

Medicines in Development – Vaccines

Allergy

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AR201 (oral immunotherapy)	Aimmune Therapeutics Brisbane, CA	hen egg allergy	Phase II www.aimmune.com
ASP0892 (plasmid-based DNA vaccine)	Astellas Pharma Northbrook, IL Immunomic Therapeutics Rockville, MD	peanut allergy (Fast Track)	Phase I www.astellas.com
ASP2390 (plasmid-based DNA vaccine)	Astellas Pharma Northbrook, IL Immunomic Therapeutics Rockville, MD	house dust mite allergy	Phase I www.astellas.com
grass MATA MPL (injectable MPL allergy vaccine)	Allergy Therapeutics West Sussex, UK	grass pollen allergy	Phase II completed www.allergytherapeutics.com
HAL-MPE1 (subcutaneous immunotherapy)	HAL Allergy Leiden, The Netherlands	peanut hypersensitivity	Phase I completed www.hal-allergy.com
Palforzia™ peanut (Arachis hypogaea) allergen powder-dnfp	Aimmune Therapeutics Brisbane, CA	peanut allergy (1 year to 3 years)	Phase III www.aimmune.com

Allergy
Drug Name

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Development Phase

Ragwitek® short ragweed pollen allergen extract, sublingual tablet	ALK Round Rock, TX	seasonal allergic rhinitis (4 years to 17 years)	Phase III completed www.alk.net
REGN 1908-1909 (allergy immunotherapy)	Regeneron Pharmaceuticals Tarrytown, NY	cat allergy	Phase II www.regeneron.com
REGN 5713-5714-5715 (allergy immunotherapy)	Regeneron Pharmaceuticals Tarrytown, NY	birch pollen allergy	Phase I www.regeneron.com
STAGR320 (house dust mite allergy immunotherapy tablet)	Stallergenes Greer Boston, MA	house dust mite allergic rhinitis	Phase III www.stallergenesgreer.com
STMC-103H (microbiome-based therapeutic)	Siolta Therapeutics San Francisco, CA	atopic immunoglobulin E-mediated allergic disorder	Phase I www.siolattherapeutics.com
VE416 (allergy immunotherapy)	Vedanta Biosciences Cambridge, MA	peanut allergy	Phase I/II www.vedantabio.com
Viaskin Milk milk allergy immunotherapy	DBV Technologies Summit, NJ	cow's milk allergy (2 years to 17 years) (Fast Track)	Phase II www.dbv-technologies.com

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Viaskin Peanut

peanut allergy immunotherapy

DBV Technologies
Summit, NJ

peanut allergy (4 years to 11 years)
(Fast Track) (Breakthrough Therapy)

application submitted
www.dbv-technologies.com

peanut allergy (1 year to 3 years)

Phase III
www.dbv-technologies.com

peanut allergy
(adolescents and adults)

Phase I
www.dbv-technologies.com

Alzheimer's Disease

Drug Name

Sponsor

Indication

Development Phase

ACI-35
(anti-pTau vaccine)

AC Immune
Lausanne, Switzerland
Janssen
Raritan, NJ

Alzheimer's disease (treatment)

Phase I/II
www.acimmune.com

UB-311
(amyloid beta protein
inhibitor vaccine)

United Biomedical
Hauppauge, NY
United Neuroscience
Dublin, Ireland

Alzheimer's disease

Phase II
www.unitedbiomedical.com

Autoimmune Disorders

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
IFN-kinoid (IFN α kinoid therapeutic vaccine)	Neovacs Paris, France	systemic lupus erythematosus (Fast Track)	Phase II www.neovacs.fr
NeuroVax™ T cell receptor peptide vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	multiple sclerosis (Fast Track)	Phase II/III www.immuneresponsebio.com
Nexvax2 (HLA-DQ2 peptide vaccine)	ImmusanT Cambridge, MA	celiac disease (Fast Track)	Phase II www.immusant.com

Cancer

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Ad-P53 DCV (dendritic cell vaccine)	Multivir Houston, TX	small cell lung cancer (combination therapy)	Phase II www.multivir.com
adagloxad simolenin (cancer immunotherapy)	OBI Pharma Taipei, Taiwan	triple negative breast cancer	Phase III www.obipharma.com
Ad/MG1-E6E7 (adenovirus vaccine)	Turnstone Biologics New York, NY	human papillomavirus (HPV) associated cancer (combination therapy)	Phase I www.turnstonebio.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Ad/MG1-MAGEA3 (oncolytic virus vaccine)	Turnstone Biologics New York, NY	non-small cell lung cancer (NSCLC) (+pembrolizumab)	Phase I/II www.turnstonebio.com
ADXS-503 (genetically-modified cancer vaccine)	Advaxis Princeton, NJ	NSCLC	Phase I/II www.advaxis.com
ADXS-NEO (patient specific neopeptide-based cancer vaccine)	Advaxis Princeton, NJ	solid tumors	Phase I www.advaxis.com
ADXS-PSA (genetically-modified cancer vaccine)	Advaxis Princeton, NJ	metastatic castration-resistant prostate cancer (+pembrolizumab)	Phase I/II www.advaxis.com
AE37 peptide vaccine (cancer immunotherapy)	NuGenerex Immuno-Oncology Miramar, FL	triple negative breast cancer	Phase II www.generex.com
AGI-134 (synthetic alpha-Gal glycolipid cancer vaccine)	BioLineRx Tel Aviv, Israel	solid tumors	Phase I www.biogenerex.com
AlloStim T-cell therapy-device combination vaccine	Immunovative Therapies Jerusalem, Israel	metastatic colorectal cancer	Phase II www.immunovative.com

Cancer
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Development Phase

ATP128
(recombinant protein vaccine)

Amal Therapeutics
Geneva, Switzerland

colorectal cancer (monotherapy
and combination therapy)

Phase I
www.amaltherapeutics.com

AutoSynVax™
autologous synthetic vaccine

Agenus
Lexington, MA

solid tumors (adjuvant therapy)

