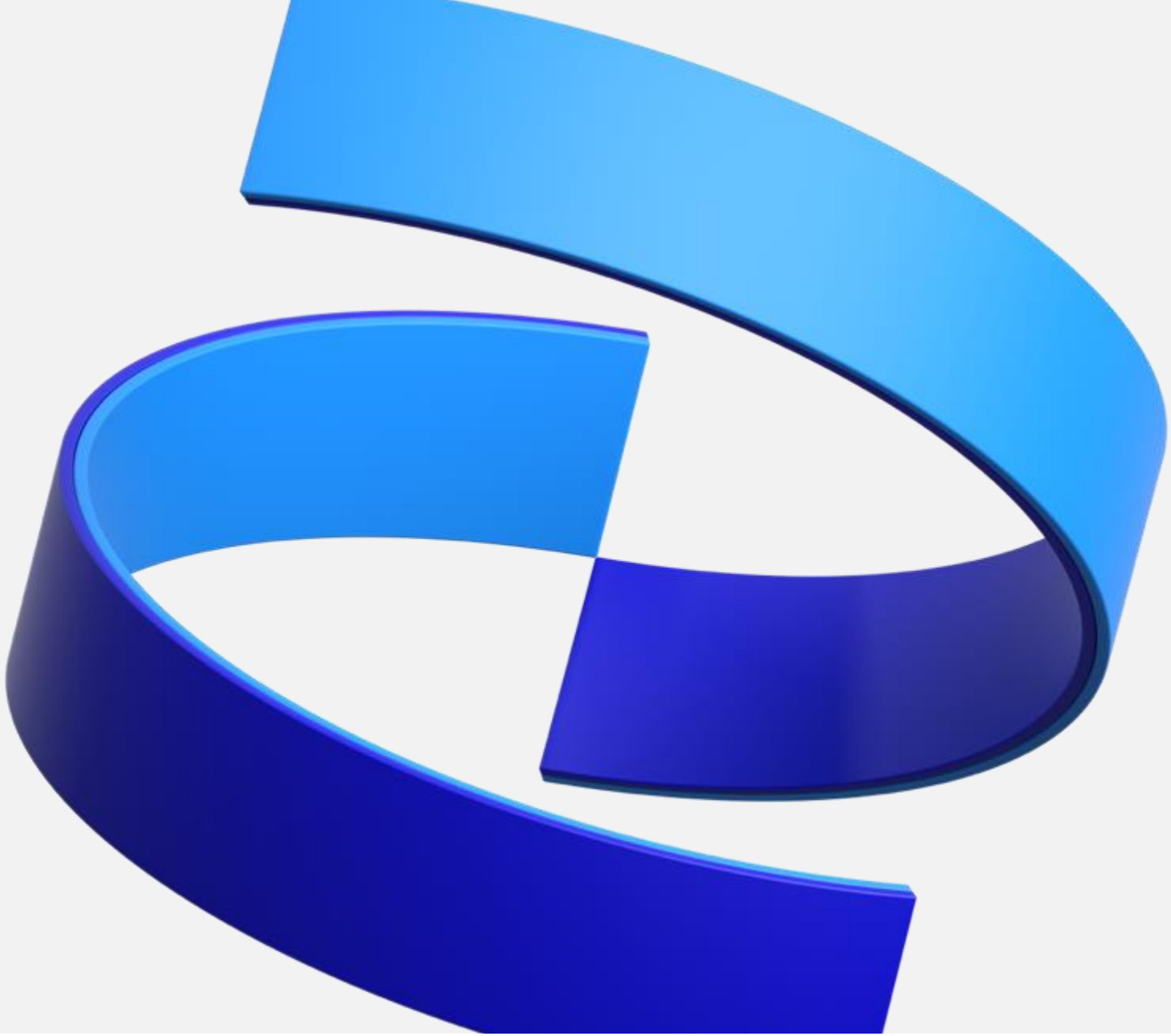
Pfizer Pipeline



August 4, 2026

Disclaimer

- The information contained on these pages is accurate as of August 4, 2026 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 products will advance to the next phase of development, 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, 2025 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 Pfizer's 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 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.

