

A large, stylized graphic of a blue ribbon forming a continuous loop, resembling a Möbius strip, with a slight gap. The ribbon is a vibrant blue color and is set against a light gray background.

Pfizer Pipeline

November 4, 2025

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- 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 that target unmet medical need or represent potential significant commercial opportunities.
- Visit www.pfizer.com/pipeline, Pfizer's online database where you can learn more about our portfolio of investigational medicines and vaccines and find out more about our Research and Development efforts around the world.



Table of Contents

Pfizer Pipeline Snapshot	4
Inflammation and Immunology	5-6
Internal Medicine	7
Oncology	8-12
Vaccines	13
Programs Discontinued Since Last Update	14
Appendix: Regulatory Designation Definitions	15-18

Pfizer Pipeline Snapshot



Pfizer Pipeline Snapshot as of November 4, 2025

Recent Approvals and Pipeline Highlights

Pipeline represents progress of R&D programs as of November 4, 2025

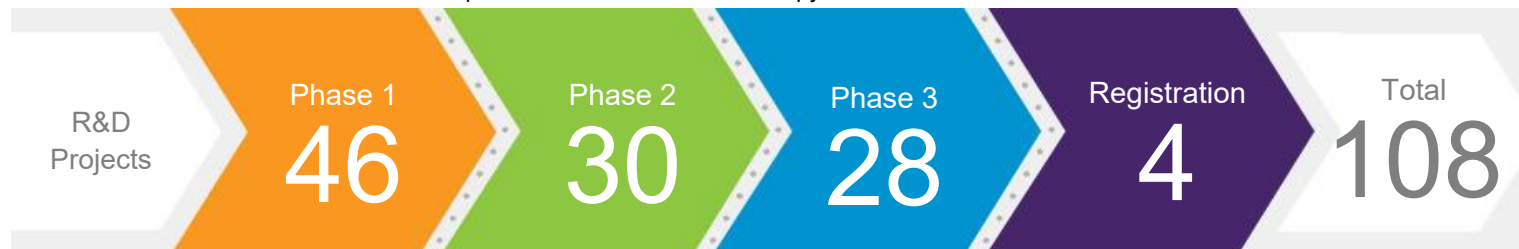
- 11 programs advanced or are new
- 11 program discontinued since last update
- Included are 59 NMEs, 42 additional indications

Pfizer and Astellas Pharma Inc. announced positive topline results from the Phase 3 EV-303 clinical trial (also known as KEYNOTE-905). The EV-303 study is evaluating PADCEV™ (enfortumab vedotin), a Nectin-4 directed antibody-drug conjugate, in combination with KEYTRUDA™ (pembrolizumab), a PD-1 inhibitor, as neoadjuvant and adjuvant treatment (before and after surgery) versus surgery alone, the current standard of care, in patients with muscle-invasive bladder cancer (MIBC) who are not eligible for or declined cisplatin-based chemotherapy. At the first interim efficacy analysis, the trial demonstrated a clinically meaningful and statistically significant improvement in event-free survival (EFS), the study's primary endpoint, and overall survival (OS), a key secondary endpoint, with neoadjuvant and adjuvant PADCEV plus KEYTRUDA versus surgery alone. An additional secondary endpoint of pathologic complete response (pCR) rate was also met.

Pfizer and BioNTech SE announced the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for the companies' LP.8.1-adapted monovalent COVID-19 vaccine (COMIRNATY® LP.8.1; COVID-19 Vaccine, mRNA) for use in adults ages 65 years and older, as well as in individuals ages 5 through 64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Pfizer and Metsera, Inc. announced the companies have entered into a definitive agreement under which Pfizer will acquire Metsera, a clinical-stage biopharmaceutical company accelerating the next generation of medicines for obesity and cardiometabolic diseases. The Boards of Directors of both Metsera and Pfizer have unanimously approved the transaction. The transaction is expected to close in the fourth quarter of 2025, subject to the satisfaction of customary closing conditions, including receipt of required regulatory approvals and approval by Metsera's shareholders.