Phase I
www.agenusbio.com

AV-GBM-1
(dendritic cell vaccine)

AIVITA Biomedical
Irvine, CA

glioblastoma

Phase II
www.aivitabiomedical.com

AV-MEL-1
(dendritic cell vaccine)

AIVITA Biomedical
Irvine, CA

melanoma

Phase I
www.aivitabiomedical.com

axalimogene filolisbac (AXAL)
(cancer immunotherapy)

Advaxis
Princeton, NJ

HPV-related cancer

in clinical trials
www.advaxis.com

biropepimut-S (GL-0817)
(MAGE-A3 vaccine)

Gliknik
Baltimore, MD

head and neck cancer

Phase II
www.gliknik.com

ORPHAN DRUG

bizalimogene ralaplasmid (VGX-3100)
(DNA plasmid immunotherapy)

Inovio Pharmaceuticals
Plymouth Meeting, PA

cervical high grade squamous
intraepithelial lesion (HSIL)

Phase III
www.inovio.com

anal HSIL, vulvar HSIL

Phase II
www.inovio.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BN-Brachyury vaccine (prime-boost vaccine) ORPHAN DRUG	Bavarian Nordic Morrisville, NC	chordoma	Phase II www.bavarian-nordic.com
B-Vaxx (B-cell peptide cancer vaccine)	Imugene Sydney, Australia Ohio State University Columbus, OH	solid tumors	Phase II www.imugene.com
CMB305 (prime-boost cancer immunotherapy) ORPHAN DRUG	Merck Kenilworth, NJ	soft tissue sarcoma	Phase II completed www.merck.com
		NY-ESO-1 solid tumors	Phase I completed www.merck.com
CMP-001 (G10 in a virus-like particle vaccine)	Checkmate Pharmaceuticals Cambridge, MA	PD-1/L1 refractory advanced melanoma (+pembrolizumab)	Phase II www.checkmatepharma.com
CV301 (cancer immunotherapy) ORPHAN DRUG	Bavarian Nordic Morrisville, NC	bladder cancer (combination therapy), colorectal cancer (combination therapy)	Phase II www.bavarian-nordic.com
		colorectal cancer (combination therapy), pancreatic cancer (combination therapy)	Phase I/II www.bavarian-nordic.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
CV9202 (BI 1361949) (self-adjuvanting mRNA vaccine)	Boehringer Ingelheim Ridgefield, CT CureVac Boston, MA	NSCLC	Phase I/II www.curevac.com
DCVAC/Pca (stapuldencel-T) (dendritic cell vaccine)	SOTIO Boston, MA	prostate cancer	Phase III completed www.sotio.com
DCVax®-Direct autologous dendritic cell vaccine	Northwest Biotherapeutics Bethesda, MD	solid tumors	Phase I/II www.nwbio.com
DCVax®-L autologous dendritic cell vaccine ORPHAN DRUG	Northwest Biotherapeutics Bethesda, MD	glioblastoma	Phase III www.nwbio.com
DCVax®-Prostate autologous dendritic cell vaccine	Northwest Biotherapeutics Bethesda, MD	prostate cancer	Phase II completed www.nwbio.com
DPV-001 (tumor-derived autophagosome-enriched vaccine)	UbiVac Portland, OR	NSCLC	Phase II completed www.ubivac.com
		prostate cancer	Phase I completed www.ubivac.com

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DPX-Survivac (peptide cancer vaccine) ORPHAN DRUG	IMV Nova Scotia, Canada	ovarian cancer (Fast Track)	Phase II www.imv-inc.com
		bladder cancer, hepatocellular carcinoma, NSCLC (+pembrolizumab)	Phase II www.imv-inc.com
DSP-7888 (WT1 cancer vaccine) ORPHAN DRUG	Boston Biomedical Cambridge, MA	glioblastoma (combination therapy)	Phase II www.bostonbiomedical.com
		solid tumors (combination therapy)	Phase I/II www.bostonbiomedical.com
Elenagen™ p62 anti-cancer DNA vaccine	CureLab Oncology Boston, MA	solid tumors	Phase I/II www.curelaboncology.com
ERC1671 (cancer vaccine) ORPHAN DRUG	Epitopoietic Research Pasadena, CA	glioblastoma	Phase II www.erc-immunotherapy.com
ETBX-011 (adenovirus vector vaccine)	Etubics Seattle, WA ImmunityBio Culver City, CA	CEA-expressing cancer	Phase I/II completed www.etubics.com

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Development Phase

galinpepimut-S (cancer peptide vaccine) ORPHAN DRUG	Sellas Life Sciences New York, NY	acute myeloid leukemia (AML) (Fast Track)	Phase III www.sellaslifesciences.com
		advanced cancer (+pembrolizumab)	Phase II www.sellaslifesciences.com
GD2-GD3 vaccine (bivalent ganglioside neuroblastoma vaccine) ORPHAN DRUG	Y-mAbs Therapeutics New York, NY Memorial Sloan Kettering CC New York, NY	high-risk neuroblastoma	Phase II www.ymabs.com
GEN-009 (neoantigen cancer vaccine)	Genocea Biosciences Cambridge, MA	solid tumors	Phase I/II www.genocea.com
GI-6207 (baker's yeast vaccine)	ImmunityBio Culver City, CA	chordoma	Phase II www.immunitybio.com
GI-6301 (yeast-brachyury vaccine)	ImmunityBio Culver City, CA	medullary thyroid cancer	Phase II www.immunitybio.com
GRANITE (personalized neoantigen immunotherapy)	Gritstone Oncology Emeryville, CA	colorectal cancer (Fast Track), NSCLC, pancreatic cancer	Phase I/II www.gritstoneoncology.com

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Development Phase

GRN-1201
(cancer peptide vaccine)

BrightPath Biotherapeutics
Tokyo, Japan

NSCLC

Phase II
www.brightpathbio.com

HB-201 intratumoral
(cancer vaccine)

