



# Pfizer Pipeline

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As of May 1, 2018

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# 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 May 1, 2018.
- Visit [Pfizer.com/pipeline](https://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.

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# Pfizer Pipeline Snapshot



Pipeline represents progress of R&D programs as of May 1, 2018

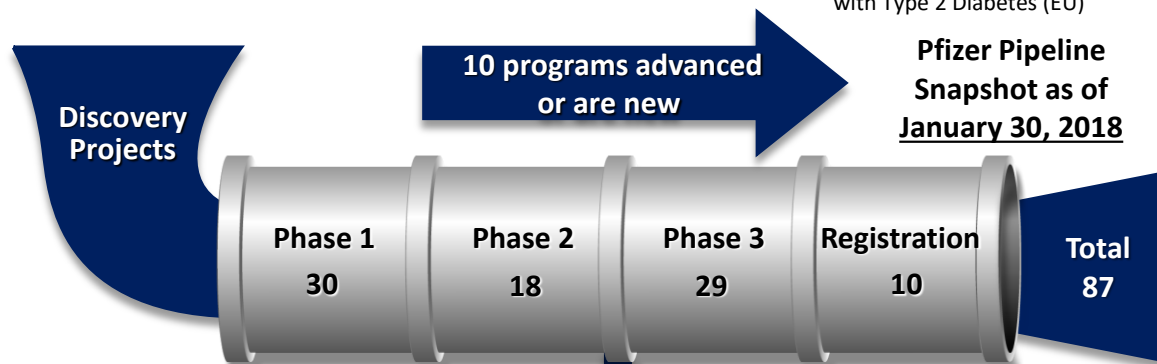
Included are 49 NMEs, 39 additional indications, plus 8 biosimilars

#### Recent Approvals

- Bosulif (bosutinib) for 1st Line Chronic Myelogenous Leukemia (EU)
- Mylotarg (gemtuzumab ozogamicin) for 1<sup>st</sup> Line Acute Myeloid Leukemia (EU)
- Steglatro (ertugliflozin) and Fixed-Dose Combinations Steglujan (ertugliflozin and sitagliptin) and Segluromet (ertugliflozin and metformin HCL) for Adults with Type 2 Diabetes (EU)

\* A portion of the increase in the number of projects in Phase 1 and Phase 2 between the January 30, 2018 and May 1, 2018 updates is attributable to a change in project counting practices. Multiple indications previously combined and reflected as a single project are now being counted separately.

This change has been implemented to increase transparency and provide a more comprehensive view of our early and mid-stage portfolio.



Pipeline represents progress of R&D programs as of January 30, 2018

Included are 56 NMEs, 24 additional indications, plus 7 biosimilars

#### Recent Approvals

- Bosulif (bosutinib) for 1<sup>st</sup> Line Chronic Myelogenous Leukemia (US)
- IXIFI (PF-06438179, infliximab-qbtX), as a biosimilar to Remicade (infliximab) for all eligible indications of the reference product (US)
- Steglatro (ertugliflozin) and Fixed-Dose Combinations Steglujan (ertugliflozin and sitagliptin) and Segluromet (ertugliflozin and metformin HCL) for Adults with Type 2 Diabetes (US)
- Sutent (sunitinib) for Adjuvant Treatment of Renal Cell Carcinoma (US)
- Xeljanz (tofacitinib) and Xeljanz XR for Psoriatic Arthritis (US)



