatment)	Phase I completed <a href="http://www.iliadbio.com">www.iliadbio.com</a>
<i>Clostridium difficile</i> toxoid vaccine	Sanofi Pasteur Swiftwater, PA	<i>Clostridium difficile</i> infections (prevention)	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
CSJ148 (simplexvirus glycoprotein B inhibitor vaccine)	Novartis Pharmaceuticals East Hanover, NJ	cytomegalovirus infections in stem cell transplantation (prevention)	Phase I/II <a href="http://www.novartis.com">www.novartis.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
DAR-901 (killed whole cell booster vaccine)	Aeras Rockville, MD Dartmouth-Hitchcock Medical Center Hanover, NH	tuberculosis	Phase I <a href="http://www.aeras.org">www.aeras.org</a>
<b>Dengvaxia®</b> dengue vaccine tetravalent	Sanofi Pasteur Swiftwater, PA	dengue fever (prevention) (FAST TRACK)	application submitted <a href="http://www.sanofi.com">www.sanofi.com</a>
EBOV GP vaccine (recombinant glycoprotein nanoparticle vaccine)	Novavax Gaithersburg, MD	Ebola virus infections (prevention)	Phase I <a href="http://www.novavax.com">www.novavax.com</a>
<b>Flublok Quadrivalent</b> influenza virus vaccine	Protein Sciences Meriden, CT	influenza A/B virus (prevention)	application submitted <a href="http://www.proteinsciences.com">www.proteinsciences.com</a>
<b>FluHance</b> influenza virus vaccine (rNA)	Protein Sciences Meriden, CT	influenza virus infections (prevention)	Phase II <a href="http://www.proteinsciences.com">www.proteinsciences.com</a>
<b>Fluzone® QIV HD</b> quadrivalent inactivated influenza vaccine, high dose	Sanofi Pasteur Swiftwater, PA	influenza virus infections	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a>
<b>GelVax® H5N1</b> nasal H5N1 pandemic vaccine (vero)	Nanotherapeutics Alachua, FL	influenza A virus H5N1 subtype (prevention)	Phase I <a href="http://www.nanotherapeutics.com">www.nanotherapeutics.com</a>
GEN-003 (protein subunit T cell-enabled immunotherapy)	Genocea Biosciences Cambridge, MA	herpes simplex virus (HSV) type 2 infections (treatment)	Phase II <a href="http://www.genocea.com">www.genocea.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GLS-5300 (DNA vaccine)	GeneOne Life Science Seoul, South Korea Inovio Pharmaceuticals Plymouth Meeting, PA	Middle East respiratory syndrome coronavirus (MERS CoV) (prevention)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
GLS-5700 (DNA vaccine)	GeneOne Life Science Seoul, South Korea Inovio Pharmaceuticals Plymouth Meeting, PA	Zika virus infections (prevention)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
GOVX-B11 (DNA vaccine)	GeoVax Smyrna, GA	HIV infections (prevention)	Phase II completed <a href="http://www.geovax.com">www.geovax.com</a>
group B <i>streptococcus</i> conjugated vaccine	GlaxoSmithKline Rockville, MD	group B streptococcal infections (prevention) (maternal immunization)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
GS-4774 (Tarmogen T cell stimulator)	Gilead Sciences Foster City, CA GlobeImmune Louisville, CO	chronic hepatitis B virus infections	Phase II <a href="http://www.gilead.com">www.gilead.com</a> <a href="http://www.globeimmune.com">www.globeimmune.com</a>
GSK692342 (recombinant vaccine)	GlaxoSmithKline Rockville, MD	tuberculosis (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
GSK2838504A (recombinant vaccine)	GlaxoSmithKline Rockville, MD	reduction of frequency of COPD exacerbations associated with non-typeable <i>Haemophilus influenzae</i> and <i>Moraxella catarrhalis</i> (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>