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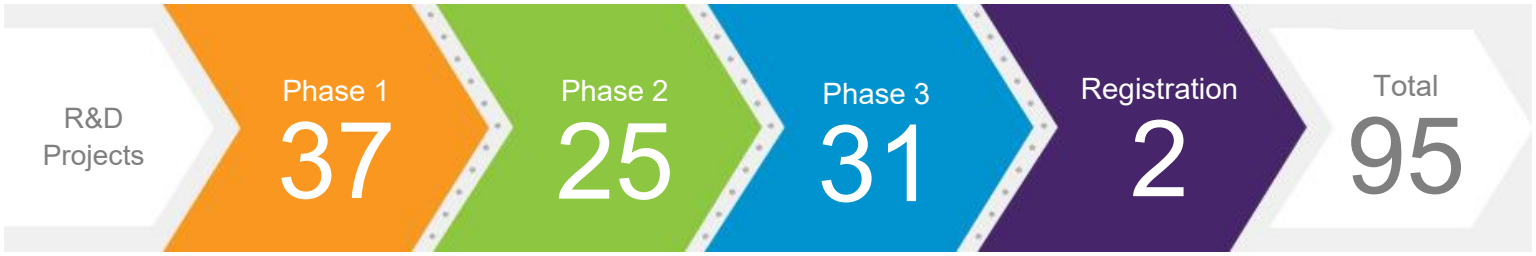
Pfizer Pipeline Snapshot



Pfizer Pipeline Snapshot as of August 4, 2026

Recent Approvals and Pipeline Highlights

Pipeline represents progress of R&D programs as of August 4, 2026

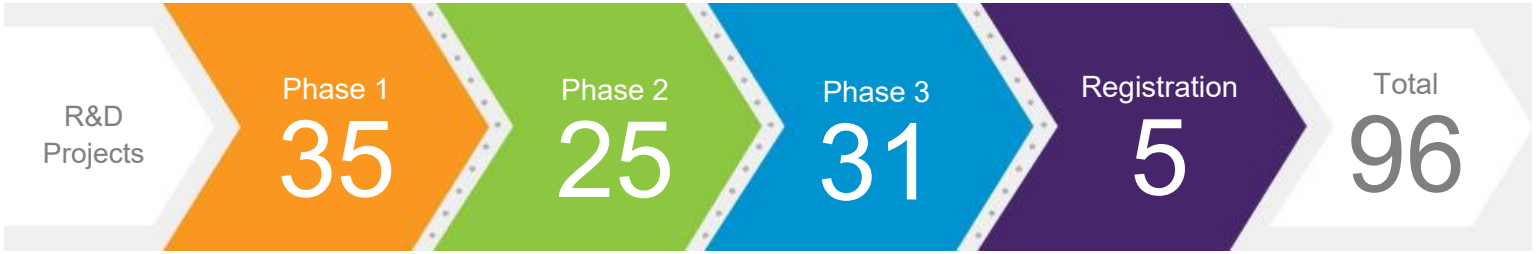
- 12 programs advanced or are new
- 7 program discontinued since last update
- Included are 56 NMEs, 39 additional indications

Pfizer Inc. and Astellas Pharma Inc. announced that the U.S. Food and Drug Administration (FDA) has approved PADCEV® (enfortumab vedotin-ejfv), a Nectin-4 directed antibody-drug conjugate, plus the PD-1 inhibitor, Keytruda® (pembrolizumab) or Keytruda QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph) as neoadjuvant and adjuvant (before and after surgery) treatment for adult patients with muscle-invasive bladder cancer regardless of cisplatin eligibility[i]. This now marks the first platinum-free regimen approved for adult patients with MIBC, regardless of cisplatin eligibility.

