

# **Pfizer Pipeline**

As of October 30, 2018

#### **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 October 30, 2018.
- 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.

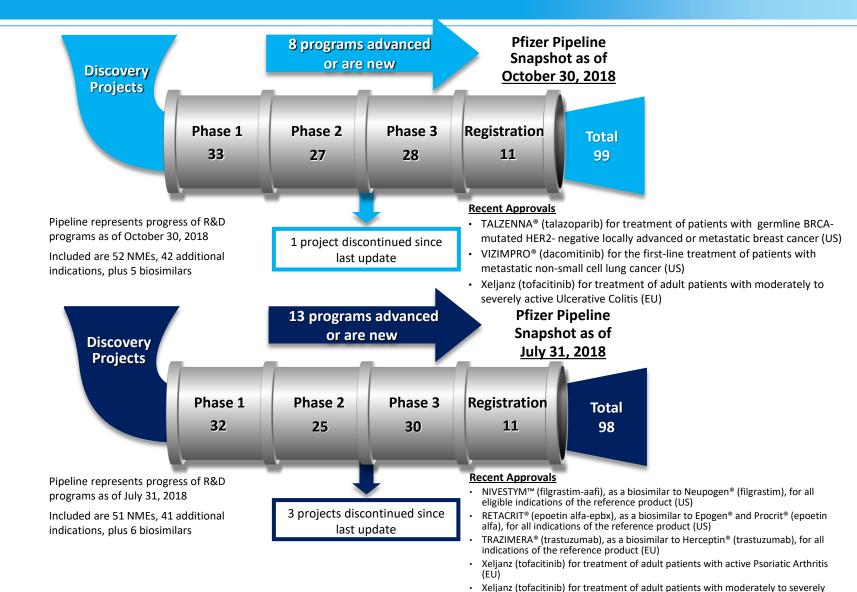


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#### **Pfizer Pipeline Snapshot**



active Ulcerative Colitis (US)



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Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	crisaborole (PF-06940799)	PDE4 Inhibitor	Atopic Dermatitis (E.U.)	Registration
	Xeljanz (tofacitinib)	JAK Inhibitor	Modified Release 11mg Tablet for Rheumatoid Arthritis (E.U.)	Registration
	PF-04965842	JAK Inhibitor	Atopic Dermatitis (BREAKTHROUGH)	Phase 3
	Xeljanz (tofacitinib)	JAK Inhibitor	Ankylosing Spondylitis	Phase 3
	Dekavil	IL-10	Rheumatoid Arthritis (Biologic)	Phase 2
	► Dekavil	IL-10	Inflammatory Bowel Disease (Biologic)	Phase 2
	PF-06480605	TNFSF15 Blocker	Ulcerative Colitis (Biologic)	Phase 2
	PF-06650833	IRAK4	Rheumatoid Arthritis	Phase 2
	PF-06651600	JAK3	Alopecia Areata (BREAKTHROUGH)	Phase 2
la flancos ati an	PF-06651600	JAK3	Rheumatoid Arthritis	Phase 2
Inflammation and	PF-06651600	JAK3	Ulcerative Colitis	Phase 2
Immunology	PF-06651600	JAK3	Crohn's Disease	Phase 2
	PF-06700841	TYK2/JAK1	Alopecia Areata	Phase 2
	PF-06700841	TYK2/JAK1	Psoriasis	Phase 2
	PF-06700841	TYK2/JAK1	Ulcerative Colitis	Phase 2
	PF-06700841	TYK2/JAK1	Crohn's Disease	Phase 2
	PF-06823859	interferon, beta 1, fibroblast (IFNB1) Blocker	Inflammatory Disorders (Biologic)	Phase 2
	PF-06763809	Transcription factor inhibitor	Psoriasis	Phase 1
	PF-06817024	Cytokine Modulator	Atopic Dermatitis (Biologic)	Phase 1
	PF-06826647	TYK2 Inhibitor	Inflammatory Bowel Disease	Phase 1



► Indicates that the project is either new or has progressed in phase since Indicates Regulatory Designation – See Definitions in Backup

chemokine inhibitor

Lupus (Biologic)

