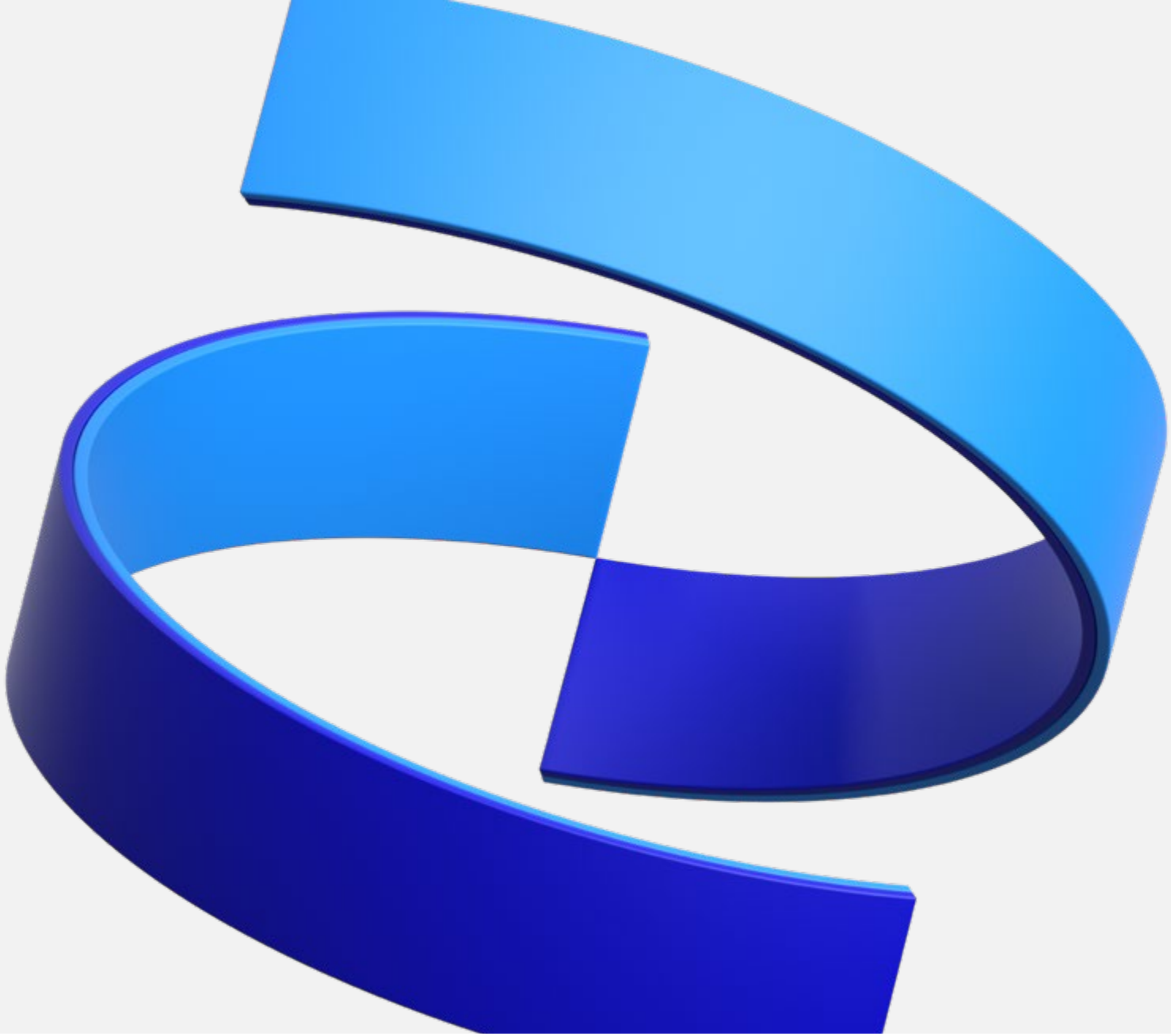
Pfizer Pipeline

May 2, 2023



Disclaimer

- The information contained on these pages is accurate as of May 2, 2023 to the best of Pfizer's knowledge. Pfizer assumes no obligation to update this information.

