

Medicines in Development | Vaccines

Allergy

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ADP 101 (oral immunotherapy)	Alladapt Immunotherapeutics Menlo Park, CA	food allergy (Fast Track)	Phase I/II www.alladapt.com
AIMab 7195 (immunotherapy)	Aimmune Therapeutics Bridgewater, NJ	food allergy	Phase I www.aimmune.com
AR601 (immunotherapy)	Aimmune Therapeutics Bridgewater, NJ	multi-nut allergy	Phase I www.aimmune.com
grass MATA MPL (PQGrass) (injectable MPL allergy vaccine)	Allergy Therapeutics West Sussex, United Kingdom	prevention of grass pollen allergy	Phase III www.allergytherapeutics.com
Odactra [®] house dust mite sublingual immunotherapy	ALK-Abello Bedminster, NJ	dust mite allergy (5-11 years)	Phase III www.alk.net
Palforzia [®] peanut (arachis hypogaea) allergen powder-dnfp	Aimmune Therapeutics Bridgewater, NJ	peanut allergy (1-<4 years)	Phase III www.aimmune.com
Peanut-SLIT (sublingual immunotherapy tablet)	ALK-Abello Bedminster, NJ	peanut allergy	Phase I www.alk.net

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REGN5713-5714-5715 (mAb-based allergy immunotherapy)	Regeneron Tarrytown, NY	treatment of allergic rhinitis and conjunctivitis triggered by birch tree allergy	Phase II www.regeneron.com
Viaskin™ Milk food allergy immunotherapy (DBV135)	DBV Technologies Warren, NJ	cow's milk allergy (2-17 years) (Fast Track), eosinophilic esophagitis (4-17 years)	Phase II www.dbv-technologies.com
Viaskin™ Peanut food allergy immunotherapy (DBV712)	DBV Technologies Warren, NJ	peanut allergy (1-3 years, 4-11 years) (Fast Track) (Breakthrough Therapy)	Phase III www.dbv-technologies.com
		peanut allergy (adolescents and adults)	Phase II www.dbv-technologies.com
VLP peanut (VLP vaccine)	Allergy Therapeutics West Sussex, United Kingdom	peanut allergy	Phase I www.allergytherapeutics.com

Alzheimer's Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ACI-24.060 (anti-Abeta vaccine)	AC Immune Lausanne, Switzerland	Alzheimer's disease (Fast Track), Alzheimer's disease in Down syndrome	Phase I/II www.acimmune.com
ACI-35.030/JNJ-2056 (anti-pTau vaccine)	AC Immune Lausanne, Switzerland Johnson & Johnson Innovative Medicine Raritan, NJ	Alzheimer's disease	Phase I/II www.acimmune.com www.jnj.com

Alzheimer's Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
ALZN-002 (antigen-activated immune cell-based vaccine)	Alzamend Neuro Atlanta, GA	Alzheimer's disease	Phase I/II www.alzamend.com
AV-1959D (Abeta DNA vaccine)	Nuravax Irvine, CA	Alzheimer's disease	Phase I www.nuravax.com
GV1001 (tertomide) (peptide vaccine)	GemVax & Kael Daejeon, South Korea	Alzheimer's disease	Phase II www.gemvax.com
UB-311 (amyloid beta protein inhibitor synthetic vaccine)	Vaxxinity Merritt Island, FL	Alzheimer's disease	Phase II www.vaxxinity.com

Cancer

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
adagloxad simolenin (cancer immunotherapy)	OBI Pharma San Diego, CA	triple negative breast cancer (+OBI-821)	Phase III www.obipharma.com
ADXS-504 (off-the-shelf cancer vaccine)	Ayala Pharmaceuticals Wilmington, DE	prostate cancer	Phase I www.ayalapharma.com
AlloStim (StimVax) (cancer immunotherapy)	Mirror Biologics Tampa, FL	3L colorectal cancer	Phase II www.mirrorbio.com

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AST-201 (IGFBP2 DNA vaccine)	Aston Sci. Seoul, South Korea	ovarian cancer	Phase II www.astonsci.com
ATP-128 (KISIMA) (chimeric recombinant protein vaccine)	Boehringer Ingelheim Ridgefield, CT	colorectal cancer	Phase I www.boehringer-ingelheim.com
ATP-150 (KISIMA) (chimeric recombinant protein vaccine)	Boehringer Ingelheim Ridgefield, CT	pancreatic ductal adenocarcinoma	Phase I www.boehringer-ingelheim.com
ATP-152 (KISIMA) (chimeric recombinant protein vaccine)	Boehringer Ingelheim Ridgefield, CT	pancreatic ductal adenocarcinoma	Phase I www.boehringer-ingelheim.com
autogene cevumeran (RG6180/BNT122) (mRNA-based cancer vaccine)	BioNTech Cambridge, MA Roche/Genentech South San Francisco, CA	1L melanoma (+pembrolizumab), pancreatic ductal adenocarcinoma (+atezolizumab), colorectal cancer	Phase II www.biontech.com www.roche.com
		solid tumors	Phase I www.biontech.com www.roche.com
AV-GBM-1 (tumor-initiating cell vaccine)	AIVITA Biomedical Irvine, CA	glioblastoma	Phase III www.aivitabiomedical.com

Cancer

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AV-MEL-1 (tumor-initiating cell vaccine)	AIVITA Biomedical Irvine, CA	melanoma	Phase III www.aivitabiomedical.com
		melanoma (+checkpoint inhibitor)	Phase I www.aivitabiomedical.com
BI 1831169 (VSV-GP) (oncolytic virus cancer vaccine)	Boehringer Ingelheim Ridgefield, CT	solid tumors	Phase I www.boehringer-ingelheim.com
BNT111 (mRNA cancer vaccine) <small>ORPHAN DRUG</small>	BioNTech Cambridge, MA	melanoma (Fast Track)	Phase II www.biontech.com
BNT113 (mRNA cancer vaccine)	BioNTech Cambridge, MA	HPV16+ head and neck cancer	Phase II www.biontech.com
BNT116 (mRNA cancer vaccine)	BioNTech Cambridge, MA	1L metastatic non-small cell lung cancer (NSCLC)	Phase II www.biontech.com
		metastatic NSCLC	Phase I www.biontech.com
breast cancer vaccine (alpha-lactalbumin vaccine)	Anixa Biosciences San Jose, CA	prevention and treatment of triple negative breast cancer	Phase I www.anixa.com

