

Pfizer Pipeline

As of April 30, 2019

Disclaimer

- As some programs are still confidential, some candidates may not be identified in this list. In these materials, Pfizer discloses Mechanism of Action (MOA) information for some candidates in Phase 1 and for all candidates from Phase 2 through regulatory approval. With a view to expanding the transparency of our pipeline, Pfizer is including new indications or enhancements, which target unmet medical need or represent significant commercial opportunities. The information contained on these pages is correct as of April 30, 2019.
- Visit <u>Pfizer.com/pipeline</u>, Pfizer's online database where you can learn more about our portfolio of new medicines and find out more about our Research and Development efforts around the world.



Table of Contents

Pfizer Pipeline Snapshot	4	
Inflammation and Immunology	5	
Internal Medicine	6	
Oncology	7-10	
Rare Diseases	11	
Vaccines	12	
Hospital (Anti-Infectives)	13	
Projects Discontinued Since Last Update	14	
Backup: Regulatory Designation Definitions	15-16	



Pfizer Pipeline Snapshot

Discovery Projects

Phase 1 3 4 Phase 2 3 10 Phase 3 10 97

Pfizer Pipeline Snapshot as of <u>April 30, 2019</u>

Pipeline represents progress of R&D programs as of April 30, 2019

Included are 54 NMEs, 39 additional indications, plus 4 biosimilars

- 5 programs advanced or are new
 - 1 program discontinued since last update

Recent Approvals

- TRAZIMERA™ (trastuzumab-qyyp), a biosimilar to Herceptin® (trastuzumab), for the treatment of human epidermal growth factor receptor-2 (HER2) overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (U.S.)
- ZIRABEV™, a biosimilar to Avastin® (bevacizumab), for the treatment of
 metastatic carcinoma of the colon or rectum, metastatic breast cancer,
 unresectable advanced, metastatic or recurrent non-small cell lung cancer
 (NSCLC), advanced and/or metastatic renal cell cancer and persistent,
 recurrent or metastatic carcinoma of the cervix (E.U.)
- VIZIMPRO® (dacomitinib) for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations (E.U.)



Pfizer Pipeline Snapshot as of January 29, 2019

Pipeline represents progress of R&D programs as of January 29, 2019

Included are 54 NMEs, 41 additional indications, plus 5 biosimilars

- 9 programs advanced or are new
- 4 programs discontinued since last update

Recent Approvals

- DAURISMO® (glasdegib) for adult patients with newly-diagnosed acute myeloid leukemia for whom intensive chemotherapy is not an option (U.S.)
- LORBRENA® (Iorlatinib) for previously-treated ALK-positive metastatic non-small cell lung cancer (U.S.)



- Herceptin® is a registered U.S. trademark of Genentech, Inc.
- Avastin® is a registered U.S. trademark of Genentech, Inc.

Inflammation and Immunology

Discovery Projects

Phase 1
4
Phase 2
1
4
Phase 2
3
Registration
24
24

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
crisaborole (PF-06940799)	PDE4 Inhibitor	Atopic Dermatitis (E.U.)	Registration	New Molecular Entity
PF-06410293, a potential biosimilar to Humira® (adalimumab)	Tumor Necrosis Factor Inhibitor	Rheumatoid Arthritis (Biosimilar) (U.S.) / (E.U.)	Registration	Biosimilar
Xeljanz (tofacitinib)	JAK Inhibitor	Modified Release 11mg Tablet for Rheumatoid Arthritis (E.U.)	Registration	Product Enhancement
PF-04965842	JAK Inhibitor	Atopic Dermatitis (BREAKTHROUGH)	Phase 3	New Molecular Entity
PF-06651600	JAK3	Alopecia Areata (BREAKTHROUGH)	Phase 3	New Molecular Entity
Xeljanz (tofacitinib)	JAK Inhibitor	Ankylosing Spondylitis	Phase 3	Product Enhancement
Dekavil	IL-10	Rheumatoid Arthritis (Biologic)	Phase 2	New Molecular Entity
Dekavil	IL-10	Inflammatory Bowel Disease (Biologic)	Phase 2	Product Enhancement
PF-06480605	TNFSF15 Blocker	Ulcerative Colitis (Biologic)	Phase 2	New Molecular Entity
PF-06650833	IRAK4	Rheumatoid Arthritis	Phase 2	New Molecular Entity
PF-06651600	JAK3	Rheumatoid Arthritis	Phase 2	Product Enhancement
PF-06651600	JAK3	Ulcerative Colitis	Phase 2	Product Enhancement
PF-06651600	JAK3	Crohn's Disease	Phase 2	Product Enhancement
PF-06651600	JAK3	Vitiligo	Phase 2	Product Enhancement
PF-06700841	TYK2/JAK1	Alopecia Areata	Phase 2	New Molecular Entity
PF-06700841	TYK2/JAK1	Psoriasis	Phase 2	Product Enhancement
PF-06700841	TYK2/JAK1	Ulcerative Colitis	Phase 2	Product Enhancement
PF-06700841	TYK2/JAK1	Crohn's Disease	Phase 2	Product Enhancement
PF-06700841	TYK2/JAK1	Vitiligo	Phase 2	Product Enhancement
PF-06823859	interferon, beta 1, fibroblast (IFNB1) Blocker	Inflammatory Disorders (Biologic)	Phase 2	New Molecular Entity
PF-06763809	Transcription Factor Inhibitor	Psoriasis	Phase 1	New Molecular Entity
PF-06817024	Cytokine Modulator	Atopic Dermatitis (Biologic)	Phase 1	New Molecular Entity
PF-06826647	TYK2 Inhibitor	Inflammatory Bowel Disease	Phase 1	New Molecular Entity
PF-06835375	chemokine Inhibitor	Lupus (Biologic)	Phase 1	New Molecular Entity