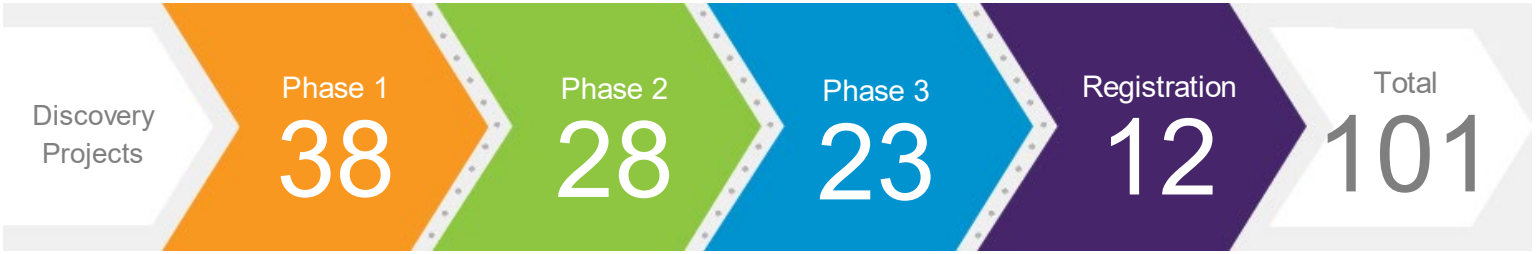
- This presentation includes forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. There can be no guarantees with respect to pipeline products that clinical studies will be successful, the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Additional information regarding these and other factors can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in our subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

- 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.

- 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.

Table of Contents

Pfizer Pipeline Snapshot



Pfizer Pipeline Snapshot as of May 2, 2023

Pipeline represents progress of R&D programs as of May 2, 2023

- 12 programs advanced or are new
- 6 programs discontinued since last update
- Included are 70 NMEs, 31 additional indications

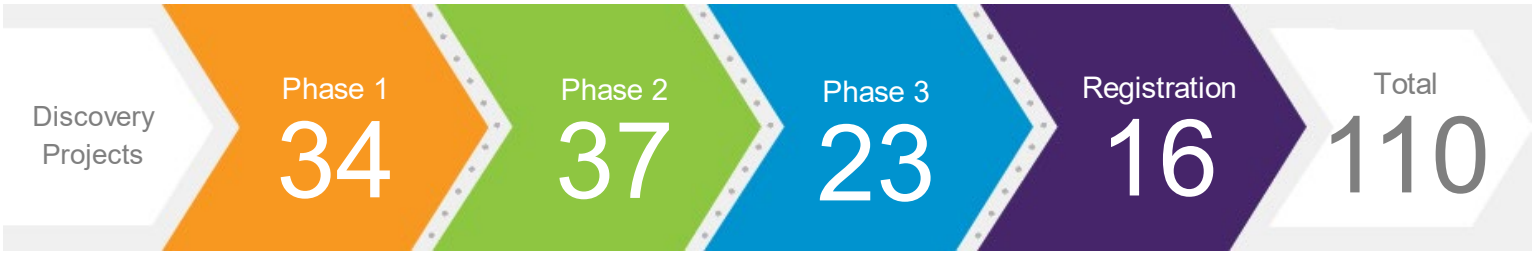
Recent Approvals

The U.S. Food and Drug Administration (FDA) has approved ZAVZPRET™ (zavegepant), the first and only calcitonin gene-related peptide (CGRP) receptor antagonist nasal spray for the acute treatment of migraine with or without aura in adults

The FDA also granted emergency use authorization (EUA) to provide a single booster dose of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine in children 6 months through 4 years of age (also referred to as under 5 years of age) at least 2 months after completion of primary vaccination with three doses of the Pfizer-BioNTech COVID-19 Original Vaccine

The European Medicines Agency (EMA) granted full authorization to Paxlovid for use in reducing the risk of hospitalization or death in patients with COVID-19 at increased risk of the disease becoming severe

The U.S. Food and Drug Administration (FDA) has approved PREVNAR 20®(20-valent Pneumococcal Conjugate Vaccine) for the prevention of invasive pneumococcal disease (IPD) caused by the 20 Streptococcus pneumoniae (pneumococcal) serotypes contained in the vaccine in infants and children six weeks through 17 years of age, and for the prevention of otitis media in infants six weeks through five years of age caused by the original seven serotypes contained in PREVNAR®.