**Infectious Diseases**

<b><u>Drug Name</u></b>	<b><u>Sponsor</u></b>	<b><u>Indication</u></b>	<b><u>Development Phase</u></b>
GSK3003891A (recombinant vaccine)	GlaxoSmithKline Rockville, MD	respiratory syncytial virus (RSV) infections (prevention) (maternal immunization)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
GSK3389245A (replication-defective recombinant viral vector vaccine)	GlaxoSmithKline Rockville, MD	RSV infections (prevention)	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK3390107A (recombinant viral vector vaccine)	GlaxoSmithKline Rockville, MD	Ebola virus infections (prevention)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
GTL001 (bivalent HPV therapeutic vaccine)	Gentical Labège-Innopole, France	high-grade lesion and cervical cancer in HPV 16/18 infections (prevention)	Phase II <a href="http://www.gentical.com">www.gentical.com</a>
H5 intradermal + GLA (influenza A virus H5N1 vaccine)	Medicago Quebec, Canada	influenza A virus H5N1 subtype (prevention)	Phase I <a href="http://www.medicago.com">www.medicago.com</a>
HBV-002 (recombinant subunit vaccine)	Hawaii Biotech Honolulu, HI	West Nile virus infections (prevention)	Phase I completed <a href="http://www.hibiotech.com">www.hibiotech.com</a>
hepatitis C recombinant viral vector vaccine	GlaxoSmithKline Rockville, MD	hepatitis C virus infections (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
<b>HEPLISAV-B™</b> (HBsAg-1018 intramuscular vaccine)	Dynavax Berkeley, CA	hepatitis B (prevention)	Phase III completed <a href="http://www.dynavax.com">www.dynavax.com</a>
<b>HepTcell</b> immunotherapy	Altimune Gaithersburg, MD	hepatitis B	Phase I <a href="http://www.altimmune.com">www.altimmune.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
herpes simplex bivalent DNA vaccine	Vical San Diego, CA	HSV infections (treatment)	Phase I/II <a href="http://www.vical.com">www.vical.com</a>
herpes simplex virus type 2 vaccine	Sanofi Pasteur Swiftwater, PA	HSV type 2 infections (prevention)	Phase I <a href="http://www.sanofipasteur.com">www.sanofipasteur.com</a>
HIV recombinant proteins vaccine	GlaxoSmithKline Rockville, MD	HIV infections (prevention)	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
HIV vaccine (Ad4-enc Clade C)	PaxVax Redwood City, CA	HIV infections (prevention)	Phase I <a href="http://www.paxvax.com">www.paxvax.com</a>
HIV vaccine (Ad4-mGag)	PaxVax Redwood City, CA	HIV infections (prevention)	Phase I <a href="http://www.paxvax.com">www.paxvax.com</a>
<b>HIVAX™</b> replication-defective HIV-1 vaccine	Genecure Norcross, GA	HIV-1 infections (prevention)	Phase I <a href="http://www.genecure.com">www.genecure.com</a>
hookworm vaccine	iBio New York, NY Sabin Vaccine Institute Washington, DC	hookworm infections	Phase I <a href="http://www.ibioinc.com">www.ibioinc.com</a>
HTNV/PUUV DNA vaccine	Ichor Medical Systems San Diego, CA US Army Medical Research and Materiel Command Fort Detrick, MD	viral hemorrhagic fever with renal syndrome (prevention)	Phase II <a href="http://www.ichorms.com">www.ichorms.com</a>

