



Pfizer Pipeline

January 30, 2024



Disclaimer

- The information contained on these pages is accurate as of January 30, 2024 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, that 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 or implied by 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	4
Anti-Infectives	5
Inflammation and Immunology	6
Internal Medicine	7-8
Oncology	9-13
Rare Diseases/Non-Malignant Hematology	14
Vaccines	15
Programs Discontinued Since Last Update	16
Appendix: Regulatory Designation Definitions	17-19

Pfizer Pipeline Snapshot



Pfizer Pipeline Snapshot as of January 30, 2024

Recent Approvals

Pipeline represents progress of R&D programs as of January 30, 2024

- 39 programs advanced or are new (includes 26 legacy Seagen programs)
- 3 programs discontinued since last update
- Included are 64 NMEs, 48 additional indications

The U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application for XTANDI® (enzalutamide), for the treatment of patients with nonmetastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR). (partnered with Astellas Pharma Inc.)

The European Commission (EC) granted conditional marketing authorization for ELREXFIO® (elranatamab) for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

The FDA approved PADCEV® (enfortumab vedotin-ejfv, an antibody-drug conjugate [ADC]) with KEYTRUDA® (pembrolizumab, a PD-1 inhibitor) for the treatment of adult patients with locally advanced or metastatic urothelial cancer (la/mUC). (partnered with Astellas Pharma Inc.)

The EC approved TALZENNA® (talazoparib), an oral poly ADP-ribose polymerase (PARP) inhibitor, in combination with XTANDI® (enzalutamide), for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.



Pfizer Pipeline Snapshot as of October 31, 2023

Anti-Infectives



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
▶ aztreonam-avibactam (PF-06947387)	Beta lactam/beta lactamase inhibitor	cIAI, HAP/VAP, cUTI including pyelonephritis and infections due to aerobic gram-negative organisms in adult patients (ACCELERATED ASSESSMENT – E.U.)	Registration	New Molecular Entity
PAXLOVID™	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (pediatric)	Phase 3	Product Enhancement
▶ sisunatovir (PF-07923568)	Respiratory syncytial virus fusion inhibitor	Respiratory Syncytial Virus infection in (Adults) (FAST TRACK – U.S.) ¹	Phase 3	New Molecular Entity
▶ sisunatovir (PF-07923568)	Respiratory syncytial virus fusion inhibitor	Respiratory Syncytial Virus infection (Pediatric) (FAST TRACK – U.S.)	Phase 2	Product Enhancement
PF-07817883	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (FAST TRACK – U.S.)	Phase 2	New Molecular Entity
CTB+AVP (PF-07612577)	Beta lactam/Beta lactamase inhibitor	Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis (FAST TRACK – 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. Sisunatovir for RSV in adults is a Ph2/3 clinical trial

Inflammation and Immunology



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Vitiligo	Phase 3	Product Enhancement
Dazukibart (PF-06823859)	interferon, beta 1, fibroblast (IFNB1) blocker	Dermatomyositis, Polymyositis (Biologic) (ORPHAN - U.S., E.U., PRIME - E.U.)	Phase 3	New Molecular Entity
fordadistrogene movaparvovec (PF-06939926)	Gene therapy, minidystrophin	Duchenne Muscular Dystrophy Ambulatory (Biologic) (FAST TRACK, RPD – U.S.; ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
▶ fordadistrogene movaparvovec (PF-06939926)	Gene therapy, minidystrophin	Duchenne Muscular Dystrophy Ambulatory (Biologic) (2-3 year-old boys)	Phase 2	Product Enhancement
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Ulcerative Colitis	Phase 2	Product Enhancement
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Crohn's Disease	Phase 2	Product Enhancement
Dekavil ¹	IL-10	Rheumatoid Arthritis (Biologic)	Phase 2	New Molecular Entity
VELSIPITY™ (etrasimod)	S1P inhibitor	Crohn's disease ²	Phase 2	Product Enhancement
VELSIPITY™ (etrasimod)	S1P inhibitor	Eosinophilic Esophagitis	Phase 2	Product Enhancement
VELSIPITY™ (etrasimod)	S1P inhibitor	Atopic Dermatitis	Phase 2	Product Enhancement
VELSIPITY™ (etrasimod)	S1P inhibitor	Alopecia Areata	Phase 2	Product Enhancement
PF-06835375	anti-CXCR5	Immune Thrombocytopenic Purpura (Biologic)	Phase 2	New Molecular Entity
PF-07275315	anti-IL-4/ IL-13/ TSLP	Atopic Dermatitis (Biologic)	Phase 2	New Molecular Entity
PF-07264660	anti-IL-4/ IL-13/ IL-33	Atopic Dermatitis (Biologic)	Phase 2	New Molecular Entity
Dazukibart (PF-06823859)	interferon, beta 1, fibroblast (IFNB1) blocker	Lupus (Biologic)	Phase 2	Product Enhancement
PF-06835375	anti-CXCR5	Lupus (Biologic)	Phase 1	Product Enhancement
PF-07054894	CCR6 antagonist	Inflammatory Bowel Disease	Phase 1	New Molecular Entity
PF-07261271	p40/TL1a bi-specific	Inflammatory Bowel Disease (Biologic)	Phase 1	New Molecular Entity
▶ PF-07899895	SIK inhibitor	Ulcerative Colitis	Phase 1	New Molecular Entity
▶ PF-07868489	anti-BMP9	Pulmonary Arterial Hypertension (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. Clinical trial conducted by Philogen S.p.A
2. Etrasimod in Crohn's disease is a Ph2/3 clinical trial