Pfizer Pipeline Snapshot as of January 31, 2023

Pipeline represents progress of R&D programs as of January 31, 2023

- 16 programs advanced or are new
- 8 programs discontinued since last update
- Included are 72 NMEs, 38 additional indications

Recent Approvals

The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) of the Pfizer-BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine as the third 3-µg dose in the three-dose primary series for children 6 months through 4 years of age. The European Medicines Agency (EMA) granted Conditional Marketing Authorization (CMA) for a 10-µg booster dose of the Pfizer-BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine in children 5 through 11 years of age.

Anti-Infectives

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
aztreonam-avibactam (PF-06947387)	Beta Lactam/Beta Lactamase Inhibitor	Infections due to Gram-negative bacteria with limited or no treatment options (adult)	Phase 3	New Molecular Entity
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 in pediatrics and adults (FAST TRACK – U.S.)	Phase 2	New Molecular Entity
PF-07923567 / RV-299	N-protein inhibitor	Respiratory Syncytial Virus infection	Phase 1	New Molecular Entity
CTB+AVP (PF-07612577)	Beta Lactam/Beta Lactamase Inhibitor	Complicated urinary tract infections (cUTI), including pyelonephritis	Phase 1	New Molecular Entity
PF-07817883	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 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

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 – U.S.)	Registration	New Molecular Entity
Etrasimod	S1P Inhibitor	Ulcerative Colitis (moderately to severely active)	Registration	New Molecular Entity
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Vitiligo	Phase 3	Product Enhancement
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
Dekavil[1]	IL-10	Rheumatoid Arthritis (Biologic)	Phase 2	New Molecular Entity
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
PF-06835375	anti-CXCR5	Immune Thrombocytopenic Purpura (Biologic)	Phase 2	Product Enhancement

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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
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[1]	Atopic Dermatitis	Phase 1	New Molecular Entity
PF-07275315	anti-IL-4/ IL-13/ TSLP	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity
PF-07264660	anti-IL-4/ IL-13/ IL-33	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity
PF-07261271	p40/TL1a bi-specific	Inflammatory Bowel Disease (Biologic)	Phase 1	New Molecular Entity

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Regulatory Designations – See Definitions in Backup

1. Molecule designed for minimal systemic exposure.

Internal Medicine

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Zavegepant (oral)[1]	calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine Prevention	Phase 2	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
lotiglipron (PF-07081532)	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Diabetes Mellitus-Type 2	Phase 2	New Molecular Entity
lotiglipron (PF-07081532)	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Obesity	Phase 2	Product Enhancement
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) Monoclonal Antibody	Cancer Cachexia (Biologic)	Phase 2	New Molecular Entity
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) Monoclonal Antibody	Heart Failure (Biologic)	Phase 2	Product Enhancement
PF-07258669	Melanocortin-4 receptor (MC4R) Antagonist	Malnutrition	Phase 1	New Molecular Entity
PF-07328948	Branched chain ketoacid dehydrogenase kinase (BDK) inhibitor	Heart Failure with Preserved Ejection Fraction	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. Zavegepant (oral) in Migraine Prevention is a Ph2/3 clinical trial