## Infectious Diseases

### Drug Name

### Sponsor

### Indication

### Development Phase

ID93 vaccine	Aeras Rockville, MD Infectious Disease Research Institute Seattle, WA	tuberculosis	Phase II <a href="http://www.aeras.org">www.aeras.org</a> <a href="http://www.idri.org">www.idri.org</a>
IHV001 (full-length single chain subunit vaccine)	Profectus Biosciences Baltimore, MD Institute of Human Virology Baltimore, MD	HIV infections (prevention)	Phase I <a href="http://www.profectusbiosciences.com">www.profectusbiosciences.com</a>
<b>Imvamune®</b> smallpox vaccine	Bavarian Nordic Redwood City, CA	smallpox (liquid-frozen vaccine)	Phase III <a href="http://www.bavarian-nordic.com">www.bavarian-nordic.com</a>
		smallpox (freeze-dried vaccine)	Phase II <a href="http://www.bavarian-nordic.com">www.bavarian-nordic.com</a>
influenza quadrivalent vaccine (plant-based VLP vaccine)	Medicago Durham, NC	seasonal influenza (prevention)	Phase II <a href="http://www.medicago.com">www.medicago.com</a>
influenza A virus H5N1 vaccine	iBio New York, NY	influenza A virus H5N1 subtype (prevention)	Phase I <a href="http://www.ibioinc.com">www.ibioinc.com</a>
influenza A virus H5N1 vaccine	PaxVax Redwood City, CA	influenza A virus H5N1 subtype (prevention)	Phase I completed <a href="http://www.paxvax.com">www.paxvax.com</a>
influenza A virus H5N1 vaccine (MF59 adjuvanted vaccine)	Seqirus Cambridge, MA	influenza A virus H5N1 subtype (prevention)	Phase II <a href="http://www.seqirus.com">www.seqirus.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
INO-1800 (clades A & C)	Inovio Pharmaceuticals Plymouth Meeting, PA Roche Basel, Switzerland	hepatitis B (treatment)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
INO-3510 (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	influenza A H5N1 and H1N1 subtypes (prevention)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
INO-4212 (polyvalent vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	Ebola virus infections (treatment)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
INO-8000 (genotype 1a/1b)	Inovio Pharmaceuticals Plymouth Meeting, PA GeneOne Life Sciences Seoul, South Korea	hepatitis C (treatment)	Phase I <a href="http://www.inovio.com">www.inovio.com</a>
JNJ-61187165/JNJ-61187191 (intramuscular prime-boost vaccine)	Janssen Vaccines & Prevention Leiden, Netherlands	RSV infections (prevention)	Phase I <a href="http://www.janssen.com">www.janssen.com</a>
JNJ-63871860 (multivalent glycoprotein conjugate vaccine)	Janssen Research & Development Raritan, NJ	<i>Escherichia coli</i> infections, urinary tract infections	Phase II <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
LIQ-001 (adjuvant influenza virus vaccine)	Liquidia Technologies Research Triangle Park, NC	influenza virus infections (prevention)	Phase I/II completed <a href="http://www.liquidia.com">www.liquidia.com</a>
malaria next-generation recombinant vaccine	GlaxoSmithKline Rockville, MD	malaria ( <i>Plasmodium falciparum</i> ) (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>



## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
MEDI-550 (pandemic influenza virus vaccine)	MedImmune Gaithersburg, MD	pandemic influenza (prevention)	Phase III <a href="http://www.medimmune.com">www.medimmune.com</a>
MEDI7510 (RSV sF+GLA-SE vaccine)	MedImmune Gaithersburg, MD	RSV disease in older adults (prevention)	Phase II <a href="http://www.medimmune.com">www.medimmune.com</a>
Men ABCWY (recombinant conjugated vaccine)	GlaxoSmithKline Rockville, MD	meningococcal ABCYW disease in adolescents (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
<b>Men Quad TT</b> 2nd generation meningococcal ACYW conjugate vaccine	Sanofi Pasteur Swiftwater, PA	meningococcal ACYW infections (prevention)	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
meningitis & pneumonia vaccine	Sanofi Pasteur Swiftwater, PA	streptococcal pneumonia	Phase I <a href="http://www.sanofi.com">www.sanofi.com</a>
MER4101 (MAS-1 adjuvant-based seasonal inactivated influenza vaccine)	Mercia Pharma New York, NY	Influenza virus infections (prevention)	Phase I <a href="http://www.merciapharma.com">www.merciapharma.com</a>
MMR vaccine (GSK209762) (live attenuated)	GlaxoSmithKline Rockville, MD	measles, mumps, rubella (prevention)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
mRNA 1440 vaccine	Valera Cambridge, MA	infections (prevention)	Phase I <a href="http://www.valeratx.com">www.valeratx.com</a>

**Infectious Diseases****Drug Name****Sponsor****Indication****Development Phase**

MVA-BN Filo  
(multivalent vaccine)

Bavarian Nordic  
Redwood City, CA  
Janssen Vaccines & Prevention  
Leiden, Netherlands

Ebola virus infections (prevention),  
Marburg virus infections (prevention)

Phase II  
[www.bavarian-nordic.com](http://www.bavarian-nordic.com)  
[www.janssen.com](http://www.janssen.com)

MVA-BN RSV  
(recombinant vaccine)

Bavarian Nordic  
Redwood City, CA

RSV infections (prevention)

Phase I  
[www.bavarian-nordic.com](http://www.bavarian-nordic.com)

MVA mosaic HIV vaccine

Janssen Vaccines & Prevention  
Leiden, Netherlands

HIV infections (prevention)

Phase I/II  
[www.janssen.com](http://www.janssen.com)

**NasoVAX™**  
recombinant influenza A  
intranasal vaccine

Altimune  
Gaithersburg, MD

influenza A virus (pandemic and  
seasonal) (prevention)