Hookipa Biotech
New York, NY

HPV-related squamous cell
carcinoma

Phase I/II
www.hookipapharma.com

HB-201 intravenous
(cancer vaccine)

Hookipa Biotech
New York, NY

HPV-related squamous cell
carcinoma

Phase I/II
www.hookipapharma.com

HER-2 pulsed dendritic cell vaccine

ImmunoRestoration
Doylestown, PA

breast cancer,
ductal carcinoma in situ

Phase I/II
www.immunorestoration.com

HS-110 (viagenpumatucl-L)
(allogeneic tumor cell vaccine)

Heat Biologics
Morrisville, NC

NSCLC

Phase II
www.heatbio.com

HyVax semi allogenic
hybrid cell vaccine

SemiAlloGen
Charleston, SC

cancer

Phase I completed

IFx-Hu2.0
(whole-cell cancer vaccine)

Morphogenesis
Tampa, FL

cutaneous melanoma, merkel cell
carcinoma, squamous cell cancer

Phase I
www.morphogenesis-inc.com

IGV-001
(autologous cell vaccine)
ORPHAN DRUG

Imvax
Philadelphia, PA

glioblastoma

Phase I
www.imvax.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ilixadencel (dendritic cell vaccine)	Immunicum Gothenburg, Sweden	advanced cancer	Phase I/II www.immunicum.com
INO-5151 (DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prostate cancer	Phase II www.inovio.com
INT230-6 (cisplatin-based intratumoral cancer therapeutic vaccine)	Intensity Therapeutics Westport, CT	solid tumors	Phase I/II www.intensitytherapeutics.com
INVAC-1 (hTERT DNA vaccine)	Invectys Paris, France	chronic lymphocytic leukemia (CLL)	Phase II www.invectys.com
ISA101 (peptide vaccine)	ISA Pharmaceuticals Leiden, The Netherlands	HPV16-positive oropharyngeal cancer	Phase II www.isa-pharma.com
ITI-1000 (dendritic cell vaccine)	Immunomic Therapeutics Rockville, MD	glioblastoma	Phase II www.immunomix.com
lifileucel (LN-144) (tumor infiltrating lymphocytes [TIL] T cell-based immunotherapy)	Iovance Biotherapeutics San Carlos, CA	melanoma (Fast Track)	Phase III www.iovance.com
ORPHAN DRUG		melanoma (+pembrolizumab)	Phase II www.iovance.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
LN-145 (tumor infiltrating lymphocytes [TIL] T cell-based immunotherapy) ORPHAN DRUG	Iovance Biotherapeutics San Carlos, CA	cervical cancer (Fast Track)	Phase III www.iovance.com
		head and neck cancer, melanoma, NSCLC	Phase II www.iovance.com
LV305 (RNA cancer immunotherapy) ORPHAN DRUG	Merck Kenilworth, NJ	NY-ESO-1 solid tumors	Phase I completed www.merck.com
MBG453 (cancer immunotherapy)	Novartis East Hanover, NJ	AML, fit AML, unfit AML, myelodysplastic syndromes	Phase II www.novartis.com
		cancer (combination therapy)	Phase I www.novartis.com
MEDI-0457 (HPV DNA vaccine)	AstraZeneca Wilmington, DE Inovio Pharmaceuticals Plymouth Meeting, PA	head and neck cancer (+durvalumab)	Phase II www.astrazeneca.com
mRNA-4157 (mRNA-based personalized cancer vaccine)	Moderna Therapeutics Cambridge, MA	solid tumors	Phase II www.modernatx.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-5671 (mRNA-based KRAS vaccine)	Moderna Therapeutics Cambridge, MA	colorectal cancer, NSCLC, pancreatic cancer	Phase I www.modernatx.com
MVI-118 (pTVG-AR DNA vaccine)	Madison Vaccines Madison, WI University of Wisconsin-Madison Madison, WI	prostate cancer	Phase II
MVI-816 (pTVG-HP DNA vaccine)	Madison Vaccines Madison, WI University of Wisconsin-Madison Madison, WI	prostate cancer	Phase II
MV-NIS (attenuated oncolytic measles virus)	Vyriad Rochester, MN	bladder cancer	Phase I www.vyriad.com
NANT cancer vaccine (activated natural killer cells- haNK for fusion) ORPHA DRUG	NantKwest Culver City, CA	merkel cell carcinoma	Phase II www.nantkwest.com
		triple negative breast cancer, pancreatic cancer, squamous cell carcinoma	Phase I www.nantkwest.com
NANT cancer vaccine (CD19.t-haNK cell therapy)	NantKwest Culver City, CA	diffuse large B-cell lymphoma	Phase I www.nantkwest.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NANT cancer vaccine (PD-L1.t-haNK cell therapy)	NantKwest Culver City, CA	PD-L1 high-expressing solid tumors	Phase I www.nantkwest.com
nelipepimut-S (cancer vaccine)	Sellas Life Sciences New York, NY	breast cancer (combination therapy) (Fast Track)	Phase II completed www.sellaslifesciences.com
neoantigen DNA vaccine	AstraZeneca Wilmington, DE Washington University Saint Louis, MO	triple negative breast cancer	Phase I www.astrazeneca.com
NEO-PV-01 (personalized neoantigen vaccine)	Neon Therapeutics Cambridge, MA	cancer (combination therapy)	Phase I www.neontherapeutics.com
NOUS-209 (neoantigen genetic vaccine)	Nouscom Basel, Switzerland	solid tumors	Phase I www.nouscom.com
OncovAX [®] autologous cancer vaccine	Vaccinogen Baltimore, MD	colorectal cancer (Fast Track)	Phase III www.vaccinogen.com
oregovomab (cancer immunotherapy) ORPHAN DRUG	OncoQuest Edmonton, Canada	ovarian cancer	Phase II completed www.oncoquestinc.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
OSE2101 (neo-epitope cancer vaccine) ORPHAN DRUG	OSE Immunotherapeutics Nantes, France	NSCLC	Phase III www.ose-immuno.com
ovapuldencel-T (AV-OVA-1) (tumor stem cell specific dendritic cancer vaccine)	AIVITA Biomedical Irvine, CA	ovarian cancer	Phase II www.aivitabiomedical.com
P53MVA (modified vaccinia virus Ankara vaccine)	Tara Immuno-Oncology New York, NY City of Hope Medical Center Duarte, CA	ovarian cancer	Phase II
PDS0101 (cancer immunotherapy)	PDS Biotechnology Princeton, NJ	cervical cancer, head and neck cancer, HPV-associated cancer	Phase II www.pdsbiotech.com
PEPIDH1M (dendritic cell vaccine)	Annias Immunotherapeutics Chapel Hill, NC	malignant glioma, recurrent medulloblastoma	Phase I www.anniasimmuno.com
PF-06936308 (vaccine-based immunotherapy)	Pfizer New York, NY	NSCLC, triple negative breast cancer	Phase I www.pfizer.com
PF-06753512 (vaccine-based immunotherapy)	Pfizer New York, NY	prostate cancer	Phase I www.pfizer.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
polyclonal antibody stimulator (fusion peptide cancer vaccine) ORPHAN DRUG	Cancer Advances Durham, NC	gastric cancer, pancreatic cancer	Phase III www.canceradvancesinc.com
		colorectal cancer	Phase II www.canceradvancesinc.com
PolyPEPI 1018 (cancer immunotherapy)	Treos Bio London, United Kingdom	colorectal cancer	Phase I/II www.treosbio.com
Prophage™ heat shock protein vaccine ORPHAN DRUG	Agenus Lexington, MA	newly-diagnosed glioblastoma	Phase II www.agenusbio.com
Proscavax PSA/IL-2/GM-CSF vaccine	Oncbiomune Pharmaceuticals Baton Rouge, LA	prostate cancer	Phase II www.oncobiomune.com
Provenge® sipuleucel-T	Dendreon Seal Beach, CA	newly-diagnosed prostate cancer	Phase III completed www.dendreon.com
PVS-RIPO (recombinant polio virus vaccine) ORPHAN DRUG	Istari Oncology Research Triangle Park, NC	glioblastoma (Breakthrough Therapy)	Phase II www.istarioncology.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PVX-2 (prime-boost therapeutic vaccine)	PapiVax Biotech New Taipei City, Taiwan	HPV16+ atypical squamous cells, LSIL	Phase II www.papivaxbiotech.com
PVX-410 (multi-peptide therapeutic cancer vaccine) ORPHAN DRUG	OncoPep Boston, MA	smoldering multiple myeloma, triple negative breast cancer	Phase I completed www.oncopep.com
REIC gene therapy (MTG201) (AAV-based gene therapy) ORPHAN DRUG	Momotaro-Gene Okayama, Japan	malignant pleural mesothelioma	Phase II www.mt-gene.com
		prostate cancer	Phase I/II www.mt-gene.com
RO7198457 (RG6180) (messenger RNA vaccine)	BioNTech Mainz, Germany Genentech South San Francisco, CA	1L melanoma	Phase II www.gene.com
		solid tumors	Phase I www.gene.com
RV001 (RhoC cancer vaccine)	RhoVac Lund, Sweden	prostate cancer	Phase II www.rhovac.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
seviprotimut-L (cell line vaccine) ORPHAN DRUG	Polynoma San Diego, CA	malignant melanoma	Phase III www.polynoma.com
SL-701 (dendritic cell vaccine) ORPHAN DRUG	Stemline Therapeutics New York, NY	glioblastoma (adults)	Phase I/II completed www.stemline.com
SLATE (neoantigen immunotherapy)	Gritstone Oncology Emeryville, CA	solid tumors	Phase I/II www.gritstoneoncology.com
SNS-301 (nanoparticle-based therapeutic cancer vaccine)	Sensei Biotherapeutics Gaithersburg, MD	2L head and neck cancer	Phase II www.senseibio.com
		head and neck cancer (neoadjuvant), 2L myelodysplastic syndromes	Phase I www.senseibio.com
SQZ-PBMC-HPV (cancer immunotherapy)	SQZ Biotech Watertown, MA	HPV-positive solid tumors	Phase I www.sqzbiotech.com
SV-BR-1-GM cancer vaccine (allogeneic genetically-engineered cell vaccine)	BriaCell Therapeutics Berkeley, CA	breast cancer (combination therapy)	Phase I/II www.briacell.com