Internal Medicine (1 of 2)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
fidanacogene elaparvovec (PF-06838435)	Gene therapy, coagulation factor IX (F9)	Hemophilia B (Biologic) (RMAT, BREAKTHROUGH – U.S., ORPHAN - U.S., E.U.)	Registration	New Molecular Entity
▶ marstacimab (PF-06741086)	Anti-tissue factor pathway inhibitor	Hemophilia (Biologic) (FAST TRACK – U.S.; ORPHAN - U.S., E.U.)	Registration	New Molecular Entity
NGENLA™ (somatrogon)	Human growth hormone agonist	Adult Growth Hormone Deficiency (Biologic) (ORPHAN - U.S., E.U.)	Phase 3	Product Enhancement
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
Inclacumab (PF-07940370)	Anti-P-selectin inhibitor	Sickle Cell Disease (Biologic) (ORPHAN – U.S., RARE PEDIATRIC DISEASE – U.S.)	Phase 3	New Molecular Entity
Oxbryta® (voxelotor)	HbS polymerization inhibitor	Sickle Cell Disease - Pediatric	Phase 3	Product Enhancement
ZAVZPRET™ (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	Type 2 Diabetes Mellitus	Phase 2	New Molecular Entity
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) agonist	Obesity	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. Zavegepant (oral) for Migraine Prevention is a Ph2/3 clinical trial

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 2	New Molecular Entity
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) monoclonal antibody	Heart Failure (Biologic)	Phase 2	Product Enhancement
PF-07940367 (GBT021601)	HbS polymerization inhibitor	Sickle Cell Disease (ORPHAN – U.S.) ¹	Phase 2	New Molecular Entity
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
PF-07853578	PNPLA3 modulator	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 1	New Molecular Entity
PF-07293893	AMPK γ 3 activator	Heart Failure	Phase 1	New Molecular Entity
PF-06954522	Glucagon-like peptide 1 receptor (GLP-1R) agonist	Type 2 Diabetes Mellitus	Phase 1	New Molecular Entity
▶ PF-07976016	Weight loss agent	Obesity	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-07940367 (GBT021601) is currently in a Ph2/Ph3 study

Oncology (1 of 5)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
► TIVDAK® (tisotumab vedotin)	TF-directed antibody-drug conjugate	Recurrent or Metastatic Cervical Cancer (innovaTV 301) (Biologic) (PRIORITY REVIEW – U.S.) ¹	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 (CREST) (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 (TALAPRO-3)	Phase 3	Product Enhancement
BRAFTOVI® (encorafenib) + ERBITUX® (cetuximab) + chemotherapy	BRAF kinase inhibitor	1 st line BRAF-Mutant Metastatic Colorectal Cancer (BREAKWATER)	Phase 3	Product Enhancement
ELREXFIO™ (elranatamab-bcmm)	BCMA-CD3 bispecific antibody	Multiple Myeloma Double-Class Exposed (MM-5) (Biologic)	Phase 3	Product Enhancement
ELREXFIO™ (elranatamab-bcmm)	BCMA-CD3 bispecific antibody	Newly Diagnosed Multiple Myeloma Post-Transplant Maintenance (MM-7) (Biologic)	Phase 3	Product Enhancement
ELREXFIO™ (elranatamab-bcmm)	BCMA-CD3 bispecific antibody	Newly Diagnosed Multiple Myeloma Transplant-Ineligible (MM-6) (Biologic)	Phase 3	Product Enhancement
vepedgestrant (ARV-471)	ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer ² (VERITAC 2)	Phase 3	New Molecular Entity
► IBRANCE® + vepdegestrant (ARV-471)	CDK 4,6 kinase inhibitor ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer ² (VERITAC 1)	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.

