

# **Pfizer Pipeline**

As of January 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 January 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.

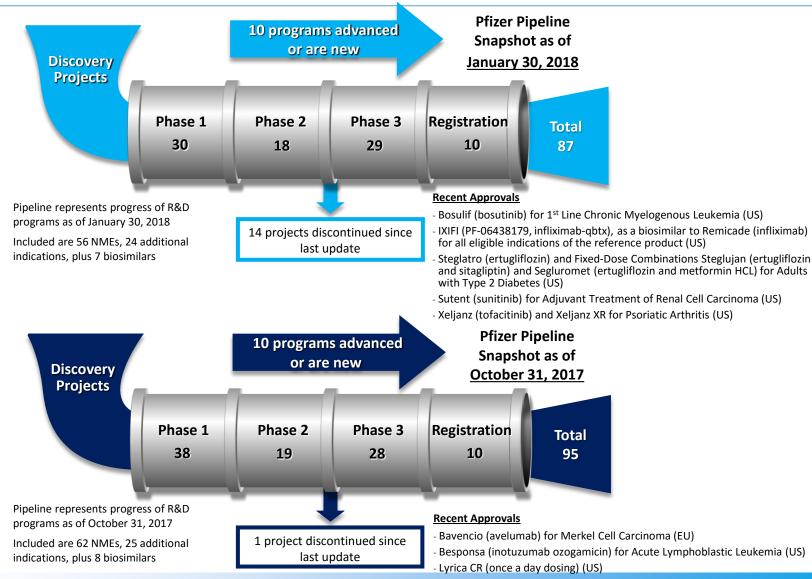


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#### **Pfizer Pipeline Snapshot**





- Mylotarg (gemtuzumab ozogamicin) for Acute Myeloid Leukemia (US)

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	Xeljanz (tofacitinib)	JAK Inhibitor	Ulcerative Colitis	Registration
	Xeljanz (tofacitinib)	JAK Inhibitor	Psoriatic Arthritis (E.U.)	Registration
	▶ PF-04965842	JAK Inhibitor	Atopic Dermatitis	Phase 3
	Dekavil	IL-10	Rheumatoid Arthritis, *Inflammatory Bowel Disease (Biologic)	Phase 2
	PF-06480605	TNFSF15 Blocker	Ulcerative Colitis (Biologic)	Phase 2
	PF-06650833	IRAK4	Rheumatoid Arthritis	Phase 2
Inflammation	PF-06651600	JAK3	Alopecia Areata, Rheumatoid Arthritis, Ulcerative Colitis	Phase 2
and Immunology	PF-06700841	TYK2/JAK1	Alopecia Areata, Psoriasis, Ulcerative Colitis	Phase 2
	PF-06342674	interleukin 7 receptor precursor Modulator	Diabetes Mellitus-Type 1 (Biologic)	Phase 1
	PF-06423264	acetyl-Coenzyme A carboxylase alpha+beta Inhibitor	Acne	Phase 1
	PF-06817024	Cytokine Modulator	Atopic Dermatitis (Biologic)	Phase 1
	PF-06823859	interferon, beta 1, fibroblast (IFNB1) Blocker	Lupus (Biologic)	Phase 1
	PF-06826647	TYK2 Inhibitor	Inflammatory Bowel Disease	Phase 1
	▶ PF-06835375	chemokine inhibitor	Lupus (Biologic)	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: Additional indications in Phase 1

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	ertugliflozin (PF-04971729)	SGLT-2 Inhibitor	Diabetes Mellitus-Type 2 (E.U.)	Registration
Metabolic Disease	PF-05221304	Acetyl CoA-Carboxylase (ACC) Inhibitor	Non-Alcoholic Steatohepatitis (NASH) (FAST TRACK)	Phase 2
and Cardiovascular Risks	▶ PF-06835919	Ketohexokinase (KHK) Inhibitor	Non-Alcoholic Steatohepatitis (NASH)	Phase 2
Cardiovascular Risks	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

▶ 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
	Bosulif (bosutinib)	Abl and src-family Kinase Inhibitor	1st Line Chronic Myelogenous Leukemia (E.U.) (ORPHAN - E.U.)	Registration
	Mylotarg	CD33-targeted cytotoxic agent	1st Line Acute Myeloid Leukemia (E.U.) (Biologic) (ORPHAN - E.U.)	Registration
	Sutent (sunitinib)	Multiple Tyrosine Kinase Inhibitor	Renal Cell Carcinoma Adjuvant (E.U.)	Registration
	Bavencio (avelumab)	Anti PD-L1 Inhibitor	2nd Line Non-Small Cell Lung Cancer (Biologic)	Phase 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
Oncology	Bavencio (avelumab)	Anti PD-L1 Inhibitor	Platinum Resistant/Refractory Ovarian Cancer (Biologic)	Phase 3
(1 of 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
	dacomitinib (PF-00299804)	pan-HER Inhibitor	1st Line EGFR-activating mutant Non-Small Cell Lung Cancer (ORPHAN - U.S.)	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	High Risk Early Breast Cancer	Phase 3



