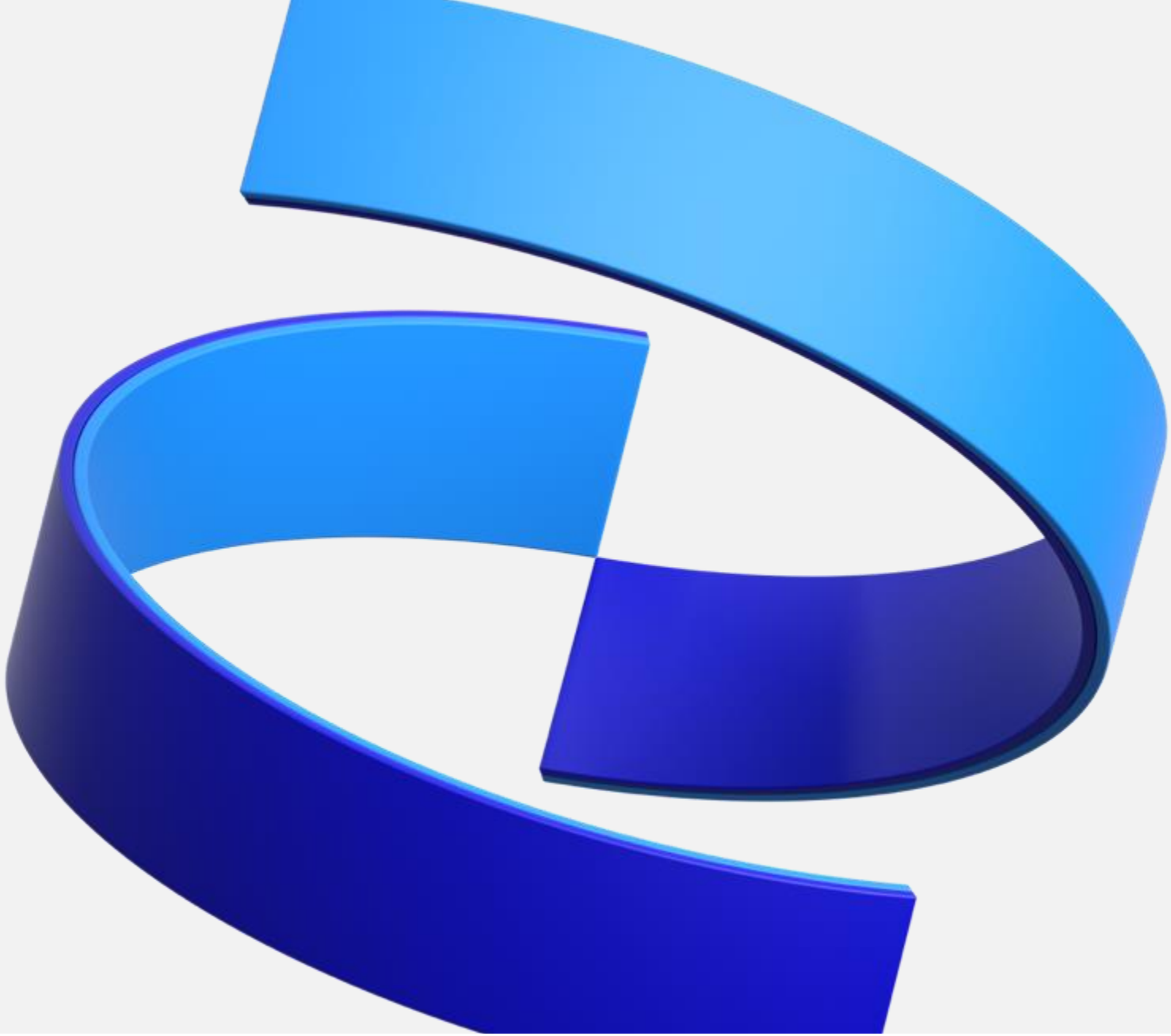
Pfizer Pipeline



October 29, 2024

Disclaimer

- The information contained on these pages is accurate as of October 29, 2024 to the best of Pfizer's knowledge. Pfizer assumes no obligation to update this information.