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Development Phase

SurVaxM® peptide vaccine ORPHAN DRUG	MimiVax Buffalo, NY	glioblastoma	Phase II www.mimivax.com
		high-grade glioma, medulloblastoma, multiple myeloma, neuroendocrine tumors	Phase I www.mimivax.com
TG4050 (neoantigen therapeutic vaccine)	Transgene Boston, MA	ovarian cancer	Phase I www.transgene.fr
TLPLDC (tumor lysate, particle-loaded, dendritic cell vaccine)	Elios Therapeutics Austin, TX	melanoma	Phase II www.eliotherapeutics.com
TPIV100 (HER2/neu T cell vaccine)	Marker Therapeutics Houston, TX	breast cancer	Phase II www.markertherapeutics.com
TPIV 200 (multi-epitope anti-folate receptor vaccine) ORPHAN DRUG	Marker Therapeutics Houston, TX	ovarian cancer (Fast Track), triple negative breast cancer	Phase II www.markertherapeutics.com
UV1 vaccine (intradermal synthetic peptide vaccine)	Ultimovacs Oslo, Norway	malignant melanoma	Phase I www.ultimovacs.com

<u>Cancer Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
V937 (cancer immunotherapy) ORPHAN DRUG	Merck Kenilworth, NJ	metastatic melanoma (+pembrolizumab)	Phase II www.merck.com
VAC2 (dendritic cell vaccine)	Lineage Cell Therapeutics Carlsbad, CA	NSCLC	Phase I www.lineagecell.com
VBI-1901 (eVLP-based vaccine)	VBI Vaccines Cambridge, MA	glioblastoma	Phase I/II www.vbivaccines.com
VE800 (cancer immunotherapy)	Vendanta Biosciences Cambridge, MA	cancer	Phase I www.vedantabio.com
Vigil™ genetically-modified autologous tumor cell vaccine and bi-shRNAfurin	Gardalis Dallas, TX	Ewing's sarcoma (first relapse)	Phase III www.gradalisinc.com
		1L maintenance ovarian cancer, melanoma	Phase II www.gradalisinc.com
		solid tumors	Phase I www.gradalisinc.com

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Sponsor

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Development Phase

Voyager-V1 (genetically-modified vesicular stomatitis virus)	Vyriad Rochester, MN	head and neck cancer, NSCLC (+pembrolizumab)	Phase II www.vyriad.com
		metastatic colorectal cancer (+avelumab)	Phase II www.vyriad.com
		solid tumors	Phase I www.vyriad.com

YE-NEO-001 (NANT neopeptide yeast vaccine)	NantBioScience Culver City, CA	solid tumors	Phase I www.nantkwest.com
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Gastrointestinal Diseases
Drug Name

Sponsor

Indication

Development Phase

antolimab (AK002) (immunoglobulin G1 monoclonal antibody) ORPHAN DRUG	Allakos Redwood City, CA	eosinophilic duodenitis, eosinophilic gastritis	Phase III www.allakos.com
		eosinophilic esophagitis	Phase II/III www.allakos.com