Pfizer Inc. announced the U.S. Food and Drug Administration (FDA) approved IBRANCE® (palbociclib) in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-positive (HER2+) locally advanced or metastatic breast cancer (MBC) following induction treatment. The approval is based on positive results from the Alliance Foundation Trials, LLC (AFT)-sponsored Phase 3 PATINA trial.

Pfizer Inc. announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for HYMPAVZI® (marstacimab-hncq) to include the treatment of patients with hemophilia A or B 12 years and older with inhibitors and pediatric patients (ages 6 to 11 years) with or without inhibitors. HYMPAVZI is now indicated in the U.S. for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 6 years of age and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors.

Pfizer Inc. announced that the European Commission (EC) has granted marketing authorization to expand the approved indication for HYMPAVZI® (marstacimab) to include patients 12 years of age and older weighing at least 35 kg with hemophilia A (congenital factor VIII [FVIII] deficiency) with FVIII inhibitors or hemophilia B (congenital factor IX [FIX] deficiency) with FIX inhibitors. HYMPAVZI offers a combination of superior bleed protection compared to on-demand (OD) treatment that is well-tolerated with a straightforward, once-weekly subcutaneous injection administration that does not require routine treatment-related lab monitoring for this difficult-to-treat inhibitor patient population 12 years of age and older.



Pfizer Pipeline Snapshot as of May 5, 2026

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
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	Chronic Spontaneous Urticaria	Phase 2	Product Enhancement
LITFULO™ (ritlecitinib)	JAK3/TEC inhibitor	Hidradenitis Suppurativa	Phase 2	Product Enhancement
PF-06835375	anti-CXCR5	Immune Thrombocytopenic Purpura (Biologic)	Phase 2	New Molecular Entity
tilrekimig (PF-07275315)	anti-IL-4/ IL-13/ TSLP	Atopic Dermatitis (Biologic)	Phase 2	New Molecular Entity
tilrekimig (PF-07275315)	anti-IL-4/ IL-13/ TSLP	Asthma (Biologic)	Phase 2	Product Enhancement
tilrekimig (PF-07275315)	anti-IL-4/ IL-13/ TSLP	Chronic Obstructive Pulmonary Disease	Phase 2	Product Enhancement
ompekimig	anti-IL-4/ IL-13/ IL-33	Atopic Dermatitis (Biologic)	Phase 2	New Molecular Entity

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

1. Orphan Drug designation for dazukibart applies only to dermatomyositis indication

Inflammation and Immunology (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-07868489	anti-BMP9	Pulmonary Arterial Hypertension (Biologic) (ORPHAN – U.S.)	Phase 2	New Molecular Entity
PF-07261271[1]	p40/TL1A bispecific	Ulcerative Colitis	Phase 2	New Molecular Entity
►PF-08049820	STAT6 inhibitor	Atopic Dermatitis	Phase 2	New Molecular Entity
Dekavil[2]	IL-10	Rheumatoid Arthritis (Biologic)	Phase 1	New Molecular Entity
PF-06835375	anti-CXCR5	Lupus (Biologic)	Phase 1	Product Enhancement
PF-07832837	undisclosed	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity
►PF-08065010	undisclosed	Rheumatoid Arthritis	Phase 1	New Molecular Entity
►PF-08103402	undisclosed	Inflammatory Diseases	Phase 1	New Molecular Entity

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

1. Pfizer and Roche have a global collaboration for PF-07261271 (Anti-p40/TL1A – bispecific antibody)
2. Dekavil clinical trial conducted by Philogen S.p.A