1. TIVDAK® is being co-developed with Genmab
2. Vepdegestrant is being co-developed with Arvinas

Oncology (2 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
► PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Cisplatin-Ineligible/Decline Muscle-Invasive Bladder Cancer (EV-303) (Biologic) ¹	Phase 3	Product Enhancement
► PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Cisplatin-Eligible Muscle-Invasive Bladder Cancer (EV-304) (Biologic) ¹	Phase 3	Product Enhancement
► TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	HER2+ Adjuvant Breast Cancer (CompassHER2 RD)	Phase 3	Product Enhancement
► TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	2L/3L HER+ Metastatic Breast Cancer (HER2CLIMB-02)	Phase 3	Product Enhancement
► TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	1L HER2+ Maintenance Metastatic Breast Cancer (HER2CLIMB-05)	Phase 3	Product Enhancement
► TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	1L HER2+ Metastatic Colorectal Cancer (MOUNTAINEER-03)	Phase 3	Product Enhancement
► Disitamab vedotin (DV)	HER2-directed antibody-drug conjugate	1L HER2 (≥IHC1+) Metastatic Urothelial Cancer (SGNDV-001) (Biologic) ²	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

1. PADCEV® is being co-developed with Astellas
2. Disitamab vedotin (DV) is being co-developed with RemeGen

Oncology (3 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
vepedegestrant (ARV-471)	ER-targeting PROTAC [®] protein degrader	ER+/HER2- Early Breast Cancer ¹	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 2	New Molecular Entity
PF-07220060	CDK4 inhibitor	Breast Cancer Metastatic	Phase 2	New Molecular Entity
▶ PADCEV [®] (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Locally Advanced or Metastatic Solid Tumors (Biologic) ²	Phase 2	Product Enhancement
▶ TIVDAK [®] (tisotumab vedotin)	TF directed antibody-drug conjugate	Advanced Solid Tumors (Biologic) ³	Phase 2	Product Enhancement
▶ TUKYSA [®] (tucatinib)	HER2 tyrosine kinase inhibitor	2L+ Metastatic Urothelial Cancer (HER2 Expression)	Phase 2	Product Enhancement
▶ TUKYSA [®] (tucatinib)	HER2 tyrosine kinase inhibitor	Locally Advanced or Metastatic Solid Tumors with HER2 Alterations	Phase 2	Product Enhancement
▶ Disitamab vedotin (DV)	HER2-directed antibody-drug conjugate	2L+ Urothelial Cancer with HER2 Expression (Biologic) ⁴	Phase 2	Product Enhancement
▶ Disitamab vedotin (DV)	HER2-directed antibody-drug conjugate	Locally Advanced or Metastatic Solid Tumors with HER2 Expression (Biologic) ⁴	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

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

1. Vepdegestrant is being co-developed with Arvinas
2. PADCEV[®] is being co-developed with Astellas
3. TIVDAK[®] is being co-developed with Genmab
4. Disitamab vedotin (DV) is being co-developed with RemeGen



Oncology (4 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-06940434	Integrin alpha-V/beta-8 antagonist	Solid Tumors (Biologic)	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	SHP2 tyrosine phosphatase 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 1 and Class 2 inhibitor	Solid Tumors	Phase 1	New Molecular Entity
PF-07104091	CDK2 inhibitor	Ovarian Cancer	Phase 1	Product Enhancement
PF-07220060 + enzalutamide	CDK4 inhibitor	Prostate Cancer	Phase 1	Product Enhancement
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
► PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Urothelial Cancer (Biologic) ¹	Phase 1	Product Enhancement
► TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	HER2+ Gastrointestinal Cancers (SGNTUC-024) ²	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

1. PADCEV® is being co-developed with Astellas
2. TUKYSA® for HER2+ GI cancers is currently in a Ph1b/2 study

Oncology (5 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
▶ PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer (Biologic) ¹	Phase 1	Product Enhancement
▶ TIVDAK® (tisotumab vedotin)	Tissue Factor-directed antibody-drug conjugate	Recurrent or Metastatic Cervical Cancer (Biologic) ²	Phase 1	Product Enhancement
▶ PF-08046049 (SGN-BB228)	CD228-directed antibody-Anticalin® bispecific protein ³	Advanced Melanoma and Other Solid Tumors (Biologic)	Phase 1	New Molecular Entity
▶ SGN-B6A	Integrin beta-6-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
▶ SGN-B7H4V	B7H4-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
▶ PF-08046052 (SGN-EGFRd2)	EGFR-targeted bispecific gamma delta T-cell engager	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
▶ PF-08046054 (SGN-PDL1V)	PD-L1-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
▶ PF-08046040 (SGN-CD70)	Non-fucosylated CD70-directed antibody	Myelodysplastic Syndrome and Acute Myeloid Leukemia (Biologic)	Phase 1	New Molecular Entity
▶ PF-08046050 (SGN-CEACAM5C)	CEACAM5-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
▶ PF-08046045 (SGN-35T)	CD-30 directed antibody-tripeptide MMAE conjugate	Advanced Solid Tumors and Lymphomas (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. PADCEV® is being co-developed with Astellas
2. TIVDAK® is being co-developed with Genmab
3. Anticalin is a registered US trademark of Pieris Pharmaceuticals GmbH

