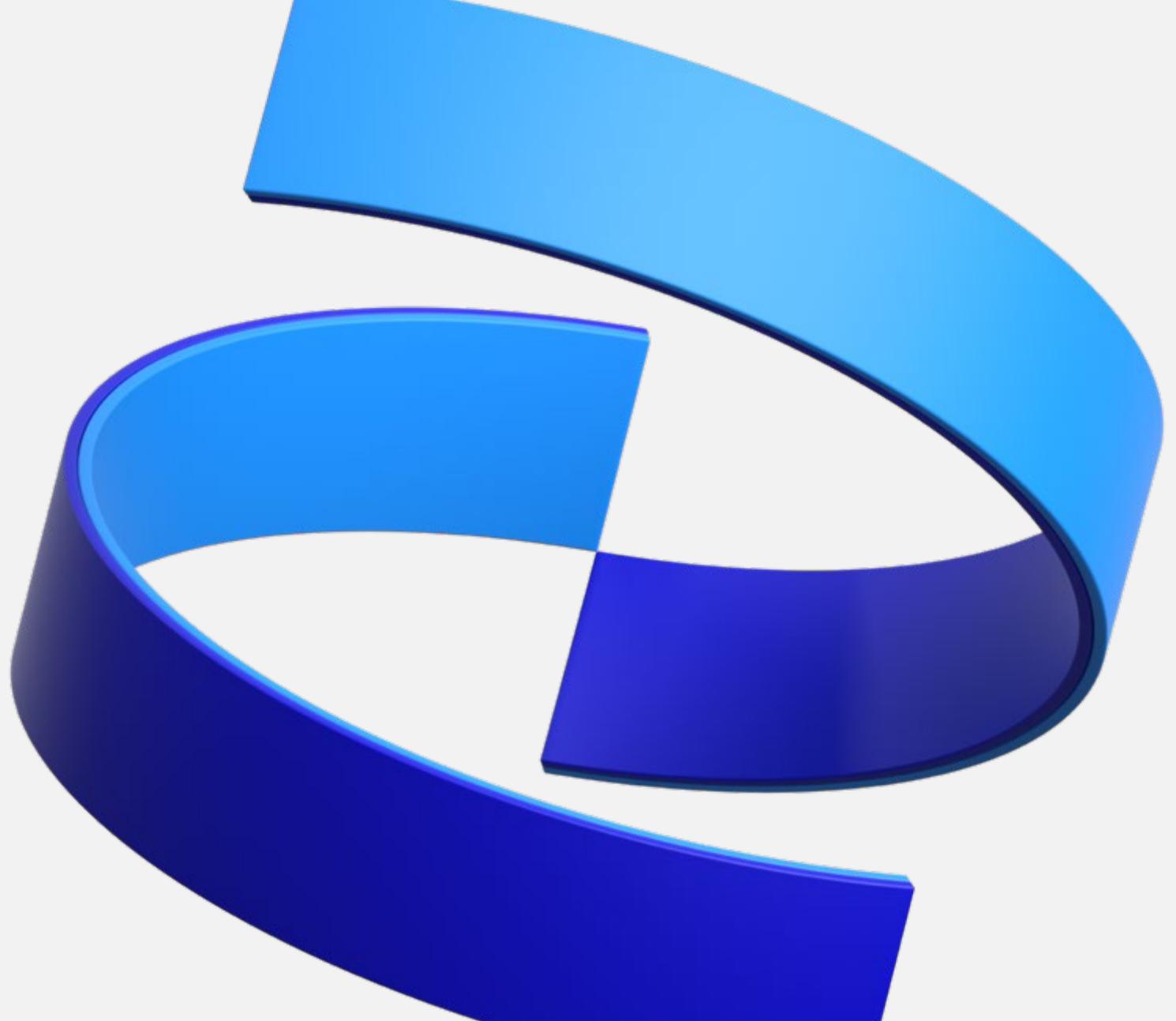




Pfizer Pipeline

July 28, 2022



Disclaimer

- As some programs are still confidential, some candidates may not be identified in this list. In these materials, Pfizer discloses Mechanism of Action (MOA) information for some candidates in Phase 1 and for all candidates from Phase 2 through regulatory approval. With a view to expanding the transparency of our pipeline, Pfizer is including new indications or enhancements, which target unmet medical need or represent significant commercial opportunities. The information contained on these pages is correct as of July 28, 2022.
- Visit www.pfizer.com/pipeline, Pfizer's online database where you can learn more about our portfolio of new medicines and find out more about our Research and Development efforts around the world.