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Bria-IMT™ (SV BR 1 GM cancer vaccine)	BriaCell Therapeutics Philadelphia, PA	breast cancer (Fast Track)	Phase III www.briacell.com
CE120 (immunotherapy nanoformulation)	Cello Therapeutics San Diego, CA	solid tumors	Phase I www.cellotherapeutics.com
CVGBM (mRNA cancer vaccine)	CureVac Boston, MA	surgically-resected glioblastoma	Phase I www.curevac.com
DCVax®-Direct solid tumors vaccine	Northwest Biotherapeutics Bethesda, MD	solid tumors	Phase I www.nwbio.com
DCVax®-L brain cancer vaccine ORPHAN DRUG	Northwest Biotherapeutics Bethesda, MD	glioblastoma	Phase III www.nwbio.com
DOC1021 (dendritic cell vaccine) ORPHAN DRUG	Diakonon Oncology Houston, TX	glioblastoma (Fast Track)	Phase I www.diakonononcology.com
DPV-001 (tumor-derived autophagosome- enriched vaccine)	UbiVac Portland, OR	NSCLC (adjuvant)	Phase II www.ubivac.com
ELI-002 (amphiphile cancer vaccine)	Elicio Therapeutics Boston, MA	colorectal cancer, pancreatic ductal adenocarcinoma	Phase II www.elicio.com

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EO2401 (microbiome-derived antigen vaccine)	Enterome Paris, France	glioblastoma, adrenal tumors (+nivolumab)	Phase I/II www.enterome.com
EO2463 (microbiome based multi-peptide vaccine)	Enterome Paris, France	follicular lymphoma, marginal zone lymphoma	Phase I/II www.enterome.com
EO4010 (cancer vaccine)	Enterome Paris, France	colorectal cancer	Phase I/II www.enterome.com
ERC1671 (cancer vaccine) <small>ORPHAN DRUG</small>	Epitopeic Research Pasadena, CA	glioblastoma (Fast Track), gliosarcoma (Fast Track)	Phase II www.erc-immunotherapy.com
galinpepimut-S (GPS) (cancer peptide vaccine) <small>ORPHAN DRUG</small>	Sellas Life Sciences New York, NY	acute myeloid leukemia (Fast Track)	Phase III www.sellalifesciences.com
		malignant plural mesothelioma (Fast Track), ovarian cancer	Phase II www.sellalifesciences.com
GLSI-100 (HER2/Neu GP2 vaccine)	Greenwich Life Sciences Stafford, TX	breast cancer	Phase III www.greenwichlifesciences.com
GRANITE (personalized tumor-specific neoantigen-based cancer vaccine)	Gritstone bio Emeryville, CA	microsatellite-stable colorectal cancer (Fast Track)	Phase II/III www.gritstonebio.com

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<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK4106647 (recombinant adjuvanted vaccine)	GSK Philadelphia, PA	prevention of HPV-related cancer, genital warts and precancerous or dysplastic lesions (9-45 years, male and female)	Phase II www.gsk.com
GT-30 (GNOS-PV02) (personalized neoantigen DNA vaccine)	Geneos Therapeutics Philadelphia, PA	hepatocellular carcinoma (combination therapy)	Phase I/II www.geneostx.com
HB-200 (HB-201/HB-202) (arenavirus cancer vaccine)	Hookipa Pharma New York, NY	treatment of HPV-related squamous cell carcinoma (Fast Track)	Phase II www.hookipapharma.com
HB-700 (arenavirus cancer vaccine)	Hookipa Pharma New York, NY	KRAS-mutated tumors	Phase I www.hookipapharma.com
HER2-pulsed DC vaccine (dendritic cell vaccine)	ImmunoRestoration Doylestown, PA	HER2+ breast cancer	Phase II www.immunorestoration.com
IBRX-042 (hAd5 vector-based vaccine)	ImmunityBio Culver City, CA	HPV-related cancer	Phase I www.immunitybio.com
IFx-2.0 (plasmid DNA cancer vaccine)	TuHURA Biosciences Tampa, FL	cutaneous squamous cell carcinoma, Merkel cell carcinoma, non-melanoma skin cancer	Phase I www.tuhura.com
IGV-001 (autologous cell vaccine) <small>ORPHAN DRUG</small>	Imvax Philadelphia, PA	glioblastoma (Fast Track)	Phase II www.imvax.com

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INO-3112 (DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	head and neck cancer	Phase II www.inovio.com
INO-5401 (DNA cancer vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	glioblastoma	Phase II www.inovio.com
		BRCA 1/2 mutated cancer	Phase I www.inovio.com
IO102-IO103 (combination immune-modulating cancer vaccine)	IO Biotech New York, NY	1L melanoma (+pembrolizumab) (Breakthrough Therapy)	Phase III www.iobiotech.com
		bladder cancer, head and neck cancer, melanoma, NSCLC (+pembrolizumab)	Phase II www.iobiotech.com
ISA101b (HPV-16 vaccine) <small>ORPHAN DRUG</small>	ISA Pharmaceuticals Oegstgeest, Netherlands	cervical cancer, oropharyngeal cancer (Fast Track)	Phase II www.isa-pharma.com
ITI-1000 (dendritic cell vaccine)	Immunomic Therapeutics Rockville, MD	glioblastoma	Phase II www.immunomix.com
ITI-1001 (DNA vaccine)	Immunomic Therapeutics Rockville, MD	glioblastoma	Phase I www.immunomix.com

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ITI-3000 (DNA vaccine)	Immunomic Therapeutics Rockville, MD	Merkel cell carcinoma (Fast Track)	Phase I www.immunomix.com
Lenti-HPV-07 (lentiviral vector immunotherapy)	Theravectys Paris, France	treatment of HPV-related cervical and oropharyngeal cancer	Phase I www.theravectys.com
lerapolturev (oncolytic recombinant polio virus vaccine) ORPHAN DRUG	Istari Oncology Morrisville, NC	glioblastoma (+/- pembrolizumab) (Breakthrough Therapy), melanoma (+/- anti-PD-1) (Fast Track)	Phase II www.istarioncology.com
		NMIBC (intravesicular)	Phase I www.istarioncology.com
LTX-315 (oncolytic immunotherapy)	Lytix Biopharma Oslo, Norway	melanoma (+pembrolizumab)	Phase II www.lytixbiopharma.com
maveropepimut-S (peptide cancer vaccine) ORPHAN DRUG	BioVaxys Toronto, Canada	fallopian tube cancer, ovarian cancer, peritoneal cancer (Fast Track)	Phase II www.biovaxys.com
mRNA-4359 (mRNA checkpoint cancer vaccine)	Moderna Therapeutics Cambridge, MA	solid tumors	Phase I www.modernatx.com
mRNA-5671 (mRNA KRAS cancer vaccine)	Moderna Therapeutics Cambridge, MA	KRAS-positive cancers	Phase I www.modernatx.com