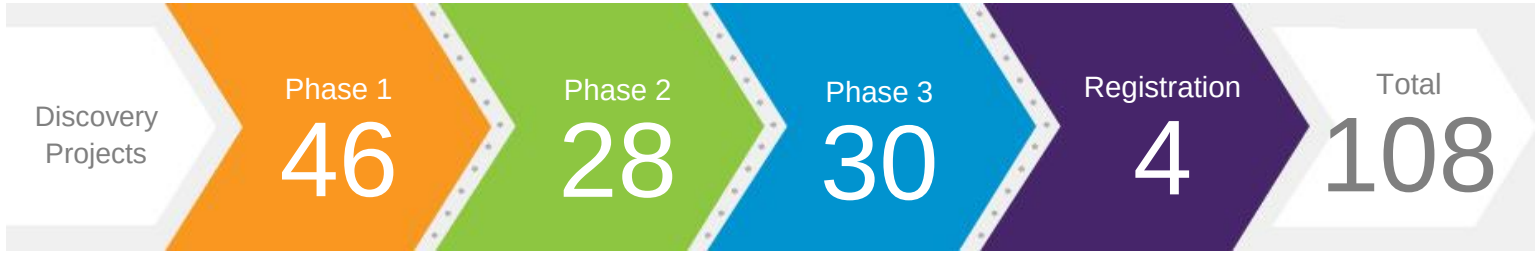
- This presentation includes forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. There can be no guarantees with respect to pipeline products that clinical studies will 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, 2023 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 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 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 October 29, 2024

Pipeline represents progress of R&D programs as of October 29, 2024

- 3 programs advanced or are new
- 6 programs discontinued since last update
- Included are 66 NMEs, 42 additional indications

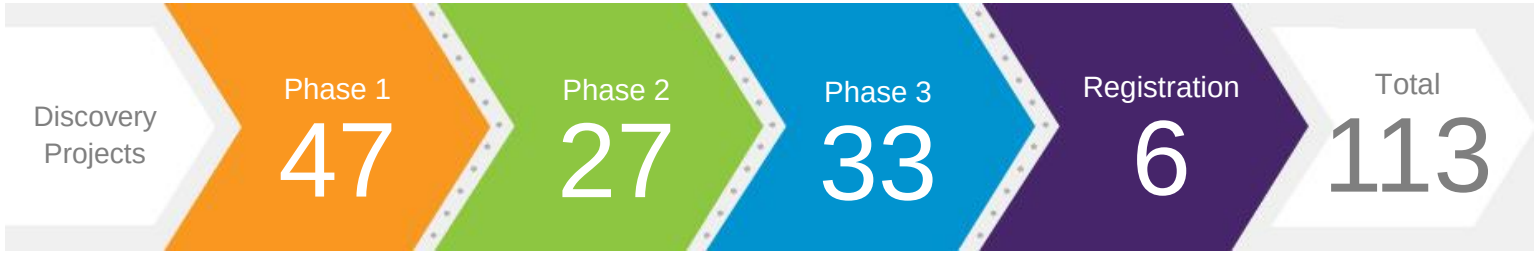
Recent Approvals and Pipeline Highlights

Pfizer and BioNTech announced top-line results from their Phase 3 clinical trial to evaluate the companies' combined mRNA vaccine candidate against influenza and COVID-19 in healthy individuals 18-64 years of age. The combination candidate consists of Pfizer's mRNA-based influenza vaccine candidate with the companies' licensed COVID-19 vaccine. The Phase 3 trial measured two primary immunogenicity objectives (immunogenicity against SARS-CoV-2 as well as immunogenicity against influenza A and B), of which one was met. The companies are evaluating adjustments to the candidate and are discussing next steps with health authorities.