Internal Medicine

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
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
berobenatide (MET-097i) (PF-08653944)	GLP-1 receptor agonist	Chronic Weight Management (Biologic)	Phase 3	New Molecular Entity
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) monoclonal antibody	Cachexia in Cancer (Biologic)	Phase 2	New Molecular Entity
PF-07328948	Branched chain ketoacid dehydrogenase kinase (BDK) inhibitor	Heart Failure	Phase 2	New Molecular Entity
berobenatide (MET-097i) + MET-233i (PF-08653944 + PF-08653945)	GLP-1 receptor agonist + amylin analog[1]	Chronic Weight Management (Biologic)	Phase 2	New Molecular Entity
MET-233i (PF-08653945)	Amylin analog[1]	Chronic Weight Management (Biologic)	Phase 2	New Molecular Entity
PF-07999415	undisclosed	Obesity (Biologic)	Phase 1	New Molecular Entity
MET-034i +/- berobenatide (MET-097i) (PF-08654696 +/- PF-08653944)	GIPR agonist +/- GLP-1 receptor agonist	Chronic Weight Management (Biologic)	Phase 1	New Molecular Entity
MET-815i[2] (PF-08656795)	GLP-1 receptor agonist	Chronic Weight Management (Biologic)	Phase 1	New Molecular Entity
PF-08642534[3]	GLP-1 receptor agonist	Chronic Weight Management	Phase 1	New Molecular Entity

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

1. With dual amylin and calcitonin receptor activity
2. MET-815i is berobenatide (MET-097i) prodrug
3. Pfizer and YaoPharma have a collaboration agreement for PF-08642534

Oncology (1 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	1L HER2+ Maintenance Metastatic Breast Cancer (HER2CLIMB-05)	Registration	Product Enhancement
►TALZENNA® (talazoparib)	PARP inhibitor	Combo w/ XTANDI® (enzalutamide) for DNA Damage Repair (DDR)-Deficient Metastatic Castration Sensitive Prostate Cancer (TALAPRO-3) (PRIORITY REVIEW – U.S.)	Registration	Product Enhancement
sasanlimab (PF-06801591) + Bacillus Calmette-Guerin (BCG)	Anti-PD-1	High-Risk Non-Muscle-Invasive Bladder Cancer (CREST) (Biologic)	Phase 3	New Molecular Entity
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
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	HER2+ Adjuvant Breast Cancer (CompassHER2 RD)	Phase 3	Product Enhancement
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	1L HER2+ Metastatic Colorectal Cancer (MOUNTAINEER-03)	Phase 3	Product Enhancement

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

Oncology (2 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
disitamab vedotin (PF-08046051)	HER2-directed antibody-drug conjugate	1L HER2 (≥IHC1+) Metastatic Urothelial Cancer (DV-001) (Biologic)[1]	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
fetrastobart vedotin (PF-08046054)	PD-L1-directed antibody-drug conjugate	2L+ Non-Small Cell Lung Cancer (PADL1NK-005) (Biologic)	Phase 3	New Molecular Entity
PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Metastatic Colorectal Cancer (Symbiotic-GI-03) (Biologic)	Phase 3	New Molecular Entity
PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Non-Small Cell Lung Cancer (squamous) (Symbiotic-Lung-01) (Biologic)[2]	Phase 3	Product Enhancement
PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Non-Small Cell Lung Cancer (non-squamous) (Symbiotic-Lung-01) (Biologic)[2]	Phase 3	Product Enhancement
►PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Bladder-Sparing Muscle-Invasive Bladder Cancer (EV-309) (Biologic)[3]	Phase 3	Product Enhancement

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

1. Pfizer and RemeGen have a collaboration agreement to co-develop disitamab vedotin (DV)
2. 3SBio, Inc. is conducting Phase 2 trials in China. Pfizer will conduct global trials, including in China
3. Pfizer and Astellas have a collaboration agreement to co-develop PADCEV®

Oncology (3 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Locally Advanced or Metastatic Solid Tumors (EV-202) (Biologic)[1]	Phase 2	Product Enhancement
TIVDAK® (tisotumab vedotin)	Tissue Factor-directed antibody-drug conjugate	Advanced Solid Tumors (TV-207) (Biologic)[2]	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 (PF-08046051)	HER2-directed antibody-drug conjugate	2L+ Metastatic Urothelial Cancer with HER2 Expression (Biologic)[3]	Phase 2	Product Enhancement
atirmociclib (PF-07220060)	CDK4 inhibitor	2L HR+/HER2- Metastatic Breast Cancer (FourLight-1)	Phase 2	Product Enhancement
atirmociclib (PF-07220060)	CDK4 inhibitor	Early Breast Cancer	Phase 2	Product Enhancement
►PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Small Cell Lung Cancer (Symbiotic-Lung-04)	Phase 2	Product Enhancement
►PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Gastroesophageal (Symbiotic-GI-16)	Phase 2	Product Enhancement
►PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	Transformed Small Cell Lung Cancer (Symbiotic-Lung-14)	Phase 2	Product Enhancement