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MV-NIS (attenuated oncolytic measles virus)	Vyriad Rochester, NY	bladder cancer	Phase I www.vyriad.com
MVI-118 (pTVG-AR DNA vaccine)	Madison Vaccines Madison, WI University of Wisconsin Madison, WI	prostate cancer	Phase II www.madisonvaccines.com
MVI-816 (pTVG-HP DNA vaccine)	Madison Vaccines Madison, WI University of Wisconsin Madison, WI	prostate cancer	Phase II www.madisonvaccines.com
NOUS-209 (neoantigen genetic vaccine)	Nouscom Basel, Switzerland	solid tumors	Phase I/II www.nouscom.com
oregovomab (cancer immunotherapy) ORPHAN DRUG	Canariobio Seoul, South Korea	newly-diagnosed ovarian cancer	Phase III www.canariobio.com
		recurrent ovarian cancer	Phase II www.canariobio.com
OST-HER2 (live attenuated <i>Listeria monocytogenes</i> immunotherapy) ORPHAN DRUG	OS Therapies Rockville, MD	recurrent/resected osteosarcoma (Fast Track)	Phase II www.ostherapies.com
		solid tumors	Phase I www.ostherapies.com

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PD1-Vaxx (IMU-201) (cancer immunotherapy)	Imugene Sydney, Australia	NSCLC	Phase I www.imugene.com
PEP-CMV (dendritic cell vaccine)	Annias Immunotherapeutics Durham, NC Duke University Durham, NC	recurrent medulloblastoma, brain tumor (pediatric), glioma	Phase I www.anniasimmuno.com
polyclonal antibody stimulator (G17DT) (fusion protein cancer vaccine) ORPHAN DRUG	Cancer Advances Durham, NC	gastrointestinal cancer	Phase III www.canceradvances.com
PolyPEPI 1018 (immunotherapy vaccine)	Treos Bio Boston, MA	colorectal cancer	Phase II www.treosbio.com
PRGN-2009 (DNA vaccine)	Precigen Germantown, MD	cervical cancer, squamous cell cancer	Phase II www.precigen.com
PVX-410 (multi-peptide cancer vaccine) ORPHAN DRUG	OncoPep Cambridge, MA	metastatic triple negative breast cancer	Phase II www.oncopep.com
		smoldering multiple myeloma	Phase I www.oncopep.com

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REIC gene therapy (MTG201) (AAV-based gene therapy) ORPHAN DRUG	Momotaro-Gene Okayama, Japan	malignant pleural mesothelioma	Phase II www.mt-gene.com
seviprostimut-L (allogeneic polyvalent partially purified shed melanoma antigens vaccine) ORPHAN DRUG	Polynoma San Diego, CA	melanoma (Fast Track)	Phase III www.polynoma.com
SL-701 (IL-13R α 2, EphA2, Survivin vaccine) ORPHAN DRUG	Stemline Therapeutics New York, NY	glioblastoma	Phase II www.stemline.com
SLATE (off the shelf cancer vaccine)	Gritstone bio Emeryville, CA	KRAS-driven solid tumors	Phase I/II www.gritstonebio.com
SP-002 (recombinant interferon-gamma vaccine) ORPHAN DRUG	Stamford Pharmaceuticals Austin, TX	basal cell carcinoma (combination therapy)	Phase II www.stamfordpharmaceuticals.com
STM-416 (intraoperative cancer immunotherapy)	Surge Therapeutics Cambridge, MA	recurrent bladder cancer (prevention of recurrence and progression)	Phase I/II www.surgetx.com
SurVaxM (peptide vaccine) ORPHAN DRUG	MimiVax Buffalo, NY	glioblastoma (Fast Track)	Phase II www.mimivax.com

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TAEK-VAC-HerBy vaccine	Bavarian Nordic San Diego, CA	brachyury/HER2-expressing cancer	Phase I www.bavarian-nordic.com
TG4050 (viral based neoantigen vaccine)	Transgene Boston, MA	head and neck squamous cell cancer, ovarian cancer	Phase I www.transgene.fr
tipapkinogene sovacivec (TG4001) (therapeutic cancer vaccine)	Transgene Boston, MA	HPV-related cancers	Phase I/II www.transgene.fr
TLPO (tumor lysate particle only vaccine)	Elios Therapeutics Austin, TX	solid tumors	Phase II www.eliotherapeutics.com
TLPLDC (tumor lysate particle loaded dendritic cell vaccine)	Elios Therapeutics Austin, TX	melanoma	Phase I completed www.eliotherapeutics.com
TVI-Brain-1 (cancer vaccine immunotherapy) ORPHAN DRUG	TVAX Biomedical Olathe, KS	glioblastoma (Fast Track)	Phase II/III www.tavxbiomedical.com
UV1 vaccine (synthetic peptide vaccine) ORPHAN DRUG	Ultimovacs Oslo, Norway	malignant melanoma (Fast Track)	Phase II www.ultimovacs.com

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V940/mRNA-4157 (mRNA personalized cancer vaccine)	Merck Rahway, NJ Moderna Therapeutics Cambridge, MA	melanoma (adjuvant) (Breakthrough Therapy), NSCLC (adjuvant), cutaneous squamous cell carcinoma (+pembrolizumab)	Phase III www.merck.com www.modernatx.com
		bladder cancer, renal cell carcinoma (+pembrolizumab)	Phase II www.merck.com www.modernatx.com
		solid tumors	Phase I www.merck.com www.modernatx.com
VAC85135 (neoantigen vaccine)	Johnson & Johnson Innovative Medicine Raritan, NJ	myeloproliferative neoplasms (+ipilimumab)	Phase I www.jnj.com
VB10.16 (DNA vaccine)	Nykode Therapeutics Oslo, Norway	HPV16+ cervical cancer (+/- atezolizumab)	Phase II www.nykode.com
VB10.NEO (DNA vaccine)	Nykode Therapeutics Oslo, Norway	solid tumors (+atezolizumab)	Phase I www.nykode.com
VBI-1901 (bivalent eVLP cancer vaccine) <small>ORPHAN DRUG</small>	VBI Vaccines Cambridge, MA	glioblastoma (Fast Track)	Phase II www.vbivaccines.com