Rare Diseases/Non-Malignant Hematology



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
VTX-801	Recombinant AAV (rAAV) vector-based gene therapy	Wilson Disease (Biologic) (FAST TRACK – U.S., ORPHAN – U.S.) 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



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
COVID-19 Vaccine	Prophylactic vaccine – mRNA	COVID-19 Infection (in collaboration with BioNTech) (U.S. – 5 - 11 years of age)	Registration	Product Enhancement
COVID-19 Vaccine	Prophylactic vaccine – mRNA	COVID-19 Infection (in collaboration with BioNTech) (U.S. – children 6 months to 4 years of age)	Registration	Product Enhancement
PF-06425090	Prophylactic vaccine – protein subunit	Primary <i>Clostridioides difficile</i> Infection (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-07307405	Prophylactic vaccine – protein subunit	Lyme Disease (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-07252220	Prophylactic vaccine – mRNA	Influenza (adults)	Phase 3	New Molecular Entity
COVID-19 Vaccine	Prophylactic vaccine – mRNA	COVID-19 Infection (in collaboration with BioNTech) (U.S. – 6 months through 11 years of age)	Phase 3	Product Enhancement
▶ PF-07926307	Prophylactic vaccine – mRNA	Combination COVID-19 & Influenza (in collaboration with BioNTech) (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
▶ ABRYSSVO™	Prophylactic vaccine – protein subunit	Respiratory Syncytial Virus Infection (18-59 years of age)	Phase 3	Product Enhancement
PF-06760805	Prophylactic vaccine – polysaccharide conjugate	Invasive Group B Streptococcus Infection (maternal) (BREAKTHROUGH, FAST TRACK – U.S., PRIME - EU)	Phase 2	New Molecular Entity
PF-07960613	Prophylactic vaccine – protein subunit and mRNA	Combination Respiratory Syncytial Virus & modRNA COVID-19	Phase 2	New Molecular Entity
PF-07845104	Prophylactic vaccine – saRNA	Influenza (adults)	Phase 1	New Molecular Entity
PF-07941314	Prophylactic vaccine – protein subunit and mRNA	Combination Respiratory Syncytial Virus & Influenza (adults)	Phase 1	New Molecular Entity
PF-07911145	Prophylactic vaccine – mRNA	Varicella (in collaboration with BioNTech)	Phase 1	New Molecular Entity
ABRYSSVO™	Prophylactic vaccine – protein subunit	Respiratory Syncytial Virus Infection (pediatric)	Phase 1	Product Enhancement
▶ PF-07872412	Prophylactic vaccine – polysaccharide conjugate	Pneumococcal Infection (FAST TRACK – U.S.)	Phase 1	New Molecular Entity
▶ PF-07985819	Prophylactic vaccine – mRNA	Pandemic influenza	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

Programs Discontinued from Development since October 31, 2023

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
fosmanogepix (APX001)	Gwt1 inhibitor	Invasive Fungal Infections ¹	Phase 2	New Molecular Entity
PF-07062119	GUCY2c CD3 bispecific antibody	Advanced/Metastatic Gastrointestinal Cancer (Biologic)	Phase 1	New Molecular Entity
PF-07260437	B7H4-CD3 bispecific	Breast Cancer Metastatic (Biologic)	Phase 1	New Molecular Entity



Appendix

Regulatory Designations (U.S.)

- **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.) 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. More information about the qualifying criteria and features of the RMAT program can be found on the FDA's website.
- **Rare Pediatric Disease (RPD)** (U.S.) designation may be granted to a drug intended to treat a rare pediatric disease that is serious or life-threatening in which the serious or life-threatening manifestations primarily affect patients from birth to 18 years, including neonates, infants, children, and adolescents. More information about the qualifying criteria and features of the RPD program can be found on the FDA's website.
- **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.

Regulatory Designations (E.U.)

- **Orphan Drug** (E.U.) 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.
- **Accelerated Assessment** (E.U.) designation reduces the timeframe for the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) to review a marketing-authorisation application. Applications may be eligible for accelerated assessment if the CHMP decides the product is of major interest for public health and therapeutic innovation.
- **PRIME** (E.U.) designation 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.