polyclonal antibody stimulator (fusion peptide cancer vaccine)	Cancer Advances Durham, NC	GERD	Phase II www.canceradvancesinc.com
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Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
AGS-v PLUS (protein-based vaccine)	Imutex London, United Kingdom National Institutes of Health Bethesda, MD	mosquito-born infectious diseases (prevention)	Phase I www.imutex.com
ASP3772 (conjugate pneumococcal vaccine)	Affinivax Cambridge, MA Astellas Pharma US Northbrook, IL	pneumococcal infections	Phase II www.affinivax.com www.astellas.com
AV0328 (PNAG-expressing pathogenic microbes vaccine)	Alopexx Vaccine Concord, MA	bacterial infections (prevention and treatment)	Phase I/II www.alopexx.com
AV7909 (anthrax vaccine)	Emergent BioSolutions Gaithersburg, MD	anthrax (Fast Track)	Phase III www.emergentbiosolutions.com
Bexsero meningococcal group B vaccine	GlaxoSmithKline Research Triangle Park, NC	meningococcal B disease (prevention) (infants) (+13-valent pneumococcal vaccine)	Phase III www.gsk.com
BG505 SOSIP 664 gp140 vaccine adjuvanted	GlaxoSmithKline Research Triangle Park, NC International AIDS Vaccine Initiative New York, NY	HIV infections	Phase I www.gsk.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
BPZE1 (live attenuated pertussis vaccine)	ILiAD Biotechnologies Weston, FL	pertussis (prevention)	Phase II www.iliadbio.com
BW-1008 (intranasal vaccine)	BlueWillow Biologics Ann Arbor, MI	influenza virus infections (prevention)	Phase I www.bluewillow.com
BW-1010 (intranasal nanoemulsion-based mucosal vaccine)	BlueWillow Biologics Ann Arbor, MI	anthrax (prevention)	Phase I www.bluewillow.com
CHIKV VLP (Chikungunya virus VLP vaccine)	Emergent BioSolutions Gaithersburg, MD	Chikungunya virus infections (prevention) (Fast Track)	Phase II www.emergentbiosolutions.com
Coda-Vax-H1N1 (intranasal influenza vaccine)	Codagenix Farmingdale, NY	influenza A virus H1N1 infections (prevention)	Phase I www.codagenix.com
CRV-101 (varicella vaccine)	Curevo Vaccine Seattle, WA	shingles (herpes zoster) (prevention)	Phase I www.curevovaccine.com
deltaFLU (universal influenza intranasal vaccine)	Vivaldi Biosciences Fort Collins, CO	seasonal influenza infections (prevention)	Phase II www.vivaldibiosciences.com
DermaVir HIV DNA vaccine topical	Genetic Immunity Baltimore, MD	HIV-1 infections (treatment)	Phase II www.geneticimmunity.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Ebola GP vaccine (recombinant glycoprotein nanoparticle vaccine)	Novavax Gaithersburg, MD	Ebola virus infections (prevention)	Phase I www.novavax.com
Flucelvax Quadrivalent® influenza vaccine	Seqirus Holly Springs, NC	influenza virus infections (6 months to 47 months) (prevention)	Phase III www.seqirus.com
GOVX-B01 (DNA vaccine)	GeoVax Labs Smyrna, GA	HIV infections (therapeutic)	Phase I www.geovax.com
GOVX-B11 (DNA vaccine)	GeoVax Labs Smyrna, GA	HIV infections (prevention)	Phase II www.geovax.com
GSK2904545A (recombinant protein vaccine, adjuvanted)	GlaxoSmithKline Research Triangle Park, NC	active immunization to prevent C. diff diseases and recurrence	Phase I www.gsk.com
GSK3389245A (replication-defective recombinant viral vector vaccine)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (pediatric) (prevention)	Phase II www.gsk.com
GSK3437949A (recombinant protein vaccine, adjuvanted)	GlaxoSmithKline Research Triangle Park, NC	malaria (prevention)	Phase II www.gsk.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK3528869A (prime-boost vaccine)	GlaxoSmithKline Research Triangle Park, NC	hepatitis B infections (treatment)	Phase I/II www.gsk.com
GSK3536819A (recombinant protein vaccine, conjugated)	GlaxoSmithKline Research Triangle Park, NC	meningococcal A, B, C, W and Y disease prevention in adolescents	Phase II www.gsk.com
GSK3536852A (conjugated and outer membrane vaccine)	GlaxoSmithKline Research Triangle Park, NC	shigella infections (prevention)	Phase II www.gsk.com
GSK3844766A (recombinant protein vaccine, adjuvanted)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (prevention)	Phase I/II www.gsk.com
GSK3888550A (recombinant protein vaccine)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (prevention)	Phase II www.gsk.com
GSK3902986A (conjugated and outer membrane vaccine)	GlaxoSmithKline Research Triangle Park, NC	shigella infections (prevention)	Phase II www.gsk.com
GSK3903133A (self-amplifying mRNA vaccine)	GlaxoSmithKline Research Triangle Park, NC	rabies (prevention)	Phase I www.gsk.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
H1N1 seasonal influenza virus vaccine (monovalent)	Vaxart South San Francisco, CA	influenza A virus H1N1 infections (prevention)	Phase II www.vaxart.com
H7N9 influenza vaccine	EpiVax Providence, RI	H7N9 influenza infections (prevention)	Phase I www.epivax.com
HB-101 (bivalent vaccine)	Hookipa Biotech New York, NY	cytomegalovirus infections (prevention)	Phase II www.hookipapharma.com
HepTcell™ peptide therapeutic vaccine	Altimune Gaithersburg, MD	hepatitis B (treatment)	Phase I www.altimmune.com
herpes simplex virus type 2 therapeutic vaccine	Immune Design (Merck) Seattle, WA Sanofi Bridgewater, NJ	HSV-2 infections (treatment)	Phase I/II www.sanofi.com
HeV-sG-V (hendra virus vaccine)	Auro Vaccines Pearl River, NY	nipah virus infections (prevention)	Phase I www.aurobindo.com
HTNV/PUUV DNA vaccine	Ichor Medical Systems San Diego, CA U.S. Army Medical Research Institute of Infectious Diseases Frederick, MD	viral hemorrhagic fevers (Hantaan & Pumala) (prevention)	Phase II www.ichorms.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
human rabies immunoglobulin vaccine	Bio Products Laboratory Herts, United Kingdom	rabies (prevention)	Phase II/III www.bplgroup.com
INO-4212 (DNA-based vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	Ebola virus infections (prevention)	Phase I completed www.inovio.com
INO-4500 (Lassa fever vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA Coalition for Epidemic Preparedness Innovations Washington, DC	Lassa fever (prevention)	Phase I www.inovio.com