# Pfizer Pipeline – May 1, 2018

New Molecular Entity

New Indication or Enhancement

| Therapeutic Area            | Compound Name           | Mechanism of Action                            | Indication   | Phase        |
|-----------------------------|-------------------------|--|--|--------------|
| Inflammation and Immunology | ▶ Xeljanz (tofacitinib) | JAK Inhibitor                                  | Modified Release 11mg Tablet for Rheumatoid Arthritis (E.U.) | Registration |
|                             | Xeljanz (tofacitinib)   | JAK Inhibitor                                  | Ulcerative Colitis   | Registration |
|                             | Xeljanz (tofacitinib)   | JAK Inhibitor                                  | Psoriatic Arthritis (E.U.)                                   | Registration |
|                             | PF-04965842             | JAK Inhibitor                                  | Atopic Dermatitis ( <b>BREAKTHROUGH</b> )                    | Phase 3      |
|                             | Dekavil                 | IL-10  | Rheumatoid Arthritis (Biologic)                              | Phase 2      |
|                             | PF-06480605             | TNFSF15 Blocker                                | Ulcerative Colitis (Biologic)                                | Phase 2      |
|                             | PF-06650833             | IRAK4  | Rheumatoid Arthritis   | Phase 2      |
|                             | PF-06651600             | JAK3   | Alopecia Areata  | Phase 2      |
|                             | PF-06651600             | JAK3   | Rheumatoid Arthritis   | Phase 2      |
|                             | PF-06651600             | JAK3   | Ulcerative Colitis   | Phase 2      |
|                             | ▶ 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      |
|                             | Dekavil                 | IL-10  | Inflammatory Bowel Disease (Biologic)                        | Phase 1      |
|                             | PF-06342674             | interleukin 7 receptor precursor Modulator     | Diabetes Mellitus-Type 1 (Biologic)                          | 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  |              |



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

Indicates Regulatory Designation – See Definitions in Backup

# Pfizer Pipeline – May 1, 2018 (cont'd)

| Therapeutic Area  | Compound Name | Mechanism of Action                                     | Indication  | Phase   |
|---|---------------|---|---|---------|
| <b>Metabolic Disease<br/>and<br/>Cardiovascular Risks</b> | PF-05221304   | Acetyl CoA-Carboxylase (ACC)<br>Inhibitor               | Non-Alcoholic Steatohepatitis (NASH)<br><b>(FAST TRACK)</b> | Phase 2 |
|   | PF-06835919   | Ketohexokinase (KHK) Inhibitor                          | Non-Alcoholic Steatohepatitis (NASH)                        | Phase 2 |
|   | PF-06865571   | Diacylglycerol O-Acyltransferase 2<br>(DGAT2) Inhibitor | Non-Alcoholic Steatohepatitis (NASH)                        | Phase 1 |
|   | PF-06882961   | Glucagon-like peptide 1 receptor<br>(GLP-1R) Agonist    | Diabetes Mellitus-Type 2                                    | Phase 1 |

Indicates Regulatory Designation – See Definitions in Backup

# Pfizer Pipeline – May 1, 2018 (cont'd)

New Molecular Entity

New Indication or Enhancement

| Therapeutic Area     | Compound Name               | Mechanism of Action                | Indication   | Phase        |
|----------------------|-----------------------------|------------------------------------|--|--------------|
| Oncology<br>(1 of 3) | ▶ dacomitinib (PF-00299804) | pan-HER Inhibitor                  | 1st Line EGFR-activating mutant Non-Small Cell Lung Cancer ( <b>ORPHAN - U.S., PRIORITY REVIEW</b> ) | Registration |
|                      | ▶ lorlatinib (PF-06463922)  | ALK Inhibitor                      | 2nd Line ALK Non-Small Cell Lung Cancer ( <b>BREAKTHROUGH, ORPHAN - U.S., PRIORITY REVIEW</b> )      | Registration |
|                      | Sutent (sunitinib)          | Multiple Tyrosine Kinase Inhibitor | Renal Cell Carcinoma Adjuvant (E.U.)   | Registration |
|                      | ▶ Xtandi (enzalutamide)     | Androgen receptor inhibitor        | Non-metastatic Castrate Resistant Prostate Cancer ( <b>PRIORITY REVIEW</b> )                         | 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      |
|                      | 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)) ( <b>BREAKTHROUGH</b> )        | Phase 3      |
|                      | Bavencio (avelumab)         | Anti PD-L1 Inhibitor               | Locally Advanced Squamous Cell Carcinoma of the Head and Neck (Biologic)                             | Phase 3      |
|                      | Ibrance (palbociclib)       | CDK 4,6 Kinase Inhibitor           | High Risk Early Breast Cancer  | Phase 3      |