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Pfizer Pipeline Snapshot



Pfizer Pipeline Snapshot as of July 28, 2022

Pipeline represents progress of R&D programs as of July 28, 2022

- 12 programs advanced or are new
- 1 program discontinued since last update
- Included are 67 NMEs, 37 additional indications

Recent Approvals

- COMIRNATY® (COVID-19 Vaccine, mRNA), for COVID-19 infection in individuals 12 through 15 years of age (U.S.)

COMIRNATY® Booster (Pfizer/BioNTech COVID-19 vaccine) expanded Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on May 17, 2022 to include a booster dose after completion of the primary series of the Pfizer-BioNTech COVID-19 Vaccine in children 5 through 11 years of age (U.S.). On June 17, 2022, FDA granted EUA of the Pfizer-BioNTech COVID-19 Vaccine as a three 3-µg dose series for children 6 months through 4 years of age (also referred to as 6 months to less than 5 years of age) (U.S.).



Pfizer Pipeline Snapshot as of May 3, 2022

Pipeline represents progress of R&D programs as of May 3, 2022

- 15 programs advanced or are new
- 4 programs discontinued since last update
- Included are 65 NMEs, 31 additional indications

Recent Approvals

- NGENLA (somatropin) for the treatment of pediatric patients with growth hormone deficiency (E.U.)
- APEXXNAR (PCV20) for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults (E.U.)
- VYDURA (rimegepant) for both the acute treatment of migraine and prophylaxis of episodic migraine in adults (E.U.)

COMIRNATY® Booster (Pfizer/BioNTech COVID-19 vaccine) expanded Emergency Use Authorization (EUA) from FDA on Mar 29, 2022 to include a second booster dose in adults ages 50 years and older who have previously received a first booster of any authorized COVID-19 vaccine, and a second booster dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine (U.S.). Conditional marketing authorization (CMA) from the European Medicines Agency (EMA) on the first booster was expanded to include adolescents 12 through 17 years of age on Feb 24, 2022 (E.U.)

Inflammation and Immunology (1 of 2)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Alopecia Areata (BREAKTHROUGH)	Phase 3	New Molecular Entity
Etrasimod	S1P Inhibitor	Ulcerative Colitis (moderately to severely active)	Phase 3	New Molecular Entity
Dekavil ¹	IL-10	Rheumatoid Arthritis (Biologic)	Phase 2	New Molecular Entity
PF-06480605	TNFSF15 Blocker	Ulcerative Colitis (Biologic)	Phase 2	New Molecular Entity
ritlecitinib +/- zimlovisertib; ritlecitinib + tofacitinib	JAK3/TEC Inhibitor/IRAK4 Inhibitor/JAK Inhibitor	Rheumatoid Arthritis	Phase 2	New Molecular Entity
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Ulcerative Colitis	Phase 2	Product Enhancement
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Crohn's Disease	Phase 2	Product Enhancement
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Vitiligo	Phase 2	Product Enhancement
PF-06823859	interferon, beta 1, fibroblast (IFNB1) Blocker	Dermatomyositis (Biologic) (ORPHAN - U.S., E.U., PRIME - E.U.)	Phase 2	New Molecular Entity
PF-07038124	Topical PDE4 Inhibitor	Atopic Dermatitis and Psoriasis	Phase 2	New Molecular Entity
Etrasimod	S1P Inhibitor	Eosinophilic Esophagitis	Phase 2	Product Enhancement
Etrasimod	S1P Inhibitor	Alopecia Areata	Phase 2	Product Enhancement
Etrasimod	S1P Inhibitor	Crohn's disease ²	Phase 2	Product Enhancement
► Etrasimod	S1P Inhibitor	Atopic Dermatitis	Phase 2	Product Enhancement

► Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

1. Clinical trial to be conducted by Philogen S.p.A
2. Etrasimod in Crohn's disease is a Ph2/3 clinical trial

Inflammation and Immunology (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
RIST4721 ¹	CXCR2 antagonist	Palmoplantar Pustulosis	Phase 2	New Molecular Entity
▶ RIST4721 ¹	CXCR2 antagonist	Hidradenitis Suppurativa	Phase 2	Product Enhancement
PF-06835375	anti-CXCR5	Immune Thrombocytopenic Purpura (Biologic)	Phase 2	Product Enhancement
PF-06835375	anti-CXCR5	Lupus (Biologic)	Phase 1	New Molecular Entity
PF-07054894	CCR6 Antagonist	Inflammatory Bowel Disease	Phase 1	New Molecular Entity
PF-07242813	CD1a inhibitor	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity
PF-07295324	Topical Soft JAK Inhibitor ²	Atopic Dermatitis	Phase 1	New Molecular Entity
PF-07259955	Topical Soft JAK Inhibitor ²	Atopic Dermatitis	Phase 1	New Molecular Entity
▶ PF-07275315	anti-IL4/13/TSLP	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity

▶ Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

1. RIST4721 is being developed by Arista Therapeutics, Inc. in collaboration with Arena Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc.
2. Molecule designed for minimal systemic exposure.

Internal Medicine (1 of 2)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Myfembree	Oral GnRH receptor antagonist	Combination with estradiol and norethindrone acetate for Endometriosis (U.S.)	Registration	Product Enhancement
Myfembree	Oral GnRH receptor antagonist	Combination with estradiol and norethindrone acetate for contraceptive efficacy	Phase 3	Product Enhancement
ervogastat (PF-06865571)	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 2	New Molecular Entity
ervogastat (PF-06865571) + clesacostat (PF-05221304)	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor; Acetyl CoA-Carboxylase (ACC) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis (FAST TRACK; U.S.)	Phase 2	New Molecular Entity
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Diabetes Mellitus-Type 2	Phase 2	New Molecular Entity
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Obesity	Phase 2	Product Enhancement
APD418	beta-3 adrenergic receptor (AdrR) antagonist & cardiac myotrope	Acute Heart Failure With Reduced Ejection Fraction (FAST TRACK – U.S.)	Phase 2	New Molecular Entity
Temanogrel	Serotonin 2A (5-HT2A) receptor inverse agonist	Microvascular Obstruction (MVO)	Phase 2	New Molecular Entity
Temanogrel	Serotonin 2A (5-HT2A) receptor inverse agonist	Raynaud's Phenomenon Secondary to Systemic Sclerosis	Phase 2	Product Enhancement

► Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

Internal Medicine (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) Monoclonal Antibody	Cancer Cachexia (Biologic)	Phase 1	New Molecular Entity
▶ ponsegromab (PF-06946860) ¹	Growth Differentiation Factor 15 (GDF15) Monoclonal Antibody	Heart Failure (Biologic)	Phase 1	Product Enhancement
PF-07081532	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Diabetes Mellitus-Type 2 and Obesity	Phase 1	New Molecular Entity
PF-07258669	Melanocortin-4 receptor (MC4R) Antagonist	Geriatric Anorexia	Phase 1	New Molecular Entity
PF-07202954	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 1	New Molecular Entity

▶ Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com Regulatory Designations – See Definitions in Backup

1. Ponsegromab heart failure indication was previously listed together with cancer cachexia, now listed separately

Oncology (1 of 2)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Ibrance (palbociclib)	CDK 4,6 kinase inhibitor	ER+/HER2+ Metastatic Breast Cancer (PATINA)	Phase 3	Product Enhancement
sasanlimab (PF-06801591) + Bacillus Calmette-Guerin (BCG)	Anti-PD-1	Non-Muscle-Invasive Bladder Cancer (Biologic)	Phase 3	New Molecular Entity
Talzenna (talazoparib)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for 1 st Line Metastatic Castration Resistant Prostate Cancer	Phase 3	Product Enhancement
Talzenna (talazoparib)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for DDR-deficient Metastatic Castration Sensitive Prostate Cancer	Phase 3	Product Enhancement
Xtandi (enzalutamide)	Androgen receptor inhibitor	Non-metastatic High-Risk Castration Sensitive Prostate Cancer	Phase 3	Product Enhancement
Braftovi (encorafenib) + Erbitux® (cetuximab)	<i>BRAF</i> kinase inhibitor and anti EGFR	1 st line <i>BRAF</i> -mutant Metastatic Colorectal Cancer	Phase 3	Product Enhancement
Braftovi (encorafenib) + Mektovi (binimetinib) + Keytruda® (pembrolizumab)	<i>BRAF</i> kinase inhibitor and MEK inhibitor and anti PD-1	<i>BRAF</i> -mutant Metastatic or Unresectable Locally Advanced Melanoma	Phase 3	Product Enhancement
Elranatamab	BCMA-CD3 Bispecific Antibody	Multiple Myeloma Double-Class Exposed (Biologic)	Phase 3	Product Enhancement
► Elranatamab	BCMA-CD3 Bispecific Antibody	Newly Diagnosed Multiple Myeloma (Biologic)	Phase 3	Product Enhancement
Braftovi (encorafenib) + Mektovi (binimetinib)	<i>BRAF</i> kinase inhibitor and MEK inhibitor	1 st line and 2 nd line <i>BRAF</i> -mutant Metastatic Non-Small Cell Lung Cancer	Phase 2	Product Enhancement
ARV-471	ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer	Phase 2	New Molecular Entity

► Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

- Erbitux® is a registered trademark of ImClone LLC
- Keytruda® is a registered trademark of Merck Sharp & Dohme Corp.
- PROTAC® is a registered U.S. trademark of Arvinas.

Oncology (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Elranatamab	BCMA-CD3 Bispecific Antibody	Multiple Myeloma Triple-Class Refractory (Biologic)	Phase 2	New Molecular Entity
PF-07901801 (TTI-622)	CD47-SIRP α Fusion Protein	Hematological malignancies (Biologic)	Phase 2	New Molecular Entity
Ibrance + ARV-471	CDK 4,6 kinase inhibitor ER-targeting PROTAC [®] protein degrader	ER+/HER2- Metastatic Breast Cancer	Phase 2	Product Enhancement
PF-06647020	PTK7 Targeted Cytotoxicity	NSCLC (Biologic)	Phase 1	New Molecular Entity
PF-06821497	EZH2 Inhibitor	Prostate Cancer	Phase 1	New Molecular Entity
PF-06873600	CDK 2,4,6 Inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07062119	GUCY2c CD3 Bispecific Antibody	Advanced/Metastatic Gastrointestinal Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06940434	Integrin alpha-V/beta-8 Antagonist	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07209960	interleukin 15 (IL15) Activator	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07220060	CDK4 Inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07265807	AXL/MERTK Inhibitor	Solid Tumors	Phase 1	New Molecular Entity
PF-07104091	CDK2 Inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07248144	KAT6A Epigenetic modifier	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07284890	<i>BRAF</i> BP kinase Inhibitor	Melanoma	Phase 1	New Molecular Entity
PF-07284892	SHP2 tyrosine phosphatase Inhibitor	Cancer	Phase 1	New Molecular Entity
PF-07257876	CD47xPDL1 Bispecific	NSCLC (Biologic)	Phase 1	New Molecular Entity
PF-07263689	OBIR-2 Therapeutic Vaccine	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07260437	B7H4-CD3 Bispecific	Breast Cancer Metastatic (Biologic)	Phase 1	New Molecular Entity
PF-07265028	HPK1 Inhibitor	Solid Tumors	Phase 1	New Molecular Entity
PF-07104091 + PF-07220060	CDK2 + CDK4 inhibitors	Breast Cancer Metastatic	Phase 1	New Molecular Entity
▶ PF-07104091 + Ibrance	CDK2 + CDK4/6 inhibitors	Breast Cancer Metastatic	Phase 1	Product Enhancement

▶ Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

• PROTAC[®] is a registered U.S. trademark of Arvinas.