Pfizer and BioNTech announced that the U.S. Food and Drug Administration ("FDA") has approved the supplemental Biologics License Application for individuals 12 years of age and older (COMIRNATY ® (COVID-19 Vaccine, mRNA), and granted emergency use authorization for individuals 6 months through 11 years of age (Pfizer-BioNTech COVID-19 Vaccine) of the companies' Omicron KP.2-adapted 2024-2025 Formula COVID-19 vaccine. This season's vaccine is for use as a single dose for most individuals 5 years of age and older. Pfizer and BioNTech also announced that the European Medicines Agency (EMA) has approved the companies' Omicron KP.2-adapted monovalent COVID-19 vaccine (COMIRNATY ® KP.2) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older.

Pfizer announced that the FDA has approved HYMPAVZI™ (marstacimab-hncq) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without factor VIII (FVIII) inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX (FIX) inhibitors.

Pfizer Inc. announced that the FDA has approved ABRYSVO ® (Respiratory Syncytial Virus Vaccine), the company's bivalent RSV prefusion F (RSVpreF) vaccine, for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.



Pfizer Pipeline Snapshot as of July 30, 2024

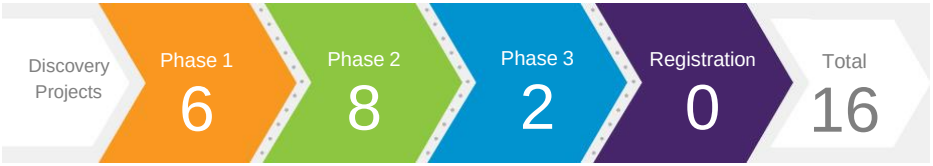
Anti-Infectives

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PAXLOVID™	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (Pediatric)[1]	Phase 3	Product Enhancement
sisunatovir (PF-07923568)	Respiratory syncytial virus fusion inhibitor	Respiratory Syncytial Virus infection (Adults) (FAST TRACK – U.S.)	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
ibuzatrelvir (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. PAXLOVID™ for pediatric population is in 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)	anti-IFN-β	Dermatomyositis, Polymyositis (Biologic) (ORPHAN - U.S. E.U.[1], FAST TRACK – U.S., PRIME - E.U.)	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
VELSIPITY™ (etrasimod)	S1P inhibitor	Crohn's Disease	Phase 2	Product Enhancement
VELSIPITY™ (etrasimod)	S1P inhibitor	Eosinophilic Esophagitis	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)	anti-IFN-β	Lupus (Biologic)	Phase 2	Product Enhancement
Dekavil[2]	IL-10	Rheumatoid Arthritis (Biologic)	Phase 1	New Molecular Entity
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. Orphan Drug designation for dazukibart applies only to dermatomyositis indication
2. Clinical trial conducted by Philogen S.p.A

Internal Medicine (1 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
NGENLA™ (somatrogon)	Human growth hormone agonist	Adult Growth Hormone Deficiency (Biologic) (ORPHAN - E.U.)[1]	Registration	Product Enhancement
giroctocogene fitelparvovec (PF-07055480)	Gene therapy, coagulation factor VIII (F8)	Hemophilia A (Biologic) (RMAT, FAST TRACK – U.S., ORPHAN - U.S., E.U.)[2]	Phase 3	New Molecular Entity
inclacumab (PF-07940370)	Anti-P-selectin inhibitor	Sickle Cell Disease (Biologic) (RPD, ORPHAN – U.S.)	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
ervogastat (PF-06865571)	Diacylglycerol O-Acyltransferase 2 (DGAT2) inhibitor	Metabolic Dysfunction-Associated Steatohepatitis (MASH)	Phase 2	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) (FAST TRACK – U.S.)	Phase 2	New Molecular Entity
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) monoclonal antibody	Cachexia in Cancer (Biologic)	Phase 2	New Molecular Entity
ponsegromab (PF-06946860)	Growth Differentiation Factor 15 (GDF15) monoclonal antibody	Heart Failure (Biologic)	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 OPKO Health have a collaboration agreement to co-develop NGENLA™
2. Pfizer and Sangamo have a collaboration agreement to co-develop giroctocogene fitelparvovec