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Verity-BCG (BCG bladder cancer vaccine)	Verity Pharmaceuticals Ewing, NJ	non-muscle invasive bladder cancer	Phase II www.veritypharma.com
Versamune-HPV (PDS0101) (HPV-specific cancer immunotherapy)	PDS Biotechnology Princeton, NJ	HPV+ head and neck cancer (Fast Track) (+/- pembrolizumab)	Phase II www.pdsbiotech.com
VGX-3100 (DNA vaccine immunotherapy)	Inovio Pharmaceuticals Plymouth Meeting, PA	anal intraepithelial dysplasia	Phase II www.inovio.com
Vigil® (autologous tumor cell immunotherapy)	Gradalis Carrollton, TX	stage III/IV ovarian cancer, advanced gynecological cancer	Phase II www.gradalis.com
vidutolimod (TLR9 agonist cancer vaccine)	Regeneron Tarrytown, NY	solid tumors	Phase II www.regeneron.com
Voyager-V1 (VV1) (genetically-modified vesicular stomatitis virus)	Vyriad Rochester, MN	neuroendocrine cancer, NSCLC (combination therapy), melanoma, head and neck cancer, colorectal cancer, solid tumors	Phase II www.vyriad.com
VT101 (alpha-TEA cancer vaccine)	Veana Therapeutics Portland, OR	HER2+ breast cancer	Phase I www.veana-therapeutics.com
VTP-850 (prime-boost viral vector vaccine)	Barinthus Biotherapeutics Germantown, MD	prostate cancer	Phase I/II www.barinthusbio.com

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ZH9 (cancer immunotherapy)	Prokarium London, United Kingdom	non-muscle invasive bladder cancer	Phase I www.prokarium.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Abrysvo™ respiratory syncytial virus vaccine	Pfizer New York, NY	prevention of respiratory syncytial virus (RSV) infections (18-59 years)	Phase III www.pfizer.com
		prevention of RSV (pediatric)	Phase I www.pfizer.com
ACAM2000® smallpox (vaccinia) vaccine, live	Emergent BioSolutions Gaithersburg, MD	prevention of monkeypox	application submitted www.emergentbiosolutions.com
AlloStim (universal antiviral vaccine)	Mirror Biologics Tampa, FL	prevention of viral infections (elderly)	Phase I/II www.mirrorbio.com
amezosvatein (CRV-101) (adjuvanted sub-unit vaccine)	Curevo Vaccine Bothell, WA	prevention of shingles (herpes zoster) (50 years and older)	Phase II www.curevovaccine.com
ARCT-2138 (sa-mRNA quadrivalent vaccine)	Arcturus San Diego, CA CSL Seqirus Summit, NJ	prevention of influenza	Phase I www.arcturustx.com www.cslseqirus.com

Infectious Disease

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ARCT-2301 (sa-mRNA bivalent vaccine)	Arcturus San Diego, CA CSL Seqirus Summit, NJ	prevention of COVID-19	Phase III www.arcturustx.com www.cslseqirus.com
ARCT-2303 (sa-mRNA monovalent vaccine)	Arcturus San Diego, CA CSL Seqirus Summit, NJ	prevention of COVID-19	Phase III www.arcturustx.com www.cslseqirus.com
Arexvy® respiratory syncytial virus vaccine, adjuvanted	GSK Philadelphia, PA	prevention of RSV (18-49 years)	Phase III www.gsk.com
AV0328 (synthetic PNAG vaccine)	Alopexx Vaccine Cambridge, MA	prevention of pneumococcal infections, prevention of meningococcal infections	Phase I www.alopexx.com
AV-COVID-19 (vaccine enabling kit)	Aivita Biomedical Irvine, CA	prevention of COVID-19	Phase II completed www.avitabiomedical.com
AZD6563 (mRNA VLP vaccine)	AstraZeneca Wilmington, DE	prevention of COVID-19	Phase I www.astrazeneca.com
AZD9838 (mRNA VLP vaccine)	AstraZeneca Wilmington, DE	prevention of COVID-19	Phase I www.astrazeneca.com

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Bexsero® meningococcal group B vaccine	GSK Philadelphia, PA	prevention of invasive disease caused by <i>N. meningitidis</i> serogroup B (2 months and older)	Phase III www.gsk.com
BLB201 (intranasal RSV vaccine)	Blue Lake Biotechnology San Jose, CA	prevention of RSV (infants) (Fast Track)	Phase I/II www.bluelakebiotechnology.com
		prevention of RSV (elderly) (Fast Track)	Phase I www.bluelakebiotechnology.com
BNT162b2+BNT162b4 (mRNA vaccine)	BioNTech Cambridge, MA Pfizer New York, NY	prevention of COVID-19 (T-cell enhancing)	Phase I www.biontech.com www.pfizer.com
BNT162b5/6/7 (mRNA vaccine)	BioNTech Cambridge, MA Pfizer New York, NY	prevention of COVID-19 (stabilized spike antigen)	Phase II www.biontech.com www.pfizer.com
BNT163 (mRNA vaccine)	BioNTech Cambridge, MA	prevention of herpes simplex virus type 2 infections	Phase I www.biontech.com
BNT165 (mRNA vaccine)	BioNTech Cambridge, MA	prevention of malaria	Phase I/II www.biontech.com

Infectious Disease

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BNT166 (mRNA vaccine)	BioNTech Cambridge, MA	prevention of monkeypox	Phase I/II www.biontech.com
BPZE1 (live attenuated vaccine)	Iliad Biotechnologies Weston, FL	prevention of pertussis (Fast Track) (adults/adolescent booster)	Phase II www.iliadbio.com
BW-1010 (intranasal nanoemulsion-based vaccine)	BlueWillow Biologics Ann Arbor, MI	prevention of anthrax	Phase I www.bluewillow.com
BW-1014 (intranasal nanoemulsion-based vaccine)	BlueWillow Biologics Ann Arbor, MI	prevention of pandemic influenza	Phase I www.bluewillow.com
CHIKV VLP (VLP-based vaccine)	Bavarian Nordic San Diego, CA	prevention of chikungunya infections (Breakthrough Therapy)	application submitted www.bavarian-nordic.com
CodaVax™- H1N1 live-attenuated universal flu vaccine	Codagenix Farmingdale, NY	prevention of influenza	Phase I www.codagenix.com
CodaVax™-RSV live attenuated vaccine	Codagenix Farmingdale, NY	prevention of RSV (adults and children) (Fast Track)	Phase I www.codagenix.com
Comirnaty® COVID-19 vaccine, mRNA	BioNTech Cambridge, MA Pfizer New York, NY	prevention of COVID-19 (5-11 years, 6 months to 4 years)	application submitted www.biontech.com www.pfizer.com