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New Indication or Enhancement

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	Early Breast Cancer in Adjuvant Setting, *Cancer	Phase 3
	Ibrance (palbociclib)	CDK 4,6 Kinase Inhibitor	HER2+ Breast Cancer	Phase 3
	Inlyta (axitinib)	VEGF Tyrosine Kinase Inhibitor	Renal Cell Carcinoma Adjuvant, *Cancer combo w/ Merck's Keytruda (PD-1, pembrolizumab)	Phase 3
	lorlatinib (PF-06463922)	ALK Inhibitor	1st Line ALK Non-Small Cell Lung Cancer (ORPHAN - U.S.)	Phase 3
	talazoparib (MDV3800)	PARP inhibitor	Germline BRCA Mutated Metastatic Breast Cancer	Phase 3
	► talazoparib (MDV3800)	PARP inhibitor	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 Castrate Resistar Cancer		Phase 3	
Oncology	Xtandi (enzalutamide)	Androgen receptor inhibitor	Non-metastatic High Risk Hormone Sensitive Prostate Cancer	Phase 3
(2 of 3)	Bavencio (avelumab)	Anti PD-L1 Inhibitor	1st Line Merkel Cell Carcinoma (E.U.), Combo w/ PF-04518600 (OX40) for: Squamous Cell Carcinoma of the Head and Neck, 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, *Combo w/ PF- 04518600 (OX40) and PF-05082566 (4-1BB) for: Cancer, * Combo w/ talazoparib (MDV3800) for: Solid Tumors, *Cancer (Biologic)	Phase 2
	glasdegib (PF-04449913)	SMO (smoothened) antagonist	Acute Myeloid Leukemia (ORPHAN - U.S., E.U.), *Cancer	Phase 2
	lorlatinib (PF-06463922)	ALK Inhibitor	2nd Line ALK Non-Small Cell Lung Cancer (BREAKTHROUGH, ORPHAN - U.S.)	Phase 2
	► talazoparib (MDV3800)	PARP inhibitor	2nd Line Metastatic Castration-Resistant Prostate Cancer	Phase 2

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New Indication or Enhancement

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	Xtandi (enzalutamide)	Androgen receptor inhibitor	Hepatocellular Carcinoma	Phase 2
	gedatolisib (PF-05212384)	Phosphatidyl inositol-3 kinase catalytic sub-unit α inhibitor / mammalian target of rapamycin inhibitor (PI3K/mTOR)	Cancer	Phase 1
	PF-04136309	CCR2 (Chemokine receptor 2) Antagonist	Pancreatic Cancer (ORPHAN - U.S.)	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
Oncology (3 of 3)	PF-06688992	Antibody Drug Conjugate	Cancer (Biologic)	Phase 1
	PF-06747775	epidermal growth factor receptor (erythroblastic)	Cancer	Phase 1
	PF-06801591	programmed cell death 1 (PDCD1) Antagonist	Cancer Immunotherapy (Biologic)	Phase 1
	▶ PF-06804103	Antibody Drug Conjugate	Cancer (Biologic)	Phase 1
	▶ PF-06863135	Bispecific protein	Multiple Myeloma (Biologic)	Phase 1
	PF-06883541	CD19 molecule Targeted Cytotoxicity CART	Cancer (Biologic)	Phase 1
	utomilumab (PF-05082566)	CD137 Agonist	Cancer (Biologic), Combo w/ Merck's Keytruda (PD-1, pembrolizumab), Combo w/ Kyowa Hakko Kirin's anti-CCR4 antibody (mogamulizumab)	Phase 1



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New Indication or Enhancement

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
	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
	maglumina)   Inhihitor	Adult Symptomatic Transthyretin Cardiomyopathy (FAST TRACK, ORPHAN - U.S., E.U. **)	Phase 3	
Rare Diseases	domagrozumab (PF-06252616)	Myostatin Inhibitor	Duchenne Muscular Dystrophy (Biologic) (FAST TRACK, ORPHAN - U.S., E.U.)	Phase 2
	PF-06838435	Gene Therapy, coagulation factor IX (F9)	Hemophilia (Biologic) (BREAKTHROUGH, ORPHAN - U.S., PRIME - 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-06741086	Tissue Factor Pathway Inhibitor (TFPI)	Hemophilia (Biologic) (ORPHAN - U.S., E.U.)	Phase 1
	▶ PF-06939926	minidystrophin	Duchenne Muscular Dystrophy (Biologic) (ORPHAN - U.S., E.U.)	Phase 1
		Vyndaqel in cardiomyopathy: One for patients with		



a genetic variant of the TTR gene (TTR-FAC; Orphan Drug Designation indication: Familial Amyloid Polyneuropathy), and another EU