Internal Medicine (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) agonist	Chronic Weight Management	Phase 1	New Molecular Entity
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) agonist	Type 2 Diabetes Mellitus	Phase 1	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	Phase 1	New Molecular Entity
PF-07293893	AMPKγ3 activator	Heart Failure	Phase 1	New Molecular Entity
PF-07853578	PNPLA3 modulator	Metabolic Dysfunction-Associated Steatohepatitis (MASH)	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	GIPR antagonist	Chronic Weight Management	Phase 1	New Molecular Entity
►PF-07940369	mechanism not disclosed	Anemia of Clonal Hematopoiesis (ACH)	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

Oncology (1 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
ADCETRIS® (brentuximab vedotin)	CD30-directed antibody-drug conjugate	Diffuse Large B-Cell Lymphoma (DLBCL) (Biologic)[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	1L 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
ELREXFIO™ (elranatamab-bcmm)	BCMA-CD3 bispecific antibody	2L+ post-CD38 Relapsed Refractory Multiple Myeloma (MM-32) (Biologic)	Phase 3	Product Enhancement
vepdegestrant (ARV-471)	ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer[2] (VERITAC 2) (FAST TRACK – U.S.)	Phase 3	New Molecular Entity
vepdegestrant (ARV-471) + IBRANCE®	CDK 4,6 kinase inhibitor + ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer[2] (VERITAC 3)	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
- PROTAC® is a registered trademark of Arvinas

1. Pfizer and Takeda have a collaboration agreement to co-develop ADCETRIS®. Takeda has ex-US/Canada rights
2. Pfizer and Arvinas have a collaboration agreement to co-develop vepdegestrant

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 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 (DV)	HER2-directed antibody-drug conjugate	1L HER2 (≥IHC1+) Metastatic Urothelial Cancer (SGNDV-001) (Biologic)[2]	Phase 3	New Molecular Entity
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
atirmociclib (PF-07220060)	CDK4 inhibitor	2L HR+/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

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
vepdegestrant (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
mevrometostat (PF-06821497) + enzalutamide	EZH2 inhibitor + androgen receptor inhibitor	Prostate Cancer	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 (Biologic)[3]	Phase 2	Product Enhancement
TUKYSA® (tucatinib)	HER2 tyrosine kinase inhibitor	2L+ HER2+ mBC (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 (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
atirmociclib (PF-07220060)	CDK4 inhibitor	Early Breast Cancer	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 trademark of Arvinas

1. Pfizer and Arvinas have a collaboration agreement to co-develop 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)

Oncology (4 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
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	Advanced 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	Advanced Solid Tumors	Phase 1	New Molecular Entity
PF-07799544	MEK brain penetrant inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
PF-07248144 + 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
atirmociclib (PF-07220060)	CDK4 inhibitor	1L Metastatic Breast Cancer	Phase 1	New Molecular Entity
PF-06940434	Integrin alpha-V/beta-8 antagonist	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)[2]	Phase 1	Product Enhancement
TIVDAK® (tisotumab vedotin)	Tissue Factor-directed antibody-drug conjugate	Recurrent or Metastatic Cervical Cancer (Biologic)[3]	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. TUKYSA® for HER2+ GI cancers is currently in a Ph1b/2 study
2. Pfizer and Astellas have a collaboration agreement to co-develop PADCEV®
3. Pfizer and Genmab have a collaboration agreement to co-develop TIVDAK®