[•] Regulatory Designations – See Definitions in Backup

[•] Humira® is a registered U.S. trademark of Abbvie Biotechnology Ltd.

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
tanezumab	Nerve Growth Factor Inhibitor	OA Signs and Symptoms (FAST TRACK), Chronic Low Back Pain (FAST TRACK), Cancer Pain (Biologic)	Phase 3	New Molecular Entity
PF-05221304	Acetyl CoA-Carboxylase (ACC) Inhibitor	Non-Alcoholic Steatohepatitis (NASH) with liver fibrosis (FAST TRACK)	Phase 2	New Molecular Entity
PF-06835919	Ketohexokinase (KHK) Inhibitor	Non-Alcoholic Steatohepatitis (NASH)	Phase 2	New Molecular Entity
▶ PF-07055341	ACCi and DGAT2 Combination	Combo of PF-05221304 and PF-06865571 for Non-Alcoholic Steatohepatitis (NASH)	Phase 2	New Molecular Entity
PF-06865571	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-Alcoholic Steatohepatitis (NASH)	Phase 1	New Molecular Entity
PF-06882961	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Diabetes Mellitus-Type 2	Phase 1	New Molecular Entity
PF-06946860	Growth Factor Blocker	Cachexia (Biologic)	Phase 1	New Molecular Entity



 $[\]blacktriangleright$ 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 4)



Company d Nama	Mechanism of Action	Indication	Phase of	Submission Tuno
Compound Name	MechanismorAction	indication	Development	Submission Type
lorlatinib (PF-06463922)	ALK inhibitor	2nd Line ALK Non-Small Cell Lung Cancer (E.U.)	Registration	New Molecular Entity
PF-05280586, a potential biosimila to Rituxan® /MabThera® (rituximab)	CD20 antigen antagonist	Follicular Lymphoma (Biosimilar) (U.S.)/ (E.U.)	Registration	Biosimilar
PF-06439535, a potential biosimila to Avastin® (bevacizumab)	r VEGFR inhibitor	Non-Small Cell Lung Cancer (Biosimilar) (U.S.)	Registration	Biosimilar
talazoparib	PARP inhibitor	Germline BRCA Mutated Metastatic Breast Cancer (E.U.)	Registration	New Molecular Entity
► Bavencio (avelumab)	Anti PD-L1	1st Line Renal Cell Carcinoma (Biologic) (Combo w/Inlyta (axitinib)) (U.S.) / (E.U.) (BREAKTHROUGH – U.S.)	Registration	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	1st Line Non-Small Cell Lung Cancer (Biologic)	Phase 3	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	1st Line Gastric Cancer (Biologic)	Phase 3	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	1st Line Urothelial Cancer (Biologic)	Phase 3	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Locally Advanced Squamous Cell Carcinoma of the Head and Neck (Biologic)	Phase 3	Product Enhancement
Daurismo (glasdegib)	SMO (smoothened) antagonist	Combo w/azacytidine in Acute Myeloid Leukemia (ORPHAN - U.S., E.U.)	Phase 3	Product Enhancement
Ibrance (palbociclib)	CDK 4,6 kinase inhibitor	High Risk Early Breast Cancer	Phase 3	Product Enhancement
Ibrance (palbociclib)	CDK 4,6 kinase inhibitor	Early Breast Cancer in Adjuvant Setting	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
- Rituxan® is a registered U.S. trademark of Biogen MA Inc.; MabThera® is a trademark of F. Hoffmann La Roche AG;
- Avastin[®] is a registered U.S. trademark of Genentech, Inc.