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COVID-influenza combination vaccine (Matrix-M adjuvant)	Novavax Gaithersburg, MD	prevention of COVID-19 and influenza	Phase II www.novavax.com
CoviLiv™ intranasal live-attenuated vaccine	Codagenix Farmingdale, NY	prevention of COVID-19 (Fast Track)	Phase III www.codagenix.com
CVXGA (BLB101) (intranasal SARS CoV-2 S vaccine)	CyanVac Athens, GA	prevention of COVID-19	Phase II www.cyanvacllc.com
dMAbs (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prevention of COVID-19	Phase I www.inovio.com
DV2-PLG-01 (rF1V vaccine) (recombinant adjuvanted plague vaccine) ORPHAN DRUG	Dynavax Technologies Emeryville, CA	prevention of pneumonic plague	Phase II www.dynavax.com
DV2-TDAP-01 (adjuvanted Tdap vaccine)	Dynavax Technologies Emeryville, CA	Tdap (tetanus, diphtheria, pertussis) booster	Phase I www.dynavax.com
DV2-ZOS-01 (Z-1018) (recombinant varicella zoster vaccine)	Dynavax Technologies Emeryville, CA	prevention of shingles (herpes zoster)	Phase I/II www.dynavax.com
Ebola/Marburg virus vaccine (VesiculoVax™-vectored vaccine)	Auro Vaccines Pearl River, NY	prevention of Ebola and Marburg virus infections	Phase I www.aurovaccines.com