Pfizer announced positive topline results from the Phase 3 HER2CLIMB-05 trial of first-line combination therapy with the tyrosine kinase inhibitor TUKYSA® (tucatinib) in patients with human epidermal growth factor receptor 2-positive (HER2+) metastatic breast cancer (MBC). HER2CLIMB-05 is evaluating TUKYSA versus placebo, both in combination with first-line standard-of-care maintenance therapy (trastuzumab plus pertuzumab) following chemotherapy-based induction. The trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) by investigator assessment in the TUKYSA arm versus the placebo arm. Treatment with TUKYSA in combination with trastuzumab and pertuzumab was tolerable, with a safety profile generally consistent with the established safety profiles of each individual therapy.



Pfizer Pipeline Snapshot as of August 5, 2025



Inflammation and Immunology (1 of 2)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Vitiligo	Phase 3	Product Enhancement
dazukibart (PF-06823859)	anti-IFN-β	Dermatomyositis, Polymyositis (Biologic) (ORPHAN - U.S. E.U. ¹ , FAST TRACK – U.S., PRIME - E.U.)	Phase 3	New Molecular Entity
HYMPAVZI™ (marstacimab)	Anti-tissue factor pathway inhibitor	Hemophilia (Pediatric: inhibitor and non-inhibitor cohorts) (Biologic) (ORPHAN – U.S.)	Phase 3	Product Enhancement
HYMPAVZI™ (marstacimab)	Anti-tissue factor pathway inhibitor	Hemophilia (inhibitor cohort) (Biologic) (FAST TRACK, ORPHAN – U.S.)	Phase 3	Product Enhancement
osivelotor (PF-07940367)	HbS polymerization inhibitor	Sickle Cell Disease (RPD, FAST TRACK, ORPHAN – U.S.)	Phase 3	New Molecular Entity
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Ulcerative Colitis	Phase 2	Product Enhancement
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Crohn's Disease	Phase 2	Product Enhancement
dazukibart (PF-06823859)	anti-IFN-β	Lupus (Biologic)	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-07275315	anti-IL-4/ IL-13/ TSLP	Asthma (Biologic)	Phase 2	Product Enhancement
PF-07264660	anti-IL-4/ IL-13/ IL-33	Atopic Dermatitis (Biologic)	Phase 2	New Molecular Entity
PF-07868489	anti-BMP9	Pulmonary Arterial Hypertension (Biologic) (ORPHAN – U.S.)	Phase 2	New Molecular Entity
► PF-07261271 ²	p40/TL1a bispecific	Inflammatory Bowel Disease (Biologic)	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



1. Orphan Drug designation for dazukibart applies only to dermatomyositis indication
2. Pfizer and Roche have a global collaboration for PF-07261271 (Anti-p40/TL1A – bispecific antibody)

Inflammation and Immunology (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Dekavil ¹	IL-10	Rheumatoid Arthritis (Biologic)	Phase 1	New Molecular Entity
PF-06835375	anti-CXCR5	Lupus (Biologic)	Phase 1	Product Enhancement
PF-07054894	CCR6 antagonist	Ulcerative Colitis	Phase 1	New Molecular Entity
PF-07899895	SIK inhibitor	Ulcerative Colitis	Phase 1	New Molecular Entity
PF-06414300	undisclosed	Ulcerative Colitis	Phase 1	New Molecular Entity
PF-07905428	undisclosed	Acne	Phase 1	New Molecular Entity
PF-07940369	undisclosed	Anemia of Clonal Hematopoiesis (ACH)	Phase 1	New Molecular Entity
PF-08049820	undisclosed	Atopic Dermatitis	Phase 1	New Molecular Entity
PF-07832837	undisclosed	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity
► PF-07985631	undisclosed	Nephropathy (Biologic)	Phase 1	New Molecular Entity

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Regulatory Designations – See Definitions in Backup