Phase I  
[www.altimmune.com](http://www.altimmune.com)

NB-1008  
(intranasal nanoemulsion-adjuvanted  
seasonal influenza vaccine)

NanoBio  
Ann Arbor, MI  
Merck  
Kenilworth, NJ

influenza virus infections  
(prevention)

Phase I  
[www.nanobio.com](http://www.nanobio.com)  
[www.merck.com](http://www.merck.com)

ND1.1  
(N5H1 avian influenza virus vaccine)

Vaxart  
South San Francisco, CA

influenza A virus H5N1 subtype  
(prevention)

Phase I completed  
[www.vaxart.com](http://www.vaxart.com)

NDV-3  
(alum-adjuvanted recombinant  
protein vaccine)

NovaDigm Therapeutics  
Grand Forks, ND

vulvovaginal candidiasis  
(prevention)

Phase I/II  
[www.novadigm.net](http://www.novadigm.net)

NmVac-4 DT  
(meningococcal ACYW vaccine)

JN-International Medical  
Omaha, NE

meningococcal ACYW infections  
(prevention)

Phase II  
[www.jn-vaccines.com](http://www.jn-vaccines.com)

## Infectious Diseases

### Drug Name

### Sponsor

### Indication

### Development Phase

#### **NuThrax™**

anthrax vaccine adsorbed with CPG 7909 adjuvant vaccine

Emergent BioSolutions  
Gaithersburg, MD

anthrax (prevention) (FAST TRACK)

Phase III  
[www.emergentbiosolutions.com](http://www.emergentbiosolutions.com)

#### **PanBlok**

influenza A virus vaccine (pandemic)

Protein Sciences  
Meriden, CT

influenza A virus H1N1 subtype,  
influenza A virus H5N1 subtype,  
influenza A virus H7N9 subtype  
(prevention)

Phase II  
[www.proteinsciences.com](http://www.proteinsciences.com)

pandemic influenza vaccine

VaxInnate  
Cranbury, NJ

influenza virus infections

Phase I  
[www.vaxinnate.com](http://www.vaxinnate.com)

pandemic VLP vaccine (H7N9 + Matrix-M™)

Novavax  
Gaithersburg, MD

influenza A virus H7N9 subtype  
(prevention) (FAST TRACK)

Phase II  
[www.novavax.com](http://www.novavax.com)

PBSVax™-vectored  
prime/boost HIV vaccine

Profectus Biosciences  
Baltimore, MD

HIV infections (prevention and  
treatment)

Phase I  
[www.profectusbiosciences.com](http://www.profectusbiosciences.com)

#### **PENNVAX®-B**

HIV DNA vaccine

Inovio Pharmaceuticals  
Plymouth Meeting, PA

HIV infections (prevention and  
treatment)

Phase I  
[www.inovio.com](http://www.inovio.com)

#### **PENNVAX®-G**

HIV DNA vaccine

Inovio Pharmaceuticals  
Plymouth Meeting, PA

HIV infections (prevention and  
treatment)

Phase I completed  
[www.inovio.com](http://www.inovio.com)

#### **PENNVAX®-GP**

HIV DNA vaccine

Inovio Pharmaceuticals  
Plymouth Meeting, PA

HIV infections (prevention and  
treatment)

Phase I  
[www.inovio.com](http://www.inovio.com)

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
<b>PepVax</b> cytomegalovirus peptide vaccine (subcutaneous)	Helocyte New York, NY	cytomegalovirus infections (prevention) in stem cell transplantation	Phase II <a href="http://www.helocyte.com">www.helocyte.com</a>
PF-06290510 (4-antigen <i>Staphylococcus aureus</i> vaccine [SA4Ag])	Pfizer New York, NY	staphylococcal infections (prevention) (FAST TRACK)	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PF-06425090 (prophylactic vaccine)	Pfizer New York, NY	<i>Clostridium difficile</i> -associated colitis (prevention) (FAST TRACK)	Phase II <a href="http://www.pfizer.com">www.pfizer.com</a>
PfSPZ vaccine (malaria vaccine live attenuated)	Sanaria Rockville, MD	<i>Falciparum</i> malaria (prevention)	Phase II <a href="http://www.sanaria.com">www.sanaria.com</a>
		<i>Falciparum</i> malaria (combination) (prevention)	Phase I <a href="http://www.sanaria.com">www.sanaria.com</a>
PR5i/V419 (pediatric hexavalent vaccine)	Merck Kenilworth, NJ Sanofi Pasteur Swiftwater, PA	diphtheria, tetanus, whooping cough (Bordetella pertussis), polio (polio types 1, 2, and 3), invasive caused by Haemophilus influenza type b, and hepatitis B (prevention)	application submitted <a href="http://www.merck.com">www.merck.com</a> <a href="http://www.sanofi.com">www.sanofi.com</a>
<b>Preflucl®</b> trivalent seasonal influenza vaccine	Nanotherapeutics Alachua, FL	seasonal influenza (prevention) (prevention)	application submitted <a href="http://www.nanotherapeutics.com">www.nanotherapeutics.com</a>