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# Pfizer Pipeline – May 1, 2018 (cont'd)

New Molecular Entity

New Indication or Enhancement

| Therapeutic Area     | Compound Name             | Mechanism of Action         | Indication   | Phase   |
|----------------------|---------------------------|-----------------------------|--|---------|
| Oncology<br>(2 of 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 |
|                      | ► glasdegib (PF-04449913) | SMO (smoothened) antagonist | Acute Myeloid Leukemia ( <b>ORPHAN - U.S., E.U.</b> )  | Phase 3 |
|                      | lorlatinib (PF-06463922)  | ALK Inhibitor               | 1st Line ALK Non-Small Cell Lung Cancer ( <b>ORPHAN - U.S.</b> )   | 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 High Risk Hormone Sensitive Prostate Cancer   | Phase 3 |
|                      | Bavencio (avelumab)       | Anti PD-L1 Inhibitor        | 1st Line Merkel Cell Carcinoma (E.U.) (Biologic)   | Phase 2 |
|                      | 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 |
|                      | talazoparib (MDV3800)     | PARP inhibitor              | 2nd Line Metastatic Castration-Resistant Prostate Cancer   | Phase 2 |
|                      | 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) for: Solid Tumors (Biologic)  | Phase 1 |



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Indicates Regulatory Designation – See Definitions in Backup



# Pfizer Pipeline – May 1, 2018 (cont'd)

New Molecular Entity

New Indication or Enhancement

| Therapeutic Area     | Compound Name             | Mechanism of Action  | Indication   | Phase   |
|----------------------|---------------------------|--|--|---------|
| Oncology<br>(3 of 3) | Bavencio (avelumab)       | Anti PD-L1 Inhibitor   | Cancer (Biologic)                                      | Phase 1 |
|                      | gedatolisib (PF-05212384) | Phosphatidyl inositol-3 kinase catalytic sub-unit $\alpha$ 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 |
|                      | Inlyta (axitinib)         | VEGF Tyrosine Kinase Inhibitor   | Cancer combo w/ Merck's Keytruda (PD-1, pembrolizumab) | 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-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               | Bisppecific protein  | Multiple Myeloma (Biologic)                            | Phase 1 |
| ▶ PF-06873600        | CDK inhibitor             | Breast Cancer Metastatic   | Phase 1  |         |

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# Pfizer Pipeline – May 1, 2018 (cont'd)