INO-4700 (MERS DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA GeneOne Life Science Seoul, South Korea	MERS coronavirus infections (prevention)	Phase II www.inovio.com
INO-4800 (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	COVID019 infections (prevention)	Phase I www.inovio.com
INO-8000 (multi-antigen DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA National Cancer Institute Bethesda, MD	hepatitis B (treatment)	Phase I www.inovio.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JNJ-63682918 (Ad26.HPV16 vector vaccine)	Janssen Raritan, NJ	HPV (prime-boost regimen) (treatment)	Phase I/II www.janssen.com
JNJ-63682931 (Ad26.HPV18 vector vaccine)	Janssen Raritan, NJ	HPV (prime-boost regimen) (treatment)	Phase I/II www.janssen.com
JNJ-63871860 (ExPEC4V) (multivalent vaccine)	Janssen Raritan, NJ	Escherichia coli infections (prevention)	Phase II completed www.janssen.com
JNJ-64152348 (Sabin inactivated polio vaccine)	Janssen Raritan, NJ	poliomyelitis (prevention)	Phase II completed www.janssen.com
JNJ-64213175 (RSV preF protein vaccine)	Janssen Raritan, NJ	RSV infections (60 years and older) (prevention)	Phase I/II www.janssen.com
JNJ-64300535 (DNA vaccine)	Janssen Raritan, NJ	hepatitis B (treatment)	Phase I www.janssen.com
. (VAC18193/VAC18194) (Ad26.RSV.preF vaccine)	Janssen Raritan, NJ	RSV infections (60 years and older) (prevention) (Breakthrough Therapy)	Phase II www.janssen.com
		RSV infections (prevention) (12 months to 24 months) (18 years to 50 years)	Phase I/II www.janssen.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JNJ-65195208 (MVA-HPV16/18)	Bavarian Nordic Morrisville, NC Janssen Raritan, NJ	HPV infections (prevention)	Phase I/II www.janssen.com
JNJ-66684657 (Ad26.ZIKV.001 Zika virus vaccine)	Janssen Raritan, NJ	Zika virus infections (prevention)	Phase I completed www.janssen.com
Jynneos® smallpox and monkeypox vaccine (freeze-dried formulation)	Bavarian Nordic Morrisville, NC	smallpox, monkeypox (prevention)	Phase III www.bavarian-nordic.com
M-001 (universal influenza vaccine)	BiondVax Pharmaceuticals Jerusalem, Israel National Institutes of Health Bethesda, MD	influenza virus infections (prevention)	Phase II completed www.biondvax.com
M2SR (H3N2 influenza vaccine)	FluGen Madison, WI	influenza A virus H3N2 subtype (prevention)	Phase II www.flugen.com
MenQuadi™ menACYW conjugate vaccine	Sanofi Bridgewater, NJ	meningococcal infections (2 years and older) (prevention)	application submitted www.sanofi.com
		meningococcal infections (6 weeks and older) (prevention)	Phase III www.sanofi.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Menveo™ meningococcal (groups A,C,Y and W-135) oligosaccharide diphtheria CRM-197 conjugate vaccine (conjugated liquid formulation)	GlaxoSmithKline Research Triangle Park, NC	meningococcal A, C, W and Y disease prevention in adolescents	Phase II www.gsk.com
mRNA-1172 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	RSV infections (prevention)	Phase I www.modernatx.com
mRNA-1273 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	COVID-19 virus infections (prevention)	Phase I www.modernatx.com
mRNA-1388 (chikungunya virus vaccine)	Moderna Therapeutics Cambridge, MA	chikungunya virus infections	Phase I completed www.modernatx.com
mRNA-1647 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	cytomegalovirus infections (prevention)	Phase II www.modernatx.com
mRNA-1653 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	metapneumovirus infections, parainfluenza virus infections (prevention)	Phase I www.modernatx.com
mRNA-1851 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	influenza H7N9 virus infections (prevention)	Phase I completed www.modernatx.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-1893 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	Zika virus infections (Fast Track) (prevention)	Phase I www.modernatx.com
MT-2271 (plant-based VLP vaccine)	Medicago Durham, NC	seasonal influenza (prevention) (adults and elderly)	Phase III www.medicago.com
MV-012-968 (recoded RSV vaccine)	Meissa Vaccines South San Francisco, CA	RSV infections (prevention) (Fast Track)	Phase I www.meissavaccines.com
MV-CHIK (chikungunya virus vaccine)	Themis Bioscience Vienna, Austria	chikungunya virus infections (Fast Track) (prevention)	Phase II www.themisbio.com
MVA-BN RSV vaccine (multivalent vaccine)	Bavarian Nordic Morrisville, NC	RSV infections (prevention)	Phase II www.bavarian-nordic.com
MVA-BN WEV vaccine (multivalent vaccine)	Bavarian Nordic Morrisville, NC	equine encephalomyelitis	Phase I www.bavarian-nordic.com
NanoFlu™ nanoparticle influenza vaccine	Novavax Gaithersburg, MD	seasonal influenza infections (65 and older) (Fast Track)	Phase III www.novavax.com
NasoShield™ anthrax intranasal vaccine	Altimune Gaithersburg, MD	anthrax (prevention)	Phase I www.altimmune.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
NasoVAX™ influenza A vaccine intranasal	Altimune Gaithersburg, MD	influenza A virus H5N1 infections (prevention)	Phase II www.altimmune.com
NDV-3A (alum-adjuvanted recombinant protein vaccine)	NovaDigm Therapeutics Grand Forks, ND	staphylococcal infections (prevention)	Phase II www.novadigm.net
Next Gen PCV (pneumococcal conjugate vaccine)	Sanofi Bridgewater, NJ	pneumococcal virus infections	Phase I www.sanofi.com
nirsevimab (RSV mAb)	AstraZeneca Bridgewater, NJ Sanofi Bridgewater, NJ	RSV infections (prevention) (Fast Track)	Phase I www.astrazeneca.com www.sanofi.com
PBSVax™ HIV-MAG DNA vaccine	Profectus Biosciences Baltimore, MD	HIV infections (treatment and prevention)	Phase I completed www.profectusbiosciences.com
PENNVAX®-GP (HIV DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA National Institutes of Health Bethesda, MD	HIV infections (prevention and treatment)	Phase I/II www.inovio.com
PF-06425090 (prophylactic vaccine)	Pfizer New York, NY	Clostridium difficile infections (prevention) (Fast Track)	Phase III www.pfizer.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PF-06482077 (20-valent pneumococcal conjugate vaccine)	Pfizer New York, NY	invasive and non-invasive pneumococcal infections (adults) (prevention) (Breakthrough Therapy)	Phase III www.pfizer.com