Rare Disease



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
somatrogon (PF-06836922)	Human Growth Hormone Agonist	Pediatric Growth Hormone Deficiency (Biologic) (ORPHAN – U.S.) ¹	Registration	New Molecular Entity
PF-07265803	p38 Mitogen-Activated Protein Kinase Antagonist	Dilated Cardiomyopathy due To Lamin A/C Gene Mutation (ORPHAN - U.S.)	Phase 3	New Molecular Entity
fidanacogene elaparovec (PF-06838435)	Gene Therapy, coagulation factor IX (F9)	Hemophilia (Biologic) (BREAKTHROUGH, ORPHAN - U.S., E.U., PRIME - E.U.)	Phase 3	New Molecular Entity
giroctocogene fitelparovec (PF-07055480)	Gene Therapy, coagulation factor VIII (F8)	Hemophilia (Biologic) (RMAT, FAST TRACK, ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
somatrogon (PF-06836922)	Human Growth Hormone Agonist	Adult Growth Hormone Deficiency (Biologic) (ORPHAN - U.S., E.U.)	Phase 3	Product Enhancement
fordadistrogene movaparovec (PF-06939926)	Gene Therapy, minidystrophin	Duchenne Muscular Dystrophy Ambulatory (Biologic) (FAST TRACK – U.S.; ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
marstacimab (PF-06741086)	anti-Tissue Factor Pathway Inhibitor (anti-TFPI)	Hemophilia (Biologic) (FAST TRACK – U.S.; ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
PF-06730512	fusion protein containing SLIT ligand portion of ROBO2 receptor	Focal Segmental Glomerulosclerosis (FSGS); ROBO2-Fc (Biologic)	Phase 2	New Molecular Entity
recifercept	Soluble recombinant human fibroblast growth factor receptor 3 (FGFR3) decoy	Achondroplasia (Biologic) (ORPHAN - U.S., EU)	Phase 2	New Molecular Entity
PF-06755347	Immunomodulation	Chronic Inflammatory Demyelinating Polyneuropathy (ORPHAN-US); Primary Immune Thrombocytopenia (Biologic)	Phase 1	New Molecular Entity
PF-07209326	E-Selectin antagonist	Sickle Cell Disease (Biologic) (ORPHAN - U.S.)	Phase 1	New Molecular Entity

► Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com Regulatory Designations – See Definitions in Backup

1. In Jan. 2022 the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for somatrogon in pediatric patients. Pfizer is evaluating the FDA's comments and will work with the agency to determine an appropriate path forward.

Vaccines (1 of 2)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection Booster (in collaboration with BioNTech) (U.S.; EU) ¹	Registration	Product Enhancement
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (U.S.; EU – 5 to 11 years of age) ²	Registration	Product Enhancement
► Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection Booster (in collaboration with BioNTech) (U.S. – 5 to 11 years of age) ²	Registration	Product Enhancement
► Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (children 2 to 4 years of age) ³	Registration	Product Enhancement
► Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (infants 6 months to <24 months) ³	Registration	Product Enhancement
PF-06425090	Prophylactic Vaccine	Primary <i>Clostridioides difficile</i> infection (FAST TRACK)	Phase 3	New Molecular Entity
PF-06482077	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (pediatric) (BREAKTHROUGH, FAST TRACK)	Phase 3	Product Enhancement

► Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

1. COMIRNATY® Booster (Pfizer/BioNTech COVID-19 vaccine) expanded EUA from FDA on Dec 9, 2021 to include individuals 16 years of age and older and on Jan 3, 2022 to include individuals 12 years of age and older; received CMA from the EMA on Oct 5, 2021 for 18 years of age and older. EUA from FDA was expanded on Mar 29, 2022 to include a second booster dose in adults ages 50 years and older who have previously received a first booster of any authorized COVID-19 vaccine, and a second booster dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine. CMA from the EMA on first booster was expanded to include adolescents 12 through 17 years of age on Feb 24, 2022
2. Comirnaty (Pfizer/BioNTech COVID-19 vaccine) received EUA from FDA on Oct 29, 2021 and CMA from EMA on Nov 25, 2021 for 5 to 11 years of age. On May 17, 2022 FDA expanded emergency use authorization (EUA) to include a booster dose after completion of the primary series of the Pfizer-BioNTech COVID-19 Vaccine in children 5 through 11 years of age.
3. Comirnaty (Pfizer/BioNTech COVID-19 vaccine) received Emergency Use Authorization (EUA) from FDA on Jun 17, 2022 as a three 3-µg dose series for children 6 months through 4 years of age. On July 8, 2022 a variation was submitted to the European Medicines Agency (EMA) requesting to update the Conditional Marketing Authorization (CMA) in the European Union (EU) with data supporting the vaccination of children ages 6 months to less than 5 years with the 3-µg dose of COMIRNATY® (COVID-19 vaccine, mRNA) as a three-dose series.