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

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

Oncology (4 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
tegtociclib (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
tegtociclib (PF-07104091) + atirmociclib	CDK2 + CDK4 inhibitors	Breast Cancer Metastatic	Phase 1	New Molecular Entity
claturafenib (PF-07799933)	BRAF Class 1 and Class 2 inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
polfurmetinib (PF-07799544)	MEK brain penetrant inhibitor	Advanced Solid Tumors	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
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 (PF-08046047)	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

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

1. TUKYSA® for HER2+ GI cancers is currently in a Ph1b/2 study

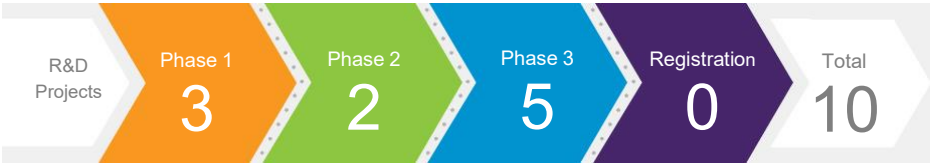
Oncology (5 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
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-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
PF-08052667 (B6N)	Integrin beta-6-directed antibody-drug conjugate	Non-muscle Invasive Bladder Cancer (Biologic)	Phase 1	New Molecular Entity
PF-08032560 (KAT6/7)	Selective inhibitor of epigenetic modifiers KAT6A, KAT6B and KAT7	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	Unresectable Locally Advanced or Metastatic Hepatocellular Carcinoma (Symbiotic-GI-13) (Biologic)	Phase 1	Product Enhancement
PF-08046033 (GPS)	Glycoprotein-NMB directed antibody drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
►PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Metastatic Urothelial Carcinoma (Symbiotic-GU-07)	Phase 1	Product Enhancement
►PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Renal Cell Carcinoma (Symbiotic-GU-08)	Phase 1	Product Enhancement
►PF-08634404 (PF'4404)	PD-1xVEGF Bispecific Antibody	1L Non-Small Cell Lung Cancer (Symbiotic-Lung-20)[1]	Phase 1	Product Enhancement
►PF-07994525	KAT2A/B catalytic inhibitor	Relapsed/Refractory Multiple Myeloma	Phase 1	New Molecular Entity

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

1. PF-08634404 (PF'4404) 1L Non-Small Cell Lung Cancer (Symbiotic-Lung-20) is currently in a Ph1b/2 study

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-07831694	Prophylactic vaccine – protein subunit	*Clostridioides difficile (C. difficile)* – updated formulation (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-07872412	Prophylactic vaccine – polysaccharide conjugate	Pneumococcal Infection - Pediatrics (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
PF-07252220	Prophylactic vaccine – mRNA	Influenza (adults)	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

►Indicates that the project is either new or has progressed in phase since the previous portfolio update on Pfizer.com
Regulatory Designations – See Definitions in Slides 16-18

Programs Discontinued from Development since May 5, 2026

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	2L+ HER2+ Metastatic Breast Cancer (HER2CLIMB-04)	Phase 2	Product Enhancement
PF-07976016	GIPR antagonist	Chronic Weight Management	Phase 2	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
PF-07985631	undisclosed	Nephropathy (Biologic)	Phase 1	New Molecular Entity
PF-07258669	Melanocortin-4 receptor (MC4R) antagonist	Malnutrition	Phase 1	New Molecular Entity
MET-224o (PF-08656796)	GLP-1 receptor agonist	Chronic Weight Management (Biologic)	Phase 1	New Molecular Entity

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.