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EBS-Lassa (rVSV-vectored vaccine)	Emergent BioSolutions Gaithersburg, MD	prevention of Lassa fever	Phase I www.emergentbiosolutions.com
flu pandemic mRNA vaccine	GSK Philadelphia, PA	prevention of H5N1 influenza	Phase I/II www.gsk.com
Fluzone® High Dose inactivated influenza vaccine	Sanofi Bridgewater, NJ	prevention of influenza (pediatric)	Phase II www.sanofi.com
GEO-CM04S1 (synthetic attenuated vaccine)	GeoVax Labs Smyrna, GA	prevention of COVID-19	Phase II www.geovax.com
GLS-5310 (DNA plasmid vaccine)	GeneOne Life Sciences Seoul, South Korea	prevention of COVID-19 (booster)	Phase I www.genels.com
GS-2829 + GS-6779 (HBV therapeutic vaccine)	Gilead Sciences Foster City, CA	treatment of hepatitis B (functional cure)	Phase I www.gilead.com
GSK3437949 (recombinant protein adjuvanted vaccine)	GSK Philadelphia, PA	prevention of malaria (<i>Plasmodium falciparum</i>)	Phase II www.gsk.com
GSK3528869 (prime-boost vaccine with viral vector administered with adjuvanted recombinant proteins)	GSK Philadelphia, PA	treatment of hepatitis B (functional cure)	Phase II www.gsk.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK3536819 (meningococcal ABCWY vaccine [1st generation])	GSK Philadelphia, PA	prevention of invasive disease caused by N. meningitidis serogroups A, B, C, W and Y (10-25 years)	application submitted www.gsk.com
GSK3536852 (generalized modules for membrane antigens vaccine)	GSK Philadelphia, PA	prevention of Shigella diarrhea	Phase II www.gsk.com
GSK3536867 (bivalent conjugate vaccine)	GSK Philadelphia, PA	prevention of salmonella (typhoid + paratyphoid A) enteric fever	Phase I www.gsk.com
GSK3943104 (recombinant adjuvanted vaccine)	GSK Philadelphia, PA	treatment for the suppression of recurrent genital herpes (adults)	Phase II www.gsk.com
GSK3993129 (adjuvanted recombinant subunit vaccine)	GSK Philadelphia, PA	prevention of cytomegalovirus (CMV) infections (women 16-49 years)	Phase II www.gsk.com
GSK4023393 (meningococcal ABCWY vaccine [2nd generation])	GSK Philadelphia, PA	prevention of invasive disease caused by N. meningitidis serogroups meningococcal A,B,C,W and Y disease (adolescents and children ages 6 weeks and older)	Phase II www.gsk.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK4077164 (bivalent GMMMA vaccine and typhoid conjugate vaccine)	GSK Philadelphia, PA	prevention of invasive non-typhoidal salmonella, prevention of invasive non-typhoidal salmonella and typhoid fever (+S. Typhi)	Phase II www.gsk.com
GSK4178116 (live attenuated vaccine)	GSK Philadelphia, PA	prevention of varicella (12 months and older)	Phase II www.gsk.com
GSK4348413 (generalized modules for membrane antigens [GMMMA] vaccine)	GSK Philadelphia, PA	prevention of gonorrhea (16-50 years) (Fast Track)	Phase II www.gsk.com
GSK4382276 (FLU-SV mRNA) (mRNA vaccine)	GSK Philadelphia, PA CureVac Boston, MA	prevention of influenza (adults)	Phase II www.gsk.com
GSK4396687 (CV0601/CV0701) (mRNA vaccine)	GSK Philadelphia, PA CureVac Boston, MA	prevention of COVID-19 (12 years and older)	Phase II www.gsk.com
GSK4406371 (live attenuated vaccine)	GSK Philadelphia, PA	prevention of measles, mumps, rubella, and varicella (in children 12 months to 12 years)	Phase II www.gsk.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
GSK5101955 (pneumococcal 24-valent vaccine)	GSK Philadelphia, PA	prevention of invasive pneumococcal disease, pneumonia and acute otitis media caused by the <i>Streptococcus pneumoniae</i> 24 serotypes included in the vaccine (ages 6 weeks to 17 years) (Breakthrough Therapy)	Phase II www.gsk.com
GSK5101956 (pneumococcal 24-valent vaccine)	GSK Philadelphia, PA	prevention of pneumonia and invasive pneumococcal disease caused by <i>Streptococcus pneumoniae</i> 24 serotypes (adults) (Breakthrough Therapy)	Phase II www.gsk.com
HB-500 (HB-501/HB-502) (arenavirus vaccine)	Hookipa Pharma New York, NY	treatment of human immunodeficiency virus (HIV) infections	Phase I www.hookipapharma.com
HDT-301 (mRNA vaccine)	HDT Bio Seattle, WA	prevention of COVID-19	Phase I www.hdt.bio
HIL-214 (VLP bivalent vaccine)	HilleVax Boston, MA	prevention of moderate-to-severe acute gastroenteritis caused by norovirus infection	Phase II/III www.hillevax.com
HIV therapeutic vaccine	Gilead Sciences Foster City, CA Gritstone Bio Emeryville, CA	treatment of HIV (functional cure)	Phase I www.gilead.com www.gritstonebio.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
HydroVax-002 (yellow fever vaccine)	Najit Technologies Beaverton, OR	prevention of yellow fever	Phase I www.najittech.com
INFLUENZA G1 mHA (mini-hemagglutinin stem-derived protein vaccine)	Johnson & Johnson Innovative Medicine Raritan, NJ	prevention of influenza	Phase I/II www.jnj.com
influenza vaccine (Matrix-M adjuvant)	Novavax Gaithersburg, MD	prevention of seasonal influenza (older adults)	Phase II www.novavax.com
INO-4201 (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prevention of Ebola (booster)	Phase I www.inovio.com
INO-6160 (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prevention of HIV	Phase I www.inovio.com
INO-6172 (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	prevention of HIV	Phase I www.inovio.com
IVX-A12 (RSV/hMPV bivalent VLP vaccine)	Icosavax Seattle, WA	prevention of RSV and metapneumovirus infections (Fast Track)	Phase II www.icosavax.com
JCXH-105 (srRNA-based herpes zoster vaccine)	Immorna Biotherapeutics Shanghai, China	prevention of shingles (herpes zoster)	Phase I www.immorna.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
JCXH-221 (mRNA-based COVID-19 vaccine)	Immorna Biotherapeutics Shanghai, China	prevention of COVID-19	Phase I/II www.immorna.com
Jynneos [®] smallpox and monkeypox vaccine (freeze-dried formulation)	Bavarian Nordic San Diego, CA	prevention of smallpox and monkeypox (adults)	application submitted www.bavarian-nordic.com
KBP-COVID-19 (plant based vaccine)	KBio Owensboro, KY	prevention of COVID-19	Phase I/II completed www.kbio.com
LZ901 (recombinant herpes zoster vaccine)	Luzhu Biotechnology Beijing, China	prevention of shingles (herpes zoster)	Phase I www.luzhubiotech.com
M2SR intranasal influenza vaccine	FluGen Madison, WI	prevention of influenza	Phase I completed www.flugen.com
MenQuadfi [®] meningococcal ACWY conjugate vaccine	Sanofi Bridgewater, NJ	prevention of meningitis (6 weeks and older)	Phase III www.sanofi.com
monovalent influenza virus oral vaccine	Vaxart South San Francisco, CA	prevention of influenza	Phase II www.vaxart.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
mResvia® mRNA RSV vaccine	Moderna Therapeutics Cambridge, MA	prevention of RSV (50 and older)	Phase III www.modernatx.com
		prevention of RSV (pediatric)	Phase II www.modernatx.com
mRNA-1010 (mRNA-based quadrivalent seasonal influenza vaccine)	Moderna Therapeutics Cambridge, MA	prevention of influenza	Phase III www.modernatx.com
mRNA-1011 (mRNA-based quadrivalent seasonal influenza vaccine)	Moderna Therapeutics Cambridge, MA	prevention of influenza	Phase II www.modernatx.com
mRNA-1012 (mRNA-based quadrivalent seasonal influenza vaccine)	Moderna Therapeutics Cambridge, MA	prevention of influenza	Phase II www.modernatx.com
mRNA-1018 (mRNA-based pandemic flu vaccine)	Moderna Therapeutics Cambridge, MA	prevention of pandemic influenza	Phase I www.modernatx.com
mRNA-1020 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of influenza	Phase II www.modernatx.com
mRNA-1030 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of influenza	Phase II www.modernatx.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-1045 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of influenza and RSV	Phase I www.modernatx.com
mRNA-1083 (mRNA-based combination vaccine)	Moderna Therapeutics Cambridge, MA	prevention of COVID-19 and influenza (Fast Track)	Phase III www.modernatx.com
mRNA-1189 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of Epstein-Barr virus infections to prevent infectious mononucleosis	Phase I www.modernatx.com
mRNA-1195 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of Epstein-Barr virus infections (to address long term EBV sequelae)	Phase I www.modernatx.com
mRNA-1215 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of Nipah virus disease	Phase I www.modernatx.com
mRNA-1230 (mRNA-based combination vaccine)	Moderna Therapeutics Cambridge, MA	prevention of COVID-19, influenza and RSV	Phase I www.modernatx.com
mRNA-1283 (mRNA vaccine)	Moderna Therapeutics Cambridge, MA	prevention of COVID-19	Phase III www.modernatx.com
mRNA-1365 (mRNA-based combination vaccine)	Moderna Therapeutics Cambridge, MA	prevention of RSV and metapneumovirus infections (Fast Track)	Phase I www.modernatx.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-1403 (mRNA-based trivalent VLP vaccine)	Moderna Therapeutics Cambridge, MA	prevention of norovirus infections	Phase I www.modernatx.com
mRNA-1405 (mRNA-based pentavalent VLP vaccine)	Moderna Therapeutics Cambridge, MA	prevention of norovirus infections	Phase I www.modernatx.com
mRNA-1468 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of shingles (herpes zoster)	Phase II www.modernatx.com
mRNA-1574 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of HIV	Phase I www.modernatx.com
mRNA-1608 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of herpes simplex virus infections	Phase II www.modernatx.com
mRNA-1644 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of HIV	Phase I www.modernatx.com
mRNA-1647 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of CMV	Phase III www.modernatx.com
mRNA-1769 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of monkeypox	Phase I www.modernatx.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-1893 (mRNA-based vaccine)	Moderna Therapeutics Cambridge, MA	prevention of Zika virus infections (Fast Track)	Phase II www.modernatx.com