**Infectious Diseases****Drug Name****Sponsor****Indication****Development Phase****PreviThrax™**

purified recombinant protective antigen anthrax vaccine adsorbed with CPG 7909 adjuvant

Emergent BioSolutions  
Gaithersburg, MD

anthrax (FAST TRACK)

Phase I  
[www.emergentbiosolutions.com](http://www.emergentbiosolutions.com)

*Pseudomonas* recombinant vaccine

GlaxoSmithKline  
Rockville, MD  
Valneva  
Lyon, France

pseudomonal infections (prevention)

Phase II  
[www.gsk.com](http://www.gsk.com)  
[www.valneva.com](http://www.valneva.com)

Px563L  
(recombinant protective antigen vaccine)

Pfenex  
San Diego, CA

anthrax

Phase I  
[www.pfenex.com](http://www.pfenex.com)

rabies VRVg  
(purified vero rabies vaccine)

Sanofi Pasteur  
Swiftwater, PA

rabies

Phase II  
[www.sanofi.com](http://www.sanofi.com)

**Remune™**

GP120-depleted HIV-1 vaccine  
ORPHAN DRUG

Immune Response BioPharma  
Atlantic City, NJ

HIV-1 infections (treatment)

application submitted  
[www.immuneresponsebiopharma.com](http://www.immuneresponsebiopharma.com)

**RemuneX**

(IR103; Remune and Amplivax combination)

Immune Response BioPharma  
Atlantic City, NJ

HIV-1 infections (treatment)

Phase III  
[www.immuneresponsebiopharma.com](http://www.immuneresponsebiopharma.com)