Oncology (1 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
►Elranatamab	BCMA-CD3 Bispecific Antibody	Multiple Myeloma Triple-Class Refractory (Biologic) (PRIORITY REVIEW, BREAKTHROUGH, FAST TRACK, ORPHAN – U.S.) (ORPHAN, PRIME – EU)	Registration	New Molecular Entity
►Braftovi (encorafinib) + Mektovi (binimetinib)	*BRAF* kinase inhibitor and MEK inhibitor	1st line BRAF-mutant Metastatic Non-Small Cell Lung Cancer	Registration	Product Enhancement
►Talzenna (talazoparib)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for 1st Line Metastatic Castration Resistant Prostate Cancer (PRIORITY REVIEW – U.S.)	Registration	Product Enhancement
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 DNA Damage Repair (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 (encorafinib) + Erbitux® (cetuximab)	*BRAF* kinase inhibitor and anti EGFR	1st line BRAF-mutant Metastatic Colorectal Cancer	Phase 3	Product Enhancement
Braftovi (encorafinib) + Mektovi (binimetinib) + Keytruda® (pembrolizumab)	*BRAF* kinase inhibitor and MEK inhibitor and anti PD-1	BRAF-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 Post-Transplant Maintenance (Biologic)	Phase 3	Product Enhancement
Elranatamab	BCMA-CD3 Bispecific Antibody	Newly Diagnosed Multiple Myeloma Transplant-Ineligible (Biologic)	Phase 3	Product Enhancement
►Vepdegestrant (ARV-471)	ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer	Phase 3	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)

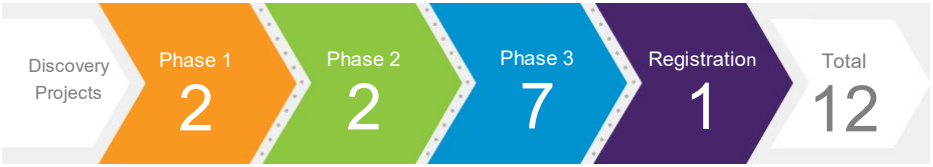
Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Ibrance + Vepdegestrant (ARV-471)	CDK 4,6 kinase inhibitor ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer	Phase 2	New Molecular Entity
►Vepdegestrant (ARV-471)	ER-targeting PROTAC® protein degrader	ER+/HER2- Early Breast Cancer	Phase 2	Product Enhancement
maplirpacept (TTI-622)	CD47-SIRPα Fusion Protein	Hematological Malignancies (Biologic)	Phase 2	New Molecular Entity
PF-06821497 + enzalutamide	EZH2 Inhibitor	Prostate Cancer	Phase 1	New Molecular Entity
PF-06647020	PTK7 Targeted Cytotoxicity	NSCLC (Biologic)[1]	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	KAT6 Epigenetic modifier	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07284892[2]	SHP2 tyrosine phosphatase Inhibitor	Cancer	Phase 1	New Molecular Entity
PF-07257876	CD47xPDL1 Bispecific	NSCLC (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-07799933 BRAF Class 2	BRAF Class 1 and Class 2 inhibitor	Cancer	Phase 1	New Molecular Entity
PF-07104091	CDK2 inhibitor	Ovarian Cancer	Phase 1	Product Enhancement
PF-07220060 + enzalutamide	CDK4 inhibitor	Prostate Cancer	Phase 1	New Molecular Entity
PF-07799544	MEK Brain Penetrant Inhibitor	Solid Tumors	Phase 1	New Molecular Entity
►PF-07248144 + PF-07220060	KAT6 Epigenetic modifier + CDK4 Inh	Breast Cancer Metastatic	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. PF-06647020 being co-developed with AbbVie
2. PF-07284892 is being tested as a single agent and in combination therapy