mRNA-1975 (mRNA-based heptavalent vaccine)	Moderna Therapeutics Cambridge, MA	prevention of Lyme disease (Fast Track)	Phase II www.modernatx.com
mRNA-1982 (mRNA-based monovalent vaccine)	Moderna Therapeutics Cambridge, MA	prevention of Lyme disease (Fast Track)	Phase II www.modernatx.com
MV-012-968 (intranasal live-attenuated vaccine)	Meissa Vaccines Redwood City, CA	prevention of RSV (pediatric) (Fast Track)	Phase II www.meissavaccines.com
MV-014-212 (intranasal live-attenuated chimeric vaccine)	Meissa Vaccines Redwood City, CA	prevention of COVID-19 (adults)	Phase I www.meissavaccines.com
MVA-BN WEV (multi-valent vaccine)	Bavarian Nordic San Diego, CA	prevention of western, eastern and Venezuelan equine encephalitis virus infections	Phase I www.bavarian-nordic.com
MVX-01 (pneumolysin-fusion protein vaccine)	Matrivax Boston, MA	prevention of pneumococcal infections	Phase I www.mativax.com
Nipah/Hendra vaccine (HeV-sG-V) (subunit vaccine)	Auro Vaccines Pearl River, NY	prevention of Nipah and Hendra virus infections	Phase I www.aurovaccines.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Novavax COVID-19 vaccine (Matrix-M adjuvant)	Novavax Gaithersburg, MD	prevention of COVID-19 (6 months to <12 years)	Phase II/III www.novavax.com
Panblok (cell-culture vaccine)	Sanofi Bridgewater, NJ	prevention of influenza	Phase I/II www.sanofi.com
PDPHV (polyvalent DNA/gp120 vaccine)	Worcester HIV Vaccine Worcester, MA	prevention of HIV	Phase I www.whvaccine.com
PF-06425090 (protein subunit vaccine)	Pfizer New York, NY	prevention of primary <i>Clostridioides difficile</i> (C. difficile) infections (Fast Track)	Phase III www.pfizer.com
PF-06760805 (polysaccharide conjugate vaccine)	Pfizer New York, NY	prevention of invasive Group B streptococcus infections (maternal) (Fast Track) (Breakthrough Therapy)	Phase II www.pfizer.com
PF-07252220 (BNT161) (mRNA vaccine)	Pfizer New York, NY BioNTech Cambridge, MA	prevention of influenza (adults)	Phase III www.pfizer.com
PF-07307405 (VLA15) (protein subunit vaccine)	Pfizer New York, NY Valneva Gaithersburg, MD	prevention of Lyme disease (Fast Track)	Phase III www.pfizer.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PF-07831694 (polysaccharide conjugate vaccine)	Pfizer New York, NY	prevention of <i>Clostridioides difficile</i> (C. difficile) infections (Fast Track)	Phase II www.pfizer.com
PF-07845104 (saRNA vaccine)	Pfizer New York, NY	prevention of influenza (adults)	Phase I www.pfizer.com
PF-07872412 (polysaccharide conjugate vaccine)	Pfizer New York, NY	prevention of pneumococcal infections (Fast Track)	Phase I www.pfizer.com
PF-07911145 (BNT167) (mRNA vaccine)	BioNTech Cambridge, MA Pfizer New York, NY	prevention of shingles (herpes zoster)	Phase I www.pfizer.com
PF-07915234 (modRNA vaccine)	Pfizer New York, NY	prevention of shingles (herpes zoster)	Phase II www.pfizer.com
PF-07921186 (modRNA vaccine)	Pfizer New York, NY	prevention of shingles (herpes zoster)	Phase II www.pfizer.com
PF-07921188 (modRNA vaccine)	Pfizer New York, NY	prevention of shingles (herpes zoster)	Phase II www.pfizer.com
PF-07926307 (BNT161+BNT162b2) (mRNA vaccine)	BioNTech Cambridge, MA Pfizer New York, NY	prevention of COVID-19 and influenza (Fast Track)	Phase III www.biontech.com www.pfizer.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
PF-07941314 (protein subunit and mRNA vaccine)	Pfizer New York, NY	prevention of influenza and RSV (adults)	Phase I www.pfizer.com
PF-07960613 (protein subunit and mRNA vaccine)	Pfizer New York, NY	prevention of COVID-19 and RSV	Phase II www.pfizer.com
PF-07985819 (mRNA vaccine)	Pfizer New York, NY	prevention of pandemic influenza	Phase I www.pfizer.com
PfSPZ-Cvac (malaria vaccine)	Sanaria Rockville, MD	prevention of malaria with malaria chemoprophylaxis	Phase II www.sanaria.com
PfSPZ vaccine (radiation attenuated vaccine)	Sanaria Rockville, MD	prevention of malaria (Fast Track)	Phase II www.sanaria.com
PHV01 (rVSV Marburg virus vaccine)	Public Health Vaccines Cambridge, MA	prevention of Marburg virus disease	Phase I www.phvaccines.com
PHV02 (rVSV Nipah vaccine)	Public Health Vaccines Cambridge, MA	prevention of Nipah virus infections	Phase I www.phvaccines.com
Qdenga [®] dengue vaccine booster	Takeda Cambridge, MA	prevention of dengue (Fast Track)	Phase III www.takeda.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
RBI-4000 (RNA vaccine)	Replicate Bioscience San Diego, CA	prevention of rabies	Phase I www.replicatebioscience.com
RiVax® ricin vaccine ORPHAN DRUG	Soligenix Princeton, NJ	prevention of ricin poisoning (Fast Track)	Phase I www.soligenix.com
samRNA vaccine (SAM-LNP-S-TCE)	Gritstone bio Emeryville, CA	prevention of COVID-19	Phase I www.gritstonebio.com
samRNA vaccine (ChAdV68S-TCE)	Gritstone bio Emeryville, CA	prevention of COVID-19	Phase I www.gritstonebio.com
SEQ-400 (bacterial adhesin protein vaccine)	Sequoia Vaccines St. Louis, MO	treatment of recurrent urinary tract infections (Fast Track)	Phase II www.sequoiavaccines.com
SM-p80 (recombinant antigen vaccine)	PAI Life Sciences Seattle, WA	prevention of schistosomiasis	Phase I www.pailifesciences.com
SP0087 (purified vero cell rabies vaccine)	Sanofi Bridgewater, NJ	prevention of rabies	Phase III www.sanofi.com
SP0125 (live attenuated RSV vaccine)	Sanofi Bridgewater, NJ	prevention of RSV (infants and toddlers)	Phase III www.sanofi.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SP0202 (21-valent pneumococcal conjugate vaccine)	Sanofi Bridgewater, NJ SK Biosciences Gyeonggi-do, South Korea	prevention of pneumococcal disease	Phase II www.sanofi.com
SP0218 (vero cell yellow fever vaccine)	Sanofi Bridgewater, NJ	prevention of yellow fever	Phase II www.sanofi.com
SP0230 (multicomponent meningococcal conjugate vaccine)	Sanofi Bridgewater, NJ	prevention of meningococcal group B infections	Phase II www.sanofi.com
		prevention of meningococcal group ABCYW infections	Phase I www.sanofi.com
SP0256 (mRNA RSV combination vaccine)	Sanofi Bridgewater, NJ	prevention of RSV (older adults)	Phase II www.sanofi.com
		prevention of RSV and/or metapneumovirus infections (60 years and older) (18-49 years)	Phase I www.sanofi.com
SP0273 (mRNA quadrivalent influenza vaccine)	Sanofi Bridgewater, NJ	prevention of influenza	Phase I www.sanofi.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
SQP0282/VAC52416 (ExPEC9V) (9-valent extraintestinal pathogenic E. coli [ExPec] vaccine)	Sanofi Bridgewater, NJ Johnson & Johnson Innovative Medicine Raritan, NJ	prevention of invasive ExPec disease	Phase III www.sanofi.com
Spikevax® COVID-19 vaccine, mRNA	Moderna Therapeutics Cambridge, MA	prevention of COVID-19 (6 months to < 12 years)	Phase II/III www.modernatx.com
SQ009 (cell-based influenza H2N3 vaccine)	CSL Seqirus Summit, NJ	prevention of influenza	Phase I www.cslseqirus.us
SQ012 (sa-mRNA influenza vaccine)	CSL Seqirus Summit, NJ	prevention of influenza	Phase I www.cslseqirus.us
SQ036 (aQIVc) (cell-based quadrivalent influenza vaccine)	CSL Seqirus Summit, NJ	prevention of influenza (50 years and older)	Phase III www.cslseqirus.us
THEMBA II T-cell vaccine (saRNA boost vaccine)	ImmunityBio Culver City, CA	prevention of COVID-19	Phase I/II www.immunitybio.com
Triplex (recombinant cytomegalovirus vaccine)	Helocyte New York, NY City of Hope Medical Center Duarte, CA	prevention of CMV	Phase II www.helocyte.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
Typhax (typhoid vaccine)	Matrivax Boston, MA	prevention of typhoid	Phase I www.mativax.com
UB-612 (multitope peptide vaccine)	Vaxxinity Merritt Island, FL	prevention of COVID-19	Phase III www.vaxxinity.com
UniFlu (universal influenza vaccine)	Emergent BioSolutions Gaithersburg, MD	prevention of influenza	Phase I www.emergentbiosolutions.com
V181 (quadrivalent dengue vaccine)	Merck Rahway, NJ	prevention of dengue (Fast Track)	Phase III www.merck.com
VAX-24 (24-valent pneumococcal conjugate vaccine)	Vaxcyte San Carlos, CA	prevention of pneumococcal infections (infants, 18-64 years, 65 and older) (Fast Track) (Breakthrough Therapy)	Phase II www.vaxcyte.com
VAX-31 (31-valent pneumococcal conjugate vaccine)	Vaxcyte San Carlos, CA	prevention of pneumococcal infections (50 years and older)	Phase II www.vaxcyte.com
VBI-1501 (eVLP vaccine)	VBI Vaccines Cambridge, MA	prevention of CMV	Phase I www.vbivaccines.com
VBI-2601 (BR11-179) (protein-based immunotherapy vaccine)	VBI Vaccines Cambridge, MA Brii Biosciences Durham, NC	treatment of hepatitis B	Phase II www.vbivaccines.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VBI- 2901 (multivalent pan-coronavirus vaccine)	VBI Vaccines Cambridge, MA	prevention of coronavirus infections (COVID-19, SARS, MERS)	Phase I www.vbivaccines.com
VBI-2902 (monovalent eVLP vaccine)	VBI Vaccines Cambridge, MA	prevention of COVID-19	Phase I/II www.vbivaccines.com
VBI-2905 (monovalent eVLP vaccine)	VBI Vaccines Cambridge, MA	prevention of COVID-19 (beta variant)	Phase I www.vbivaccines.com
VEE DNA vaccine (Venezuelan equine encephalitis virus vaccine)	PharmaJet Golden, CO U.S. Department of Defense Arlington, VA	prevention of Venezuelan equine encephalomyelitis	Phase I www.pharmajet.com
VIR-1388 (HIV T-cell vaccine)	Vir Biotechnology San Francisco, CA	prevention of HIV	Phase I www.vir.bio
VLA1601 (inactivated whole virus vaccine)	Valneva Saint-Herblain, France Emergent BioSolutions Gaithersburg, MD	prevention of Zika virus infection	Phase I www.valneva.com
VRON-0200 (intramuscular vaccine with checkpoint inhibitor)	Virion Therapeutics Philadelphia, PA	treatment of hepatitis B (functional cure)	Phase I www.viriontx.com