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
<b>RiVax™</b> ricin subunit vaccine ORPHAN DRUG	Soligenix Princeton, NJ	ricin poisoning (pre-exposure protection)	Phase I <a href="http://www.soligenix.com">www.soligenix.com</a>
Ross River vaccine	Nanotherapeutics Alachua, FL	Ross River virus infections (prevention)	Phase III <a href="http://www.nanotherapeutics.com">www.nanotherapeutics.com</a>
RSV F protein vaccine	Novavax Gaithersburg, MD	RSV infections in adults 60 years and older (FAST TRACK), maternal RSV immunization to protect infants (FAST TRACK)	Phase III <a href="http://www.novavax.com">www.novavax.com</a>
		RSV (prevention) (6 months to 5 years)	Phase I <a href="http://www.novavax.com">www.novavax.com</a>
RSV F protein subunit vaccine	Novartis Vaccines East Hanover, NJ	RSV infections (prevention and treatment)	Phase I <a href="http://www.novartis.com">www.novartis.com</a>
RSV oral vaccine	Vaxart South San Francisco, Ca	RSV (prevention)	Phase I <a href="http://www.vaxart.com">www.vaxart.com</a>
<i>S. pneumoniae</i> next generation vaccine (recombinant conjugated vaccine)	GlaxoSmithKline Rockville, MD	streptococcal pneumonia (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
SAV001 (HIV-1 vaccine)	Sumagen Seoul, South Korea	HIV-1 infections	Phase I completed <a href="http://www.sumagen.co.kr">www.sumagen.co.kr</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
seasonal influenza vaccine	VaxInnate Cranbury, NJ	influenza virus infections	Phase II <a href="http://www.vaxinnate.com">www.vaxinnate.com</a>
seasonal quadrivalent influenza vaccine VLP	Novavax Gaithersburg, MD	seasonal influenza	Phase II <a href="http://www.novavax.com">www.novavax.com</a>
<i>Shigella</i> conjugated and outer membrane vaccine (1790GAHB)	GlaxoSmithKline Rockville, MD	<i>Shigella</i> infections (prevention)	Phase II <a href="http://www.gsk.com">www.gsk.com</a>
<b>Shingrix™</b> recombinant zoster vaccine	GlaxoSmithKline Rockville, MD	herpes zoster (prevention)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
SP0173 (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine adsorbed)	Sanofi Pasteur Swiftwater, NJ	diphtheria, pertussis, tetanus (prevention)	Phase I/II <a href="http://www.sanofi.com">www.sanofi.com</a>
<i>Staphylococcus aureus</i> multivalent toxoid vaccine	Integrated BioTherapeutics Gaithersburg, MD	Staphylococcal infections (prevention)	Phase I <a href="http://www.integratedbiotherapeutics.com">www.integratedbiotherapeutics.com</a>
<b>STEBVax</b> recombinant detoxified SEB vaccine	Integrated BioTherapeutics Gaithersburg, MD	toxic shock syndrome from <i>Staphylococcus</i> enterotoxin B (SEB) exposure (prevention)	Phase I <a href="http://www.integratedbiotherapeutics.com">www.integratedbiotherapeutics.com</a>
TAK-003 (tetravalent dengue vaccine)	Takeda Deerfield, IL	dengue fever (prevention)	Phase II <a href="http://www.takeda.com">www.takeda.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TAK-214 (norovirus vaccine)	Takeda Deerfield, IL	acute gastroenteritis causes by norovirus (prevention)	Phase II <a href="http://www.takeda.com">www.takeda.com</a>
<b>Triplex</b> cytomegalovirus peptide vaccine (intramuscular)	Helocyte New York, NY	cytomegalovirus infections (prevention) in stem cell transplantation and solid organ transplantation	Phase II <a href="http://www.helocyte.com">www.helocyte.com</a>
tuberculosis recombinant subunit vaccine	Sanofi Pasteur Swiftwater, PA	tuberculosis (prevention)	Phase II <a href="http://www.sanofi.com">www.sanofi.com</a>
V114 (pneumoconjugate-15 vaccine)	Merck Kenilworth, NJ	pneumococcal infections (prevention)	Phase II <a href="http://www.merck.com">www.merck.com</a>
V160 (human cytomegalovirus vaccine)	Merck Kenilworth, NJ	cytomegalovirus infections	Phase I <a href="http://www.merck.com">www.merck.com</a>
V180 (dengue subunit vaccine)	Merck Kenilworth, NJ	dengue fever (prevention)	Phase I completed <a href="http://www.merck.com">www.merck.com</a>
V212 (heat-treated varicella-zoster virus vaccine)	Merck Kenilworth, NJ	herpes zoster (prevention)	Phase III <a href="http://www.merck.com">www.merck.com</a>
V920 (rVSV-ZEBOV)	Merck Kenilworth, NJ BioProtection Systems Ames, IA	Ebola virus infections (BREAKTHROUGH THERAPY)	Phase III <a href="http://www.merck.com">www.merck.com</a>



## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VaxiGrip® QIV IM quadrivalent inactivated influenza vaccine	Sanofi Pasteur Swiftwater, PA	influenza virus infections (3 years and older)	application submitted <a href="http://www.sanofi.com">www.sanofi.com</a>
		influenza virus infections (6-35 months)	Phase III <a href="http://www.sanofi.com">www.sanofi.com</a>
Venezuelan equine encephalitis virus vaccine	Ichor Medical Systems San Diego, CA United States Army Medical Research Institute of Infectious Diseases Frederick, MD	encephalitis virus infections (prevention)	Phase I completed <a href="http://www.ichorms.com">www.ichorms.com</a>
VesiculoVax™ Ebola virus vaccine	Profectus Biosciences Baltimore, MD	Ebola virus infections (prevention)	Phase I <a href="http://www.profectusbiosciences.com">www.profectusbiosciences.com</a>
VLA84 vaccine	Valneva Lyon, France	<i>Clostridium difficile</i> infections (prevention)	Phase II completed <a href="http://www.valneva.com">www.valneva.com</a>
VRC-EBOADC069-00-VP	Okairos Rome, Italy NIAID Bethesda, MD	Ebola virus infections (prevention)	Phase I <a href="http://www.okairos.com">www.okairos.com</a>
VXA-BYW-10 seasonal influenza B vaccine)	Vaxart South San Francisco, CA	influenza B virus infections (prevention)	Phase I <a href="http://www.vaxart.com">www.vaxart.com</a>
West Nile vaccine	Nanotherapeutics Alachua, FL	West Nile virus infections (prevention)	Phase I <a href="http://www.nanotherapeutics.com">www.nanotherapeutics.com</a>

## Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ZP-influenza (trivalent influenza vaccine)	Zosano Pharma Fremont, CA	influenza virus infections (prevention)	Phase I <a href="http://www.zosanopharma.com">www.zosanopharma.com</a>

## Other Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AE-IG vaccine (RNA-interference vaccine)	Antigen Express Wellesley, MA	inborn genetic disorders	Phase I <a href="http://www.antigenexpress.com">www.antigenexpress.com</a>
ACI-24 (anti-Abeta vaccine)	AC Immune Lausanne, Switzerland National Institutes of Health Bethesda, MD LuMind Research Down Syndrome Foundation Marlborough, MA	Alzheimer's disease associated with Downs syndrome	Phase I <a href="http://www.acimmune.com">www.acimmune.com</a>
ACI-35 (anti-pTau vaccine)	AC Immune Lausanne, Switzerland Janssen Research & Development Raritan, NJ	Alzheimer's disease	Phase I <a href="http://www.acimmune.com">www.acimmune.com</a> <a href="http://www.janssenrnd.com">www.janssenrnd.com</a>
CAD106 (Alzheimer's vaccine)	Novartis Pharmaceuticals East Hanover, NJ	Alzheimer's disease (prevention)	Phase II <a href="http://www.novartis.com">www.novartis.com</a>

## Other Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
<b>Diamyd®</b> autoimmune diabetes vaccine ORPHAN DRUG	Diamyd Medical Stockholm, Sweden University of Alabama at Birmingham Birmingham, AL	latent autoimmune diabetes in adults, type 1 diabetes	Phase I <a href="http://www.diamyd.com">www.diamyd.com</a>
DV-100 (autologous dendritic cell immunotherapy) ORPHAN DRUG	DiaVacs Edgewater, NJ	type 1 diabetes	Phase I <a href="http://www.diavac.com">www.diavac.com</a>
M2826 (ATX-MS-1467) (immune tolerizing agent [peptide-based vaccine])	EMD Serono Rockland, MA	multiple sclerosis	Phase II <a href="http://www.emdserono.com">www.emdserono.com</a>
MER5101 ( $\beta$ -amyloid-protein fragment vaccine)	Mercia Pharma New York, NY	Alzheimer's disease (treatment)	Phase I <a href="http://www.merciapharma.com">www.merciapharma.com</a>
<b>NeuroVax™</b> multiple sclerosis vaccine ORPHAN DRUG	Immune Response Biopharma Atlantic City, NJ	secondary progressive multiple sclerosis (FAST TRACK)	Phase II <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>
<b>Nexvax2™</b> HLA-DQ2 peptide vaccine	ImmusanT Cambridge, MA	celiac disease	Phase I <a href="http://www.immusant.com">www.immusant.com</a>
PAS (polyclonal antibody stimulator)	Cancer Advances Durham, NC	gastro-oesophageal reflux (GERD)	Phase II <a href="http://www.canceradvancesinc.com">www.canceradvancesinc.com</a>
PF-05402536	Pfizer New York, NY	smoking cessation	Phase I <a href="http://www.pfizer.com">www.pfizer.com</a>

## Other Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
<b>Ravax™</b> psoriasis vaccine	Immune Response Biopharma Atlantic City, NJ	psoriasis	Phase II <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.com</a>
SEL-212 (synthetic vaccine particle-rapamycin co-administered with pegsiticase)	Selecta Biosciences Watertown, MA	gout	Phase I <a href="http://www.selectabio.com">www.selectabio.com</a>
UB-311 (immunotherapeutic vaccine)	United Neuroscience New York, NY	Alzheimer's disease	Phase II <a href="http://www.unitedneuroscience.com">www.unitedneuroscience.com</a>
<b>Zorcell™</b> rheumatoid arthritis vaccine	Immune Response Biopharma Atlantic City, NJ	rheumatoid arthritis	Phase III <a href="http://www.immuneresponsebiopharma.com">www.immuneresponsebiopharma.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 July 14, 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 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 fewer than 200,000 people in the United States, or that affects more than 200,000 persons but is not expected to recover the costs of its development and marketing.

**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.