Oncology (2 of 4)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Ibrance (palbociclib)	CDK 4,6 kinase inhibitor	ER+/HER2+ Breast Cancer	Phase 3	Product Enhancement
Lorbrena (lorlatinib)	ALK inhibitor	1 st Line ALK Non-Small Cell Lung Cancer (ORPHAN - U.S.)	Phase 3	Product Enhancement
Talzenna (talazoparib)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for 1st Line Metastatic Castration-Resistant Prostate Cancer	Phase 3	Product Enhancement
Xtandi (enzalutamide)	Androgen receptor inhibitor	Metastatic Hormone Sensitive Prostate Cancer	Phase 3	Product Enhancement
Xtandi (enzalutamide)	Androgen receptor inhibitor	Non-metastatic High Risk Hormone Sensitive Prostate Cancer	Phase 3	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	1st Line Merkel Cell Carcinoma (MCC) (Biologic)	Phase 2	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Combo w/PF-04518600 (OX40) for various solid tumors (Biologic)	Phase 2	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Combo w/PF-05082566 (anti-4-1BB/CD137) for various solid tumors (Biologic)	Phase 2	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Combo w/Talzenna (talazoparib) for Locally Advanced (Primary or Recurrent) or Metastatic Solid Tumors (Biologic)	Phase 2	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Combo w/Talzenna (talazoparib) for Solid Tumors with a BRCA or ATM defect (Biologic)	Phase 2	Product Enhancement
Daurismo (glasdegib)	SMO (smoothened) antagonist	Combo w/ low-dose cytarabine (LDAC) for Acute Myeloid Leukemia (E.U.)	Phase 2	New Molecular Entity
► Daurismo (glasdegib)	SMO (smoothened) antagonist	Myelodysplastic Syndrome	Phase 2	Product Enhancement



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[•] Regulatory Designations – See Definitions in Backup

Oncology (3 of 4)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Talzenna (talazoparib)	PARP inhibitor	2 nd Line Metastatic Castration-Resistant Prostate Cancer	Phase 2	Product Enhancement
Talzenna (talazoparib)	PARP inhibitor	Germline BRCA Mutated Locally Advanced Triple Negative Breast Cancer	Phase 2	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Combo w/PF-04518600 (OX40) and PF- 05082566 (anti-4-1BB/CD137) for Cancer (Biologic)	Phase 1	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Combo w/Talzenna (talazoparib) and binimetinib for Solid Tumors (Biologic)	Phase 1	Product Enhancement
Bavencio (avelumab)	Anti PD-L1	Cancer (Biologic)	Phase 1	Product Enhancement
gedatolisib (PF-05212384)	pan-PI3K/mTOR inhibitor	Cancer	Phase 1	New Molecular Entity
Ibrance (palbociclib)	CDK 4,6 kinase inhibitor	Combo w/gedatolisib (PF-05212384) for Cancer	Phase 1	Product Enhancement
Inlyta (axitinib)	VEGFR tyrosine kinase inhibitor	Combo w/Merck's Keytruda® (PD-1, pembrolizumab) for Cancer	Phase 1	Product Enhancement
PF-04518600	OX40 receptor Agonist	Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06647020	protein tyrosine kinase 7 (PTK7) Targeted Cytotoxicity	Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06671008	cadherin 3, type 1, P-cadherin (placental) (CDH3)	Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06688992	Antibody Drug Conjugate	Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06801591	Anti-PD-1	Cancer Immunotherapy (Biologic)	Phase 1	New Molecular Entity
PF-06804103	HER2 Antibody Drug Conjugate	Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06821497	EZH2 inhibitor	Cancer	Phase 1	New Molecular Entity



⁻ Keytruda $^{\scriptsize @}$ is a registered U.S. trademark of Merck Sharp & Dohme Corp.

Oncology (4 of 4)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-06863135	BCMA-CD3 Bispecific Antibody	Multiple Myeloma (Biologic)	Phase 1	New Molecular Entity
PF-06873600	CDK 2,4,6 inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-06881894, a potential biosimilar to Neulasta® (Pegfilgrastim)	r Human Granulocyte Colony Stimulating Factor	Neutropenia in patients undergoing cancer chemotherapy (Biosimilar)	Phase 1	Biosimilar
PF-06952229	transforming growth factor, beta receptor 1 (TGFBR1) Inhibitor	Cancer	Phase 1	New Molecular Entity
▶ PF-06939999	protein arginine methyltransferase 5 (PRMT5) Inhibitor	Solid Tumors	Phase 1	New Molecular Entity



Neulasta® is a registered U.S. trademark of Amgen Inc.