1. Dekavil clinical trial conducted by Philogen S.p.A

Internal Medicine



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 (Pediatric)	Registration	Product Enhancement
ibuzatrelvir (PF-07817883)	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
NURTEC® (rimegepant)	calcitonin gene-related peptide (CGRP) receptor antagonist	Menstrually-Related Migraine	Phase 3	Product Enhancement
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) monoclonal antibody	Cachexia in Cancer (Biologic)	Phase 2	New Molecular Entity
PF-07976016	GIPR antagonist	Chronic Weight Management	Phase 2	New Molecular Entity
ervogastat (PF-06865571)	Diacylglycerol O-Acyltransferase 2 (DGAT2) inhibitor	Metabolic Dysfunction-Associated Steatohepatitis (MASH)	Phase 2	New Molecular Entity
► PF-07328948	Branched chain ketoacid dehydrogenase kinase (BDK) inhibitor	Heart Failure	Phase 2	New Molecular Entity
PF-07258669	Melanocortin-4 receptor (MC4R) antagonist	Malnutrition	Phase 1	New Molecular Entity
PF-07853578	PNPLA3 modulator	Metabolic Dysfunction-Associated Steatohepatitis (MASH)	Phase 1	New Molecular Entity
PF-07999415	undisclosed	Obesity (Biologic)	Phase 1	New Molecular Entity

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Regulatory Designations – See Definitions in Backup

Oncology (1 of 5)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
sasanlimab (PF-06801591) + Bacillus Calmette-Guerin (BCG)	Anti-PD-1	High-Risk Non-Muscle-Invasive Bladder Cancer (CREST) (Biologic)	Registration	New Molecular Entity
► vepdegestrant (ARV-471)	ER-targeting PROTAC protein degrader	ER+/HER2- Metastatic Breast Cancer ESR1mu ¹ (VERITAC 2)	Registration	New Molecular Entity
► PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Cisplatin-Ineligible/Decline Muscle-Invasive Bladder Cancer ² (EV-303) (Biologic) (PRIORITY – U.S.)	Registration	Product Enhancement
IBRANCE® (palbociclib)	CDK 4,6 kinase inhibitor	ER+/HER2+ Metastatic Breast Cancer (PATINA) (BREAKTHROUGH – U.S.)	Phase 3	Product Enhancement
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
ELREXFIO™ (elranatamab-bcmm)	BCMA-CD3 bispecific antibody	Relapsed/Refractory 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
ELREXFIO™ (elranatamab-bcmm)	BCMA-CD3 bispecific antibody	2L+ post-CD38 Relapsed Refractory Multiple Myeloma (MM-32) (Biologic)	Phase 3	Product Enhancement
sigvotatug vedotin (PF-08046047)	Integrin beta-6-directed antibody-drug conjugate	2L+ Metastatic Non-Small Cell Lung Cancer (mNSCLC) (Be6A LUNG-01) (Biologic)	Phase 3	New Molecular Entity
► sigvotatug vedotin (PF-08046047)	Integrin beta-6-directed antibody-drug conjugate	1L Metastatic Non-Small Cell Lung Cancer (mNSCLC) (tps high) (Be6A LUNG-02) (Biologic)	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

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-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 HER2+ 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 (PF-08046051)	HER2-directed antibody-drug conjugate	1L HER2 (≥IHC1+) Metastatic Urothelial Cancer (DV-001) (Biologic) ²	Phase 3	New Molecular Entity
mevrometostat (PF-06821497) + enzalutamide	EZH2 inhibitor + androgen receptor inhibitor	1/2L Metastatic Castration Resistant Prostate Cancer post-Abiraterone (MEVPRO-1)	Phase 3	New Molecular Entity
mevrometostat (PF-06821497) + enzalutamide	EZH2 inhibitor + androgen receptor inhibitor	1L Metastatic Castration Resistant Prostate Cancer NHT naive (MEVPRO-2)	Phase 3	Product Enhancement
► mevrometostat (PF-06821497) + enzalutamide	EZH2 inhibitor + androgen receptor inhibitor	1L Metastatic Castration-Sensitive Prostate Cancer NHT naive (MEVPRO-3)	Phase 3	Product Enhancement
atirmociclib (PF-07220060)	CDK4 inhibitor	1L HR+/HER2- Metastatic Breast Cancer (FourLight-3)	Phase 3	New Molecular Entity
► prifetrastat (PF-07248144)	KAT6 epigenetic modifier	2L/3L HR+/HER2- Metastatic Breast Cancer (KATSIS-1)	Phase 3	New Molecular Entity
► PF-08046054 (PDL1V)	PD-L1-directed antibody-drug conjugate	2L+ Non-Small Cell Lung Cancer (PADL1NK-005) (Biologic)	Phase 3	New Molecular Entity



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Regulatory Designations – See Definitions in Backup