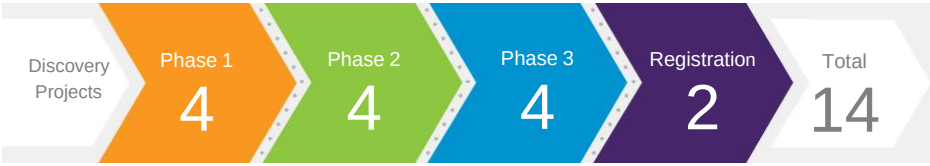
Oncology (5 of 5)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-08046049 (BB228)	CD228-directed antibody-Anticalin® bispecific protein[1]	Advanced Melanoma and Other Solid Tumors (Biologic)	Phase 1	New Molecular Entity
felmetatug vedotin (PF-08046048) (B7H4V)	B7H4-directed antibody-drug conjugate	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-08046052 (EGFRd2)	EGFR-targeted bispecific gamma delta T-cell engager	Advanced Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-08046054 (PDL1V)	PD-L1-directed antibody-drug conjugate	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
PF-08046045 (35T)	CD-30 directed antibody-tripeptide MMAE conjugate	Advanced Solid Tumors and Lymphomas (Biologic)	Phase 1	New Molecular Entity
PF-07820435	STING agonist	Advanced Solid Tumors	Phase 1	New Molecular Entity
vepdegestrant (ARV-471) + CDK4 (PF-07220060)	CDK4 kinase inhibitor + ER-targeting PROTAC® protein degrader	ER+/HER2- 1L Metastatic Breast Cancer[2]	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 Malignancies	Phase 1	New Molecular Entity
PF-07934040 (panKRAS)	selective pan KRAS inhibitor	Advanced Solid Tumors	Phase 1	New Molecular Entity
►PF-07826390 (LILRB1/2)	LILRB1/2 bispecific IgG1 antibody	Advanced Solid Tumors	Phase 1	New Molecular Entity
►PF-08052666 (MesoC2)	mesothelin-targeted antibody-drug conjugate	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 of Pfizer.com
Regulatory Designations – See Definitions in Backup

1. Anticalin® is a registered trademark of Pieris Pharmaceuticals GmbH; Pfizer Development under Exclusive License
2. Pfizer and Arvinas have a collaboration agreement to co-develop vepdegestrant

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 *Clostridioides difficile (C. Difficile)* 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
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)	Phase 3	New Molecular Entity
PF-07252220	Prophylactic vaccine – mRNA	Influenza (adults)	Phase 2	New Molecular Entity
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-07831694	Prophylactic vaccine – protein subunit	*Clostridioides difficile (C. difficile)* – 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-07845104	Prophylactic vaccine – saRNA	Influenza (adults)	Phase 1	New Molecular Entity
PF-07911145	Prophylactic vaccine – mRNA	Varicella (in collaboration with BioNTech)	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 of Pfizer.com
Regulatory Designations – See Definitions in Backup

Programs Discontinued from Development since July 30, 2024

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Oxbryta® (voxelotor)	HbS polymerization inhibitor	Sickle Cell Disease – Pediatric	Phase 3	Product Enhancement
Oxbryta® (voxelotor)	HbS polymerization inhibitor	Leg Ulcers in Patients with Sickle Cell Disease	Phase 3	Product Enhancement
PF-07941314	Prophylactic vaccine – protein subunit and mRNA	Combination Respiratory Syncytial Virus & Influenza (adults)	Phase 1	New Molecular Entity
PF-07104091	CDK2 inhibitor	Ovarian Cancer	Phase 1	Product Enhancement
PF-07220060 + enzalutamide	CDK4 inhibitor + androgen receptor inhibitor	Prostate Cancer	Phase 1	Product Enhancement
PADCEV® (enfortumab vedotin)	Nectin-4 directed antibody-drug conjugate	Urothelial Cancer (Biologic)	Phase 1	Product Enhancement

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.

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.