Infectious Disease

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
VXA-CoV2-1.1-S (recombinant COVID-19 oral vaccine)	Vaxart South San Francisco, CA	prevention of COVID-19	Phase II www.vaxart.com
VXA-CoV2-1.1-S+N (recombinant COVID-19 oral vaccine)	Vaxart South San Francisco, CA	prevention of COVID-19	Phase II www.vaxart.com
VXA-GI.1 (bivalent norovirus vaccine)	Vaxart South San Francisco, CA	prevention of norovirus infections	Phase II www.vaxart.com
VXA-GII.4 (bivalent norovirus vaccine)	Vaxart South San Francisco, CA	prevention of norovirus infections	Phase II www.vaxart.com
VXCO-100 (intramuscular vaccine)	The Vaccine Company South San Francisco, CA	prevention of COVID-19	Phase I
WEVEE VLP (virus-like particles vaccine)	Emergent BioSolutions Gaithersburg, MD	prevention of Western, Eastern and Venezuelan equine encephalitis	Phase I www.emergentbiosolutions.com

Other

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
acne mRNA vaccine	Sanofi Bridgewater, NJ	moderate-to-severe acne (18-45 years)	Phase I/II www.sanofi.com
Diamyd (autoimmune diabetes vaccine) <small>ORPHAN DRUG</small>	Diamyd Medical Stockholm, Sweden	type 1 diabetes (Fast Track)	Phase III www.diamyd.com

Other

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
INO-3107 (DNA vaccine) ORPHAN DRUG	Inovio Pharmaceuticals Plymouth Meeting, PA	recurrent respiratory papillomatosis (Breakthrough Therapy)	Phase III www.inovio.com
PRGN-2012 (gene therapy vaccine) ORPHAN DRUG	Precigen Germantown, MD	recurrent respiratory papillomatosis (Breakthrough Therapy)	Phase I/II www.precigen.com
TOL-3021 (antigen-specific immunotherapeutic vaccine)	Tolerion Portola Valley, CA	type 1 diabetes	Phase II www.tolerion.bio
UB-312 (synthetic peptide vaccine) ORPHAN DRUG	Vaxxinity Merritt Island, FL	multiple system atrophy, Parkinson's disease	Phase I www.vaxxinity.com
UB-313 (CGRP inhibitor vaccine)	Vaxxinity Merritt Island, FL	migraine	Phase I www.vaxxinity.com
VXX-401 (synthetic peptide vaccine)	Vaxxinity Merritt Island, FL	hypercholesterolemia	Phase I www.vaxxinity.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 **July 8, 2024**. The medicines in this listing include medicines being developed by U.S.-based companies conducting clinical trials in the United States and abroad, PhRMA-member companies conducting clinical 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.

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 any 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.