1. Pfizer and Astellas have a collaboration agreement to co-develop PADCEV®
2. Pfizer and RemeGen have a collaboration agreement to co-develop disitamab vedotin (DV)

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- Neoadjuvant Breast Cancer ¹	Phase 2	Product Enhancement
maplirpacept (TTI-622)	CD47-SIRPα fusion protein	Hematological Malignancies (Biologic)	Phase 2	New Molecular Entity
PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Locally Advanced or Metastatic Solid Tumors (EV-202) (Biologic) ²	Phase 2	Product Enhancement
TIVDAK® (tisotumab vedotin)	Tissue Factor-directed antibody-drug conjugate	Advanced Solid Tumors (TV-207) (Biologic) ³	Phase 2	Product Enhancement
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	2L+ HER2+ Metastatic Breast Cancer (HER2CLIMB-04)	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	HER2-directed antibody-drug conjugate	2L+ Metastatic Urothelial Cancer with HER2 Expression (Biologic) ⁴	Phase 2	Product Enhancement
disitamab vedotin	HER2-directed antibody-drug conjugate	Locally Advanced or Metastatic Solid Tumors with HER2 Expression (Biologic) ⁴	Phase 2	Product Enhancement
atirmociclib	CDK4 inhibitor	2L HR+/HER2- Metastatic Breast Cancer (FourLight-1)	Phase 2	Product Enhancement
atirmociclib	CDK4 inhibitor	Early Breast Cancer	Phase 2	Product Enhancement
SSGJ-707 (PF-08634404)	PD-1xVEGF Bispecific Antibody	1L Non-Small Cell Lung Cancer (squamous) (Biologic) ⁵	Phase 2	New Molecular Entity
SSGJ-707 (PF-08634404)	PD-1xVEGF Bispecific Antibody	1L Non-Small Cell Lung Cancer (non-squamous) (Biologic) ⁵	Phase 2	Product Enhancement
SSGJ-707 (PF-08634404)	PD-1xVEGF Bispecific Antibody	1L Metastatic Colorectal Cancer (Biologic) ⁵	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. Pfizer and Arvinas have a collaboration agreement to co-develop vepdegestrant, and intend to identify/select a third party for the commercialization of vepdegestrant
2. Pfizer and Astellas have a collaboration agreement to co-develop PADCEV®
3. Pfizer and Genmab have a collaboration agreement to co-develop TIVDAK®
4. Pfizer and RemeGen have a collaboration agreement to co-develop disitamab vedotin (DV)
5. 3SBio, Inc. is conducting Phase 2 trials in China. Pfizer will conduct global trials, including in China.

Oncology (4 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
tegotociclib (PF-07104091)	CDK2 inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
prifetrastat (PF-07248144)	KAT6 epigenetic modifier	Breast Cancer Metastatic	Phase 1	Product Enhancement
tegotociclib (PF-07104091) + atirmociclib	CDK2 + CDK4 inhibitors	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07799933	BRAF Class 1 and Class 2 inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
PF-07799544	MEK brain penetrant inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
prifetrastat (PF-07248144) + atirmociclib (PF-07220060)	KAT6 epigenetic modifier + CDK4 inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	HER2+ Gastrointestinal Cancers (SGNTUC-024) ¹	Phase 1	Product Enhancement
PF-06940434	Integrin alpha-V/beta-8 antagonist	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
TIVDAK® (tisotumab vedotin)	Tissue Factor-directed antibody-drug conjugate	Recurrent or Metastatic Cervical Cancer (TV-205) (Biologic) ²	Phase 1	Product Enhancement
PF-08046052 (EGFRd2)	EGFR-targeted bispecific gamma delta T-cell engager	Advanced Solid Tumors (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. TUKYSA® for HER2+ GI cancers is currently in a Ph1b/2 study
2. Pfizer and Genmab have a collaboration agreement to co-develop TIVDAK®