Vaccines (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (maternal) (BREAKTHROUGH, FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (older adult) (BREAKTHROUGH - U.S.)	Phase 3	Product Enhancement
Omicron variant (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (adults)	Phase 3	New Molecular Entity
PF-06886992	Prophylactic Vaccine	Serogroups ABCWY Meningococcal Infections (adolescent and young adults)	Phase 3	New Molecular Entity
PF-06842433	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (infants and children)	Phase 2	New Molecular Entity
PF-06760805	Prophylactic Vaccine	Invasive Group B Streptococcus Infection (maternal) (FAST TRACK)	Phase 2	New Molecular Entity
PF-07307405	Prophylactic Vaccine	Lyme disease (FAST TRACK)	Phase 2	New Molecular Entity
PF-07252220	Prophylactic mRNA Vaccine	Influenza (adults)	Phase 1	New Molecular Entity

► Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

Hospital (Anti-Infectives)



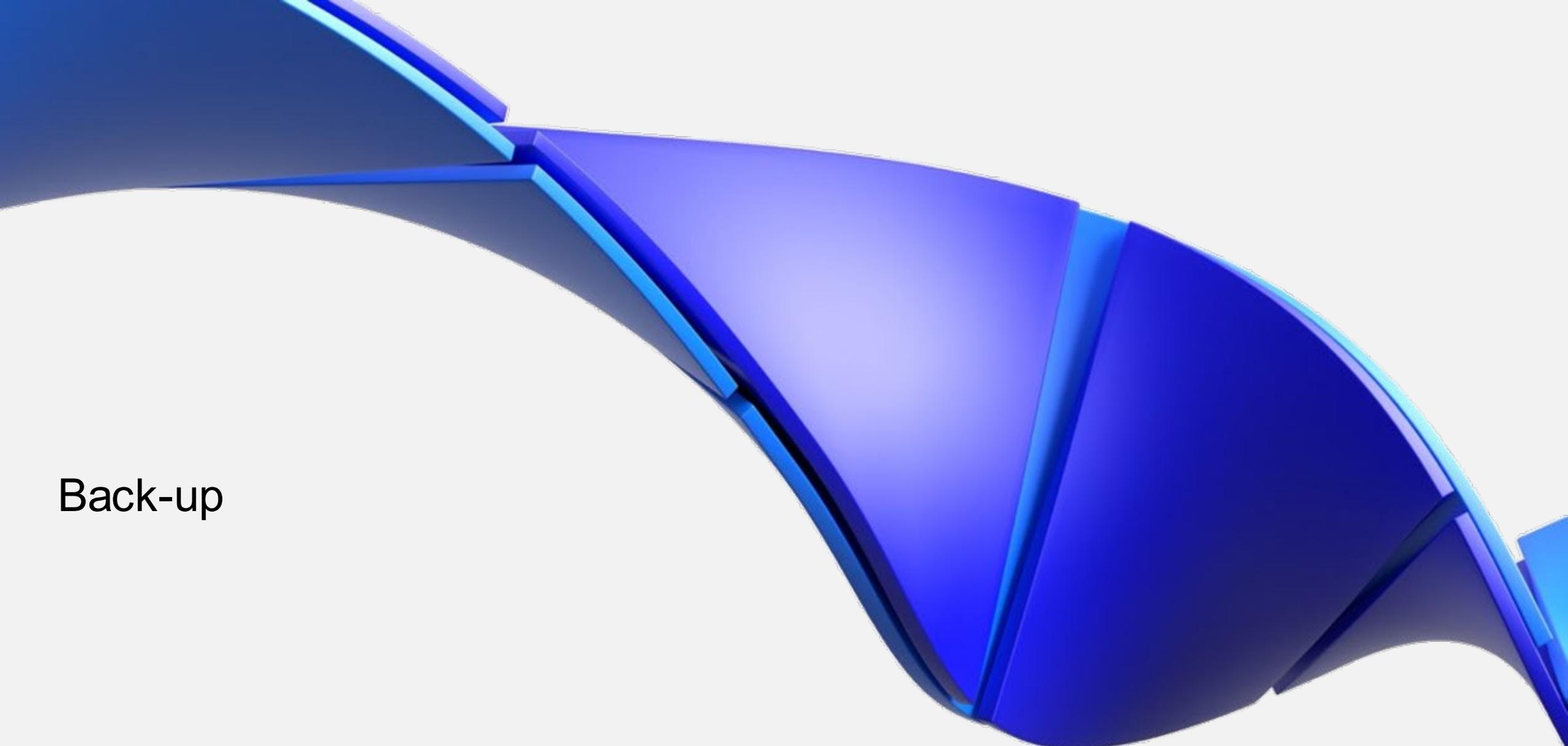
Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (high risk population) (U.S.; EU) ¹	Registration	New Molecular Entity
aztreonam-avibactam (PF-06947387)	Beta Lactam/Beta Lactamase Inhibitor	Infections due to Gram-negative bacteria with limited or no treatment options	Phase 3	New Molecular Entity
Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (standard risk population)	Phase 3	Product Enhancement
Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (post exposure prophylaxis)	Phase 3	Product Enhancement
Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (pediatric)	Phase 3	Product Enhancement
fosmanogepix (APX001)	Gwt1 inhibitor	Treatment of invasive fungal infections	Phase 2	New Molecular Entity
▶ Sisunatovir (PF-07923568)	Respiratory syncytial virus fusion inhibitor	Respiratory Syncytial Virus Infection (FAST TRACK)	Phase 2	New Molecular Entity
▶ Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (pregnant women)	Phase 1	Product Enhancement
▶ PF-07923567 / RV-299	N-protein inhibitor	Respiratory Syncytial Virus Infection	Phase 1	New Molecular Entity