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
tafamidis meglumine	Transthyretin (TTR) Dissociation Inhibitor	Transthyretin familial amyloid polyneuropathy (U.S.) (FAST TRACK, ORPHAN - U.S.)	Registration	New Molecular Entity
► Vyndaqel (tafamidis meglumine and free acid)	Transthyretin (TTR) Dissociation Inhibitor	Transthyretin Amyloid Cardiomyopathy (U.S.)/ (E.U.) (BREAKTHROUGH, FAST TRACK, PRIORITY REVIEW, ORPHAN – U.S., ORPHAN – E.U.)	Registration	Product Enhancement
fidanacogene elaparvovec (PF-06838435)	Gene Therapy, coagulation factor IX (F9)	Hemophilia (Biologic) (BREAKTHROUGH, ORPHAN - U.S., E.U., PRIME - E.U.)	Phase 3	New Molecular Entity
rivipansel (GMI-1070)	Pan-Selectin Antagonist	Acute vaso-occlusive crises associated with sickle cell disease in patients aged 6 years and above (FAST TRACK, ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
somatrogon (PF-06836922)	Human Growth Hormone Agonist	Adult Growth Hormone Deficiency (Biologic) (ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
somatrogon (PF-06836922)	Human Growth Hormone Agonist	Pediatric Growth Hormone Deficiency (Biologic) (ORPHAN - U.S., E.U.)	Phase 3	Product Enhancement
PF-06730512	SLIT2 antagonist	Focal Segmental Glomerulosclerosis (FSGS) (Biologic)	Phase 2	New Molecular Entity
PF-06741086	Tissue Factor Pathway Inhibitor (TFPI)	Hemophilia (Biologic) (ORPHAN - U.S., E.U.)	Phase 2	New Molecular Entity
PF-07055480 (SB-525)	AAV-FVIII GTx	Hemophilia (Biologic) (ORPHAN - U.S., E.U., FAST TRACK)	Phase 2	New Molecular Entity
PF-04447943	PDE9 Inhibitor	Sickle Cell Anemia (ORPHAN - U.S.)	Phase 1	New Molecular Entity
PF-05230907	Factor Xa Protein Replacement	Intracerebral Hemorrhage (Biologic) (ORPHAN - U.S.)	Phase 1	New Molecular Entity
PF-06755347	Immunomodulation	Chronic Inflammatory Demyelination Polyneuropathy	Phase 1	New Molecular Entity
PF-06939926	minidystrophin	Duchenne Muscular Dystrophy (Biologic) (ORPHAN - U.S., E.U.)	Phase 1	New Molecular Entity



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[•] Regulatory Designations – See Definitions in Backup

Vaccines



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-06425090	Prophylactic Vaccine	Primary clostridium difficile infection (FAST TRACK)	Phase 3	New Molecular Entity
PF-06482077	Prophylactic Vaccine	Invasive and non-invasive Pneumococcal infections (BREAKTHROUGH)	Phase 3	New Molecular Entity
PF-06842433	Prophylactic Vaccine	Invasive and non-invasive Pneumococcal infections	Phase 2	New Molecular Entity
PF-06753512	Therapeutic Vaccine	Prostate Cancer	Phase 1	New Molecular Entity
PF-06760805	Prophylactic Vaccine	Invasive Group B streptococcus infection	Phase 1	New Molecular Entity
PF-06886992	Prophylactic Vaccine	Serogroups ABCWY meningococcal infections	Phase 1	New Molecular Entity
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection	Phase 1	New Molecular Entity
PF-06936308	Therapeutic Vaccine	Multiple Cancers	Phase 1	New Molecular Entity



Hospital (Anti-Infectives)



Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
aztreonam-avibactam (PF-06947387)	Beta Lactam/Beta Lactamase Inhibitor	Treatment of infections caused by Gram- negative bacteria for which there are limited or no treatment options	Phase 3	New Molecular Entity



Projects Discontinued from Development since January 29, 2019

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Bavencio (avelumab)	Anti PD-L1	Combo w/Talzenna (talazoparib) for 1st Line Ovarian Cancer (Biologic)	Phase 3	Product Enhancement



Backup



Regulatory Designation Definitions

- 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 lifethreatening 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 (US) Orphan drug status may be granted to drugs and biologics that are intended for the diagnosis, prevention, or treatment of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but where it is unlikely that expected sales of the product would cover the sponsor's investment in its development. More information about the qualifying criteria, features, and incentives involved in an orphan drug designation can be found on the FDA's website.
- Orphan Drug (Europe) Orphan drug status may be granted to drugs and biologics that are intended for the diagnosis, prevention or treatment of a lifethreatening 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.
- 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 take action 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.
- **PRIME** (E.U.) The PRIME scheme is applicable to products under development which are innovative and yet to be placed on the EU market. The scheme aims to support medicinal products of major public health interest and in particular 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.