Oncology (5 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-08046040 (CD70)	Non-fucosylated CD70-directed antibody	Myelodysplastic Syndrome and Acute Myeloid Leukemia (Biologic)	Phase 1	New Molecular Entity
PF-08046050 (CEACAM5C)	CEACAM5-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
sigvotatug vedotin	Integrin beta-6-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	Product Enhancement
PF-08046044 (35C)	CD30-directed antibody TOPO1 drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07934040 (KRAS)	selective KRAS inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
PF-08052666 (MesoC2)	mesothelin-targeted antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07985045 (KRAS)	selective KRAS inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
PF-08046031 (CD228V)	CD228V directed antibody-drug conjugate	Advanced Melanoma and other Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-08046037 (PDL1iT)	Immunostimulatory Drug Conjugate (ISAC) targeted to PD-L1 with a TLR7 agonist payload	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-08046032 (CD25V)	CD25V directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
► PF-08046876 (B6C)	Integrin beta-6-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity

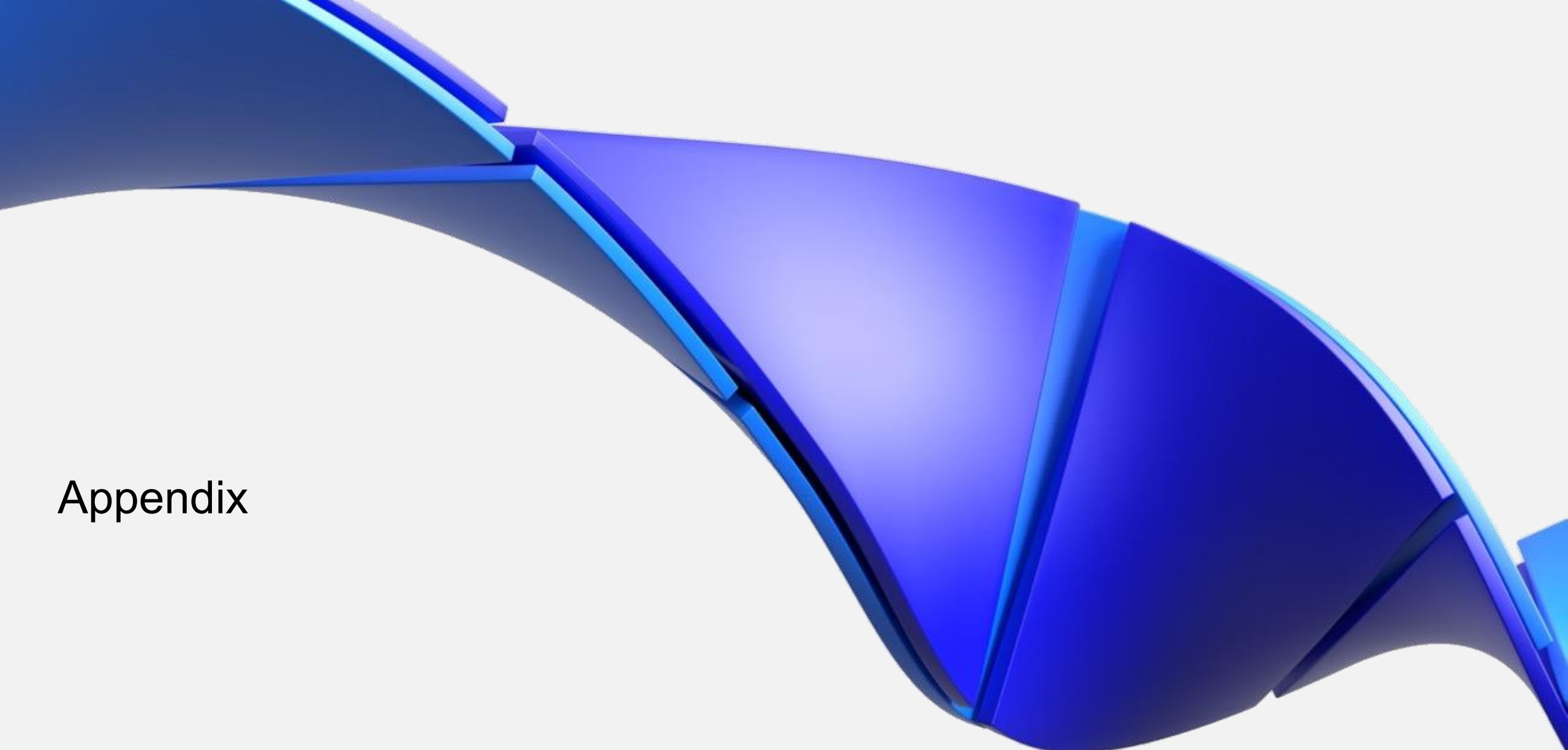
Vaccines



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-07307405	Prophylactic vaccine – protein subunit	Lyme Disease (FAST TRACK – U.S.)	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-06760805	Prophylactic vaccine – polysaccharide conjugate	Invasive Group B Streptococcus Infection (maternal) (BREAKTHROUGH, FAST TRACK – U.S., PRIME - EU)	Phase 3	New Molecular Entity
PF-07252220	Prophylactic vaccine – mRNA	Influenza (adults)	Phase 2	New Molecular Entity
PF-07831694	Prophylactic vaccine – protein subunit	<i>Clostridioides difficile</i> (<i>C. difficile</i>) – updated formulation	Phase 2	New Molecular Entity
PF-07872412	Prophylactic vaccine – polysaccharide conjugate	Pneumococcal Infection (FAST TRACK – U.S.)	Phase 2	New Molecular Entity
PF-07926307	Prophylactic vaccine – mRNA	Combination COVID-19 & Influenza (in collaboration with BioNTech)	Phase 2	New Molecular Entity
PF-07845104	Prophylactic vaccine – saRNA	Influenza (adults)	Phase 1	New Molecular Entity
ABRYSVO®	Prophylactic vaccine – protein subunit	Respiratory Syncytial Virus Infection (pediatric)	Phase 1	Product Enhancement
PF-07985819	Prophylactic vaccine – mRNA	Pandemic influenza	Phase 1	New Molecular Entity

Programs Discontinued from Development since August 5, 2025

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. – children 6 months to 4 years of age)	Registration	Product Enhancement
inclacumab (PF-07940370)	Anti-P-selectin	Vaso-occlusive (VOC) reduction in patients with Sickle Cell Disease (Biologic)	Phase 3	New Molecular Entity