▶ Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com
Regulatory Designations – See Definitions in Backup

1. PAXLOVID™ (nirmatrelvir [PF-07321332] and ritonavir) received EUA from FDA on Dec 22, 2021 for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg [88 lbs]) and who are at high risk for progression to severe COVID-19 (U.S.) and CMA from EMA on Jan 28, 2022 for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19

Programs Discontinued from Development since May 3, 2022

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
danuglipron (PF-06882961) + PF-06865571	Glucagon-like peptide 1 receptor (GLP-1R) Agonist; Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 1	New Molecular Entity



Back-up

Regulatory Designations

- **Fast Track (U.S.)** is a designation available to a product if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. This designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. More information about the qualifying criteria and features of the Fast Track program can be found on the FDA's website.
- **Breakthrough Designation (U.S.)** may be granted to a drug (alone or in combination with 1 or more other drugs) intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A drug that receives breakthrough designation is eligible for all fast track designation features and an FDA commitment to work closely with the sponsor to ensure an efficient drug development program. More information about the qualifying criteria and features of the Breakthrough program can be found on the FDA's website.
- **Orphan Drug (U.S.)** - Orphan drug status may be granted to drugs and biologics that are intended for the diagnosis, prevention, or treatment of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but where it is unlikely that expected sales of the product would cover the sponsor's investment in its development. More information about the qualifying criteria, features, and incentives involved in an orphan drug designation can be found on the FDA's website.
- **Orphan Drug (E.U.)** - Orphan drug status may be granted to drugs and biologics that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 persons in the European Union at the time of submission of the designation application, or that affect more than 5 in 10,000 persons but where it is unlikely that expected sales of the product would cover the investment in its development. More information about the qualifying criteria, features, and incentives involved in an orphan drug designation can be found on the EMA's website.
- A U.S. drug application will receive a **priority review designation** if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority designation is intended to direct overall attention and resources to the evaluation of such applications. A priority review designation means that FDA's goal is to take action on the marketing application within 6 months of receipt (compared with 10 months under standard review). More information about the qualifying criteria and features of a priority review designation can be found on the FDA's website.
- **PRIME (E.U.)** - The PRIME scheme is applicable to products under development which are innovative and yet to be placed on the EU market. The scheme aims to support medicinal products of major public health interest and in particular from the viewpoint of therapeutic innovation. Medicines eligible for PRIME must address an unmet medical need, i.e., for which there exists no satisfactory method of diagnosis, prevention or treatment in the Community or, if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected. A product eligible for PRIME should demonstrate the potential to address, to a significant extent, the unmet medical need, for example by introducing new methods of therapy or improving existing ones. Data available to support the request for eligibility should support the claim to address the unmet medical need through a clinically meaningful improvement of efficacy, such as having an impact on the prevention, onset or duration of the condition, or improving the morbidity or mortality of the disease. EMA will provide early and enhanced support to optimize the development of eligible medicines. Products granted PRIME support are anticipated to benefit from the Accelerated Assessment procedure. More information about the qualifying criteria and features of PRIME and Accelerated Assessment can be found on the EMA's website.
- **Regenerative Medicine Advanced Therapy (RMAT) (U.S.)** is a designation that is granted to regenerative medicine therapies intended to treat, modify, reverse, or cure a serious condition, for which preliminary clinical evidence indicates that the medicine has the potential to address an unmet medical need. The RMAT designation includes all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with FDA.