PF-06835375

Phase 1

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

▶ Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com



New Indication or Enhancement

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	dacomitinib (PF-00299804)	pan-HER Inhibitor	1st Line EGFR-activating mutant Non-Small Cell Lung Cancer (E.U.)	Registration
	glasdegib (PF-04449913)	SMO (smoothened) antagonist	Combo w/ low-dose cytarabine (LDAC) for: Acute Myeloid Leukemia (PRIORITY REVIEW)	Registration
	lorlatinib (PF-06463922)	ALK Inhibitor	2nd Line ALK Non-Small Cell Lung Cancer (BREAKTHROUGH, ORPHAN - U.S., PRIORITY REVIEW)	Registration
	talazoparib (MDV3800)	PARP inhibitor	Germline BRCA Mutated Metastatic Breast Cancer (E.U.)	Registration
	Xtandi (enzalutamide)	Androgen receptor inhibitor	Non-metastatic Castration-Resistant Prostate Cancer (E.U.)	Registration
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ talazoparib (MDV3800) for: 1st Line Ovarian Cancer (Biologic)	Phase 3
Oncology	Bavencio (avelumab)	Anti PD-L1 Inhibitor	2nd Line Non-Small Cell Lung Cancer (Biologic)	Phase 3
(1 of 3)	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Non-Small Cell Lung Cancer (Biologic)	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Gastric Cancer (Biologic)	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Platinum Resistant/Refractory Ovarian Cancer (Biologic)	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Ovarian Cancer (Biologic)	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Urothelial Cancer (Biologic)	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Renal Cell Carcinoma (Biologic) (Combo w/ Inlyta (axitinib)) (BREAKTHROUGH)	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Locally Advanced Squamous Cell Carcinoma of the Head and Neck (Biologic)	Phase 3
	glasdegib (PF-04449913)	SMO (smoothened) antagonist	Acute Myeloid Leukemia (ORPHAN - U.S., E.U.)	Phase 3



Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	High Risk Early Breast Cancer	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	Early Breast Cancer in Adjuvant Setting	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	HER2+ Breast Cancer	Phase 3
	lorlatinib (PF-06463922)	ALK Inhibitor	1st Line ALK Non-Small Cell Lung Cancer (ORPHAN - U.S.)	Phase 3
	talazoparib (MDV3800)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for: 1st Line Metastatic Castration-Resistant Prostate Cancer	Phase 3
	Xtandi (enzalutamide)	Androgen receptor inhibitor	Metastatic Hormone Sensitive Prostate Cancer	Phase 3
	Xtandi (enzalutamide)	Androgen receptor inhibitor	Non-metastatic High Risk Hormone Sensitive Prostate Cancer	Phase 3
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Merkel Cell Carcinoma (E.U.) (Biologic)	Phase 2
Oncology (2 of 3)	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ PF-04518600 (OX40) for: Squamous Cell Carcinoma of the Head and Neck (Biologic)	Phase 2
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ PF-05082566 (4-1BB) for: Melanoma, Non-Small Cell Lung Cancer, Small Cell Lung Cancer, Squamous Cell Carcinoma of the Head and Neck, Triple- Negative Breast Cancer (Biologic)	Phase 2
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ talazoparib (MDV3800) for: Locally Advanced (Primary or Recurrent) or Metastatic Solid Tumors (Biologic)	Phase 2
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ talazoparib (MDV3800) for: Solid Tumors with a BRCA or ATM defect (Biologic)	Phase 2
	talazoparib (MDV3800)	PARP inhibitor	2nd Line Metastatic Castration-Resistant Prostate Cancer	Phase 2
	► talazoparib (MDV3800)	PARP inhibitor	Germline BRCA Mutated Locally Advanced Triple Negative Breast Cancer	Phase 2



New Indication or Enhancement

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ PF-04518600 (OX40) and PF- 05082566 (4-1BB) for: Cancer (Biologic)	Phase 1
	► Bavencio (avelumab)	Anti PD-L1 Inhibitor	Combo w/ talazoparib (MDV3800) and Array's MEK inhibitor for: Solid Tumors (Biologic)	Phase 1
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Cancer (Biologic)	Phase 1
	gedatolisib (PF-05212384)	Phosphatidyl inositol-3 kinase catalytic sub-unit α inhibitor / mammalian target of rapamycin inhibitor (PI3K/mTOR)	Cancer	Phase 1
	glasdegib (PF-04449913)	SMO (smoothened) antagonist	Cancer	Phase 1
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	Cancer	Phase 1
Oncology (3 of 3)	Inlyta (axitinib)	VEGF Tyrosine Kinase Inhibitor	Combo w/ Merck's Keytruda (PD-1, pembrolizumab) for: Cancer	Phase 1
, ,	PF-04518600	OX40 receptor Agonist	Cancer (Biologic)	Phase 1
	PF-06647020	protein tyrosine kinase 7 (PTK7) Targeted Cytotoxicity	Cancer (Biologic)	Phase 1
	PF-06671008	cadherin 3, type 1, P-cadherin (placental) (CDH3)	Cancer (Biologic)	Phase 1
	PF-06688992	Antibody Drug Conjugate	Cancer (Biologic)	Phase 1
	PF-06801591	Anti-PD-1	Cancer Immunotherapy (Biologic)	Phase 1
	PF-06804103	Antibody Drug Conjugate	Cancer (Biologic)	Phase 1
	PF-06821497	EZH2 inhibitor	Cancer	Phase 1
	PF-06863135	Bispecific protein	Multiple Myeloma (Biologic)	Phase 1
	PF-06873600	CDK inhibitor	Breast Cancer Metastatic	Phase 1