- PROTAC® is a registered U.S. trademark of Arvinas

Rare Diseases



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.)	Registration	New Molecular Entity
fidanacogene elaparvovec (PF-06838435)	Gene therapy, coagulation factor IX (F9)	Hemophilia B (Biologic) (RMAT, BREAKTHROUGH, ORPHAN - U.S., E.U., PRIME - E.U.)	Phase 3	New Molecular Entity
giroctocogene fitelparvovec (PF-07055480)	Gene therapy, coagulation factor VIII (F8)	Hemophilia A (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 movaparvovec (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	Hemophilia (Biologic) (FAST TRACK – U.S.; ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
Inclacumab	Anti-P-selectin inhibitor	Sickle Cell Disease (Biologic) (ORPHAN – U.S.)	Phase 3	New Molecular Entity
►Voxelotor	HbS polymerization inhibitor	Sickle Cell Disease - Pediatric	Phase 3	Product Enhancement
PF-06730512	Fusion protein containing SLIT ligand portion of ROBO2 receptor	Focal Segmental Glomerulosclerosis (FSGS) (Biologic)	Phase 2	New Molecular Entity
GBT021601	HbS polymerization inhibitor	Sickle Cell Disease (ORPHAN – U.S.)	Phase 2	New Molecular Entity
PF-07209326	Anti-E-selectin inhibitor	Sickle Cell Disease (Biologic) (ORPHAN - U.S.)	Phase 1	New Molecular Entity
VTX-801	Recombinant AAV (rAAV) vector-based gene therapy	Wilson Disease (Biologic) [1]	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. Clinical trial conducted by Vivet Therapeutics

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 (in collaboration with BioNTech) (EU – children 6 months to 4 years of age)	Registration	Product Enhancement
BNT162b2 bivalent (BA.4/BA.5)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (U.S.; EU – 5 - 11 years of age)	Registration	Product Enhancement
►BNT162b2 bivalent (BA.4/BA.5)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (U.S. – children 6 months to 4 years of age)	Registration	Product Enhancement
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (older adult) (BREAKTHROUGH, PRIORITY REVIEW – U.S.)	Registration	New Molecular Entity
►PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (maternal) (FAST TRACK, BREAKTHROUGH, PRIORITY REVIEW – U.S)	Registration	Product Enhancement
PF-06886992	Prophylactic Vaccine	Serogroups ABCWY Meningococcal Infections (adolescent and young adults) (U.S.)	Registration	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

In April 2023, the FDA amended the emergency use authorization (EUA) of the Pfizer-BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine to simplify the vaccination schedule for most individuals. This action included authorizing the bivalent vaccine to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations such as older adults and the immunocompromised. The monovalent Pfizer-BioNTech COVID-19 vaccine is no longer authorized for use in the US. For detailed information regarding the filing status of the Pfizer-BioNTech COVID vaccines, please see Pfizer's Quarterly Report on Form 10-Q once it is filed with the SEC, which is expected to be in May 2023.

Vaccines (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-06425090	Prophylactic Vaccine	Primary *Clostridioides difficile* infection (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-07307405	Prophylactic Vaccine	Lyme disease (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-07252220	Prophylactic mRNA Vaccine	Influenza (adults)	Phase 3	New Molecular Entity
PF-06842433	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (infants and children) (BREAKTHROUGH – U.S.)	Phase 2	New Molecular Entity
PF-06760805	Prophylactic Vaccine	Invasive Group B Streptococcus Infection (maternal) (BREAKTHROUGH, FAST TRACK – U.S., PRIME - EU)	Phase 2	New Molecular Entity
PF-07845104	Prophylactic saRNA Vaccine	Influenza (adults)	Phase 1	New Molecular Entity
PF-07926307	Prophylactic mRNA Vaccine	Combination COVID-19 & Influenza (FAST TRACK – U.S.)	Phase 1	New Molecular Entity
►PF-07941314	Prophylactic Vaccine	Combination Respiratory Syncytial Virus & Influenza (adults)	Phase 1	New Molecular Entity
►PF-07831694[1]	Prophylactic Vaccine	*Clostridioides difficile* infection (novel formulations)	Phase 1	New Molecular Entity
►PF-07911145[2]	Prophylactic mRNA Vaccine	Varicella	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. PF-07831694 is currently in a Ph1/2 study
2. PF-07911145 is currently in a Ph1/2 study

Programs Discontinued from Development since January 31, 2023

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
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
PF-06480605	TNFSF15 Blocker	Ulcerative Colitis (Biologic)	Phase 2	New Molecular Entity
RIST4721	CXCR2 antagonist	Palmoplantar Pustulosis	Phase 2	New Molecular Entity
RIST4721	CXCR2 antagonist	Hidradenitis Suppurativa	Phase 2	Product Enhancement

Appendix

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.
- **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.
- **Priority Review** (U.S.) 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 act 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.
- **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.
- **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 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.