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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	Phase 2
Vaccines	PF-06753512	Therapeutic Vaccine	Prostate Cancer	Phase 1
	PF-06760805	Prophylactic Vaccine	Invasive Group B streptococcus infection	Phase 1
	PF-06842433	Prophylactic Vaccine	Invasive and non-invasive Pneumococcal infections	Phase 1
	PF-06886992	Prophylactic Vaccine	Serogroups ABCWY meningococcal infections	Phase 1



Biosimilar

Therapeutic Area	Compound Name	Mechanism of Action	Indication	Phase
	► Filgrastim, a potential biosimilar to Neupogen® (filgrastim)	Human Granulocyte Colony Stimulating Factor	Neutropenia in patients undergoing cancer chemotherapy (Biosimilar)	Registration
	PF-05280014, a potential biosimilar to Herceptin® (trastuzumab)	erbB2 TK Inhibitor	Metastatic Breast Cancer (Biosimilar)	Registration
	Retacrit <sup>®</sup> , a potential biosimilar to Epogen <sup>®</sup> and Procrit <sup>®</sup> (epoetin alfa)	Erythropoietin Stimulating Agent (ESA)	Treatment of Anemia (Biosimilar)	Registration
Biosimilars	PF-05280586, a potential biosimilar to Rituxan® /MabThera (rituximab)	CD20 Antigen Antagonist	Follicular Lymphoma (Biosimilar)	Phase 3
	PF-06410293, a potential biosimilar to Humira® (adalimumab)	Tumor Necrosis Factor Inhibitor	Rheumatoid Arthritis (Biosimilar)	Phase 3
	PF-06439535, a potential biosimilar to Avastin® (bevacizumab)	VEGF inhibitor	Non-Small Cell Lung Cancer (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	tanezumab	Nerve Growth Factor Inhibitor	OA Signs and Symptoms (FAST TRACK), Chronic Low Back Pain (FAST TRACK), Cancer Pain (Biologic)	Phase 3
	aztreonam-avibactam (PF- 06947387)	Beta Lactam/Beta Lactamase Inhibitor	Complicated Intra-Abdominal Infections	Phase 2
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# Projects Discontinued from Development since October 31, 2017

New Indication or Enhancement

Compound Name	Mechanism of Action	Indication	Phase
Bavencio (avelumab)	Anti PD-L1 Inhibitor	3rd Line Gastric Cancer (Biologic)	Phase 3
PF-06427878	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Hyperlipidemia	Phase 1
PF-06647263	ephrin-A4 (EFNA4) Targeted Cytotoxicity	Cancer (Biologic)	Phase 1
PF-06667272	Myeloperoxidase Inhibitor	Non-Alcoholic Steatohepatitis (NASH)	Phase 1
PF-06747143	chemokine (C-X-C motif) receptor 4 (CXCR4) Inhibitor	Acute Myeloid Leukemia (Biologic)	Phase 1
PF-06840003	indoleamine 2,3-dioxygenase 1 (IDO1) Inhibitor	Cancer	Phase 1
* PF-06372865	GABA A Receptor Agonist	Epilepsy	Phase 2
* PF-06649751	Dopamine 1 activator	Parkinson's Disease	Phase 2
* PF-04958242	AMPA Ion Channel	Schizophrenia	Phase 1
* PF-05251749	Combination: Casein kinase I delta/epsilon	Alzheimer's Disease	Phase 1
* PF-06648671	Gamma secretase complex Modulator	Alzheimer's Disease	Phase 1
* PF-06669571	Dopamine 1 activator	Cognitive Disorder	Phase 1
* PF-06751979	Enzyme Inhibitor	Alzheimer's Disease	Phase 1
* PF-06852231	cholinergic modulator	Alzheimer's Disease	Phase 1

#### **Additional Discontinuation:**

The Inlyta (axitinib) + Xalkori combination for Renal Cell Carcinoma has been discontinued in Phase 1. Since Inlyta (axitinib) remains in development for other indications it is still included in the number of programs reflected in the Pfizer Pipeline on slide 4.

<sup>\*</sup> Pfizer announced in January, 2018 that we have decided to exit our internal neuroscience discovery and early development efforts. Ongoing clinical trials may continue and disposition of programs affected by this exit is underway.



## **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 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.
- 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 a clinically meaningful improvement of efficacy, such as having 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.