PF-06760805 (multivalent vaccine)	Pfizer New York, NY	invasive group B streptococcus infections (prevention)	Phase II www.pfizer.com
PF-06842433 (prophylactic vaccine)	Pfizer New York, NY	invasive and non-invasive pneumococcal infections (prevention)	Phase II www.pfizer.com
PF-06886992 (pentavalent prophylactic vaccine)	Pfizer New York, NY	serogroups ABCWY meningococcal infections (prevention)	Phase II www.pfizer.com
PF-06928316 (prophylactic vaccine)	Pfizer New York, NY	RSV infections (prevention)	Phase II www.pfizer.com
PfSPZ-GA1 (genetically attenuated PfSPZ vaccine)	Sanaria Rockville, MD	malaria (prevention) (Fast Track)	Phase I www.sanaria.com
PfSPZ vaccine (radiation attenuated PfSPZ vaccine)	Sanaria Rockville, MD	malaria (prevention)	Phase II www.sanaria.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PfSPZ-Cvac (infectious PfSPZ vaccine administered with malaria chemoprophylaxis)	Sanaria Rockville, MD	malaria (prevention)	Phase II www.sanaria.com
polyvalent pneumococcal conjugate vaccine (pPCV)	Merck Kenilworth, NJ	pneumococcal infections (adults)	Phase I/II www.merck.com
Remune® GP120-depleted HIV-1 vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	HIV-1 infections	application submitted www.immuneresponsebio.com
		HIV-1 infections (pediatric)	Phase I/II www.immuneresponsebio.com
RiVax® recombinant subunit ricin vaccine ORPHAN DRUG	Soligenix Princeton, NJ	ricin poisoning (prevention) (Fast Track)	Phase I www.soligenix.com
RSV F protein vaccine	Novavax Gaithersburg, MD	RSV infections (infants via maternal immunization) (Fast Track)	Phase III www.novavax.com
		RSV infections (60 years and older) (Fast Track)	Phase II www.novavax.com
		RSV infections (6 months to 5 years)	Phase I www.novavax.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RSV vaccine	Sanofi Bridgewater, NJ	RSV infections (infants 4 months and older)	Phase I www.sanofi.com
SB209762 (live attenuated vaccine)	GlaxoSmithKline Research Triangle Park, NC	measles, mumps, rubella (prevention)	Phase III www.gsk.com
Sci-B-Vac® hepatitis B recombinant vaccine	VBI Vaccines Cambridge, MA	hepatitis B infections (prevention)	Phase III www.vbivaccines.com
Shan 6 (pediatric hexavalent vaccine)	Sanofi Bridgewater, NJ	haemophilus infections, tetanus, pertussis, poliomyelitis, hepatitis B, diphtheria	Phase III www.sanofi.com
Shingrix® zoster vaccine, recombinant, adjuvanted	GlaxoSmithKline Research Triangle Park, NC	prevention of shingles in children with kidney transplant (1 year to 17 years)	Phase II www.gsk.com
SP0173 (Tdap booster vaccine)	Sanofi Bridgewater, NJ	pertussis, tetanus, diphtheria (prevention)	Phase II www.sanofi.com
TAK-003 (tetraivalent hybrid virus vaccine)	Takeda Deerfield, IL	dengue (prevention) (Fast Track)	Phase III www.takeda.com
TAK-021 (EV71 vaccine)	Takeda Deerfield, IL	enterovirus A infections (prevention)	Phase I www.takeda.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
TAK-214 (VLP bivalent vaccine)	Takeda Deerfield, IL	norovirus infections (prevention)	Phase II www.takeda.com
TAK-426 (whole virus vaccine)	Takeda Deerfield, IL	Zika virus infections (prevention) (Fast Track)	Phase I www.takeda.com
Triplex cytomegalovirus gene MVA virus vaccine	HeloCyte New York, NY	cytomegalovirus infections in patients undergoing hematopoietic stem cell transplantation and solid organ transplantation (prevention)	Phase II www.helocyte.com
Typhvax typhoid fever vaccine	Matrivax Boston, MA	typhoid (prevention)	Phase I www.mativax.com
UTI vaccine	Sequoia Sciences St. Louis, MO	recurrent urinary tract infections (Fast Track)	Phase I www.sequoiasciences.com
V114 (pneumoconjugate vaccine)	Merck Kenilworth, NJ	pneumococcal infections (prevention)	Phase III www.merck.com
V160 (CMV vaccine)	Merck Kenilworth, NJ	cytomegalovirus infections (prevention)	Phase II www.merck.com
V180 (tetraivalent subunit vaccine)	Merck Kenilworth, NJ	dengue (prevention)	Phase I completed www.merck.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VAC52150 (monovalent Ebola virus vaccine)	Janssen Raritan, NJ	Ebola virus infections (prevention)	Phase III www.janssen.com
VAC52150/MVA-BN-Filo (multivalent Ebola virus vaccine)	Janssen Raritan, NJ	Ebola virus infections (prevention)	Phase III www.janssen.com
VAC52416 (ExPEC10V) (10 valent bioconjugate vaccine)	Janssen Raritan, NJ	Escherichia coli infections (60 years to 85 years) (prevention)	Phase I/II www.janssen.com
VAC89220 (Ad26.MOS4.HIV vaccine)	Janssen Raritan, NJ	HIV infections (prevention) (prime-boost regimen)	Phase III www.janssen.com
VBI-1501 (eVLP-based vaccine)	VBI Vaccines Cambridge, MA	cytomegalovirus infections (prevention)	Phase I completed www.vbivaccines.com
VBI-2601 (VLP-based vaccine)	VBI Vaccines Cambridge, MA	hepatitis B (treatment)	Phase I/II www.vbivaccines.com
VerorabVax [®] purified vero rabies vaccine	Sanofi Bridgewater, NJ	rabies (prevention)	Phase III www.sanofi.com
VLA15 (hexavalent protein subunit vaccine)	Valneva Saint-Herblain, France	Lyme disease (prevention) (Fast Track)	Phase II www.valneva.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VLA1553 (monovalent, single dose, live-attenuated vaccine)	Valneva Saint-Herblain, France	Chikungunya virus infections (prevention) (Fast Track)	Phase II www.valneva.com
VLA1601 (inactivated whole virus vaccine)	Valneva Saint-Herblain, France	Zika virus infections (prevention)	Phase I www.valneva.com
VLA84	Valneva Saint-Herblain, France	clostridium difficile infections (prevention)	Phase II www.valneva.com
VLPM01 (VLP vaccine)	VLP Therapeutics Gaithersburg, MD	malaria (prevention)	Phase I www.vlptherapeutics.com
VXA-G1.1-NN (monovalent Ad5-based norovirus vaccine)	Vaxart South San Francisco, CA	norovirus infections (prevention)	Phase I www.vaxart.com
VXA-G2.4-NS (monovalent Ad5-based norovirus vaccine)	Vaxart South San Francisco, CA	norovirus infections (prevention)	Phase I www.vaxart.com
VXA-G2.4-NS/VAX-G1.1-NN (bivalent Ad5-based norovirus vaccine)	Vaxart South San Francisco, CA	norovirus infections (prevention)	Phase I www.vaxart.com