▶ Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	tafamidis meglumine	Transthyretin (TTR) Dissociation Inhibitor	Transthyretin familial amyloid polyneuropathy (U.S.) (FAST TRACK, ORPHAN - U.S.)	Registration
	fidanacogene elaparvovec (PF- 06838435)	Gene Therapy, coagulation factor IX (F9)	Hemophilia (Biologic) (BREAKTHROUGH, ORPHAN - U.S., PRIME - E.U.)	Phase 3
	rivipansel (GMI-1070)	Pan-Selectin Antagonist	Vaso-occlusive crisis associated with Sickle Cell Disease (FAST TRACK, ORPHAN - U.S., E.U.)	Phase 3
	somatrogon (PF-06836922)	Human Growth Hormone Agonist	Adult Growth Hormone Deficiency (Biologic) (ORPHAN - U.S., E.U.)	Phase 3
	somatrogon (PF-06836922)	Human Growth Hormone Agonist	Pediatric Growth Hormone Deficiency (Biologic) (ORPHAN - U.S., E.U.)	Phase 3
Rare Diseases	Vyndaqel (tafamidis meglumine)	Transthyretin (TTR) Dissociation Inhibitor	Transthyretin Amyloid Cardiomyopathy (BREAKTHROUGH, FAST TRACK, ORPHAN - U.S., E.U. *)	Phase 3
	► PF-06741086	Tissue Factor Pathway Inhibitor (TFPI)	Hemophilia (Biologic) (ORPHAN - U.S., E.U.)	Phase 2
	PF-07055480 (SB-525)	AAV-FVIII GTx	Hemophilia (Biologic) (ORPHAN - U.S., E.U., FAST TRACK)	Phase 2
	PF-04447943	PDE9 Inhibitor	Sickle Cell Anemia (ORPHAN - U.S.)	Phase 1
	PF-05230907	Factor Xa Protein Replacement	Intracerebral Hemorrhage (Biologic) (ORPHAN - U.S.)	Phase 1
	PF-06730512	Antagonist	Nephrotic Syndrome (Biologic)	Phase 1
	PF-06939926	minidystrophin	Duchenne Muscular Dystrophy (Biologic) (ORPHAN - U.S., E.U.)	Phase 1



<sup>▶</sup> Indicates that the project is either new or has progressed in phase since the previous portfolio update of Pfizer.com

<sup>\*</sup> Note: Two EU orphan designations apply to Vyndaqel in cardiomyopathy: One for patients with familial amyloid cardiomyopathy due to a genetic variant of the TTR gene (TTR-FAC; Orphan Drug Designation indication: Familial Amyloid Polyneuropathy), and another EU orphan designation for senile systemic amyloidosis, for cardiomyopathy in patients without the gene variant (TTR-Wild Type).

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	PF-06425090	Prophylactic Vaccine	Primary clostridium difficile infection (FAST TRACK)	Phase 3
	PF-06290510	Prophylactic Vaccine	Invasive Staphylococcus aureus infections in surgical populations (FAST TRACK)	Phase 2
	PF-06482077	Prophylactic Vaccine	Invasive and non-invasive Pneumococcal infections (BREAKTHROUGH)	Phase 2
Vaccines	PF-06842433	Prophylactic Vaccine	Invasive and non-invasive Pneumococcal infections	Phase 2
vaccines	PF-06753512	Therapeutic Vaccine	Prostate Cancer	Phase 1
	PF-06760805	Prophylactic Vaccine	Invasive Group B streptococcus infection	Phase 1
	PF-06886992	Prophylactic Vaccine	Serogroups ABCWY meningococcal infections	Phase 1
	PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection	Phase 1



Biosimilar

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	PF-05280014, a potential biosimilar to Herceptin® (trastuzumab)	erbB2 TK Inhibitor	Metastatic Breast Cancer (U.S.) (Biosimilar)	Registration
	► PF-05280586, a potential biosimilar to Rituxan® /MabThera® (rituximab)	CD20 Antigen Antagonist	Follicular Lymphoma (Biosimilar)	Registration
Biosimilars	► PF-06439535, a potential biosimilar to Avastin® (bevacizumab)	VEGF inhibitor	Non-Small Cell Lung Cancer (Biosimilar)	Registration
	PF-06410293, a potential biosimilar to Humira® (adalimumab)	Tumor Necrosis Factor Inhibitor	Rheumatoid Arthritis (Biosimilar)	Phase 3
	PF-06881894, a potential biosimilar to Neulasta® (Pegfilgrastim)	Human Granulocyte Colony Stimulating Factor	Neutropenia in patients undergoing cancer chemotherapy (Biosimilar)	Phase 1
Other Areas of Focus	aztreonam-avibactam (PF- 06947387)	Beta Lactam/Beta Lactamase Inhibitor	Complicated Intra-Abdominal Infections, Hospital Acquired Pneumonia/Ventilator Associated Pneumonia	Phase 3

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# Projects Discontinued from Development since July 31, 2018

Compound Name	Mechanism of Action	Indication	Phase
domagrozumab (PF-06252616)	Myostatin Inhibitor	Duchenne Muscular Dystrophy (Biologic) (FAST TRACK, ORPHAN - U.S., E.U.)	Phase 2



# **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 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 (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.