ervogastat (PF-06865571) + clesacostat (PF-05221304)	Diacylglycerol O-Acyltransferase 2 (DGAT2) inhibitor; Acetyl CoA-Carboxylase (ACC) inhibitor	Metabolic Dysfunction-Associated Steatohepatitis (MASH)	Phase 2	New Molecular Entity
PF-07826390 (LILRB1/2)	LILRB1/2 bispecific IgG1 antibody	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer (Biologic)	Phase 1	Product Enhancement
PF-07941944	undisclosed	Respiratory Syncytial Virus Infection	Phase 1	New Molecular Entity
PF-07911145	Prophylactic vaccine – mRNA	Varicella (in collaboration with BioNTech)	Phase 1	New Molecular Entity
PF-08046049 (BB228)	CD228-directed antibody-Anticalin® bispecific protein	Advanced Melanoma and Other Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-08046045 (35T)	CD-30 directed antibody-tripeptide MMAE conjugate	Advanced Solid Tumors and Lymphomas (Biologic)	Phase 1	New Molecular Entity
PF-07314470	undisclosed	Atopic Dermatitis (Biologic)	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

An abstract, three-dimensional graphic composed of several overlapping, curved, blue and purple planes. The planes are arranged in a way that creates a sense of depth and movement, with some planes appearing to be in front of others. The colors transition from a deep blue to a lighter purple. The overall shape is organic and flowing, resembling a stylized wave or a series of connected segments.

Appendix

Regulatory Designations (U.S., 1 of 2)

- **Accelerated Approval** (U.S.) may be granted to a product for a serious or life-threatening disease or condition that has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. Approval under this program requires confirmatory trials using endpoints that demonstrate clinical benefit. More information about the qualifying criteria and features of the Accelerated Approval program can be found on the FDA's website.
- **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. A drug that receives orphan designation is eligible for incentives including tax credits for qualified clinical trials, exemption from user fees, and potential for seven years of market exclusivity after approval. More information about the qualifying criteria, features, and incentives involved in an orphan drug designation can be found on the FDA's website.

Regulatory Designations (U.S., 2 of 2)

- **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.
- **Commissioner's National Priority Review (CNPV)** (U.S.) A U.S. drug application may receive a national priority review designation. The Commissioner will establish national priorities that support this designation which may include such factors as addressing a health crisis, potential innovative therapies, unmet public health needs, and significantly increasing national security. More information about the qualifying criteria and features of national priority review designation can be found on the FDA's web site.

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.