Infectious Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
yellow fever vaccine (vero cell vaccine)	Sanofi Bridgewater, NJ	yellow fever (prevention)	Phase I www.sanofi.com
ZIKV-IG (immunoglobulin therapeutic vaccine)	Emergent BioSolutions Gaithersburg, MD	Zika virus infection (treatment) (Fast Track)	Phase I www.emergentbiosolutions.com

Respiratory Diseases

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK3277511A (recombinant protein vaccine)	GlaxoSmithKline Research Triangle Park, NC	chronic obstructive pulmonary disease (COPD)	Phase II www.gsk.com
INO-3107 (DNA-based therapeutic vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	recurrent respiratory papillomatosis	Phase II www.inovio.com

Other

<u>Drug Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
antolimab (AK002)	Allakos Redwood City, CA	chronic urticaria	Phase II www.allakos.com
		subcutaneous formulation	Phase I www.allakos.com

Other Drug Name

Sponsor

Indication

Development Phase

TOL-3021
(antigen-specific
immunotherapeutic vaccine)

Tolerion
South San Francisco, CA

type 1 diabetes

Phase II
www.tolerion.bio

UB-312
(synthetic peptide-based vaccine)

United Biomedical
Hauppauge, NY
United Neuroscience
Dublin, Ireland

Parkinson's disease

Phase II
www.unitedbiomedical.com

The content of this report has been obtained through public, government and industry sources, and the Springer "Adis Insight" database based on the latest information. Report current **as of April 14, 2020**. 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).

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.

Definitions

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.