New Molecular Entity

New Indication or Enhancement

| Therapeutic Area | Compound Name                  | Mechanism of Action   | Indication   | Phase        |
|------------------|--------------------------------|---|--|--------------|
| Rare Diseases    | tafamidis meglumine            | Transthyretin (TTR) Dissociation Inhibitor                            | Transthyretin familial amyloid polyneuropathy (U.S.) ( <b>FAST TRACK, ORPHAN - U.S.</b> )            | Registration |
|                  | rivipansel (GMI-1070)          | Pan-Selectin Antagonist   | Vaso-occlusive crisis associated with Sickle Cell Disease ( <b>FAST TRACK, ORPHAN - U.S., E.U.</b> ) | Phase 3      |
|                  | somatrogon (PF-06836922)       | Human Growth Hormone Agonist  | Adult Growth Hormone Deficiency (Biologic) ( <b>ORPHAN - U.S., E.U.</b> )                            | Phase 3      |
|                  | somatrogon (PF-06836922)       | Human Growth Hormone Agonist  | Pediatric Growth Hormone Deficiency (Biologic) ( <b>ORPHAN - U.S., E.U.</b> )                        | Phase 3      |
|                  | Vyndaqel (tafamidis meglumine) | Transthyretin (TTR) Dissociation Inhibitor                            | Adult Symptomatic Transthyretin Cardiomyopathy ( <b>FAST TRACK, ORPHAN - U.S., E.U. *</b> )          | Phase 3      |
|                  | domagrozumab (PF-06252616)     | Myostatin Inhibitor   | Duchenne Muscular Dystrophy (Biologic) ( <b>FAST TRACK, ORPHAN - U.S., E.U.</b> )                    | Phase 2      |
|                  | PF-06838435                    | Gene Therapy, coagulation factor IX (F9)                              | Hemophilia (Biologic) ( <b>BREAKTHROUGH, ORPHAN - U.S., PRIME - E.U.</b> )                           | Phase 2      |
|                  | PF-07055480 (SB-525)           | AAV-FVIII GTx   | Hemophilia (Biologic) ( <b>ORPHAN - U.S., E.U., FAST TRACK</b> )                                     | Phase 2      |
|                  | PF-04447943                    | PDE9 Inhibitor  | Sickle Cell Anemia ( <b>ORPHAN - U.S.</b> )  | Phase 1      |
|                  | PF-05230907                    | Factor Xa Protein Replacement   | Intracerebral Hemorrhage (Biologic) ( <b>ORPHAN - U.S.</b> )   | Phase 1      |
|                  | PF-06730512                    | Antagonist  | Nephrotic Syndrome (Biologic)  | Phase 1      |
|                  | PF-06741086                    | Tissue Factor Pathway Inhibitor (TFPI)                                | Hemophilia (Biologic) ( <b>ORPHAN - U.S., E.U.</b> )   | Phase 1      |
| PF-06939926      | minidystrophin                 | Duchenne Muscular Dystrophy (Biologic) ( <b>ORPHAN - U.S., E.U.</b> ) | Phase 1  |              |



\* 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).

Indicates Regulatory Designation – See Definitions in Backup

# Pfizer Pipeline – May 1, 2018 (cont'd)

| Therapeutic Area | Compound Name | Mechanism of Action  | Indication   | Phase   |
|------------------|---------------|----------------------|--|---------|
| Vaccines         | PF-06425090   | Prophylactic Vaccine | Primary clostridium difficile infection<br><b>(FAST TRACK)</b>                           | Phase 3 |
|                  | PF-06290510   | Prophylactic Vaccine | Invasive Staphylococcus aureus infections<br>in surgical populations <b>(FAST TRACK)</b> | Phase 2 |
|                  | PF-06482077   | Prophylactic Vaccine | Invasive and non-invasive Pneumococcal<br>infections                                     | Phase 2 |
|                  | 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<br>infections                                     | Phase 1 |
|                  | PF-06886992   | Prophylactic Vaccine | Serogroups ABCWY meningococcal<br>infections   | Phase 1 |

Indicates Regulatory Designation – See Definitions in Backup

# Pfizer Pipeline – May 1, 2018 (cont'd)

New Molecular Entity

Biosimilar

| Therapeutic Area     | Compound Name  | Mechanism of Action                         | Indication   | Phase        |
|----------------------|--|---|--|--------------|
| Biosimilars          | 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 |
|                      | ► PF-06439535, a potential biosimilar to Avastin® (bevacizumab)          | VEGF inhibitor                              | Non-Small Cell Lung Cancer (E.U.) (Biosimilar)   | Registration |
|                      | Retacrit®, a potential biosimilar to Epogen® and Procrit® (epoetin alfa) | Erythropoietin Stimulating Agent (ESA)      | Treatment of Anemia (Biosimilar)   | Registration |
|                      | 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 (U.S.) (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      |
|                      | tanezumab  | Nerve Growth Factor Inhibitor               | OA Signs and Symptoms ( <b>FAST TRACK</b> ), Chronic Low Back Pain ( <b>FAST TRACK</b> ), Cancer Pain (Biologic) | Phase 3      |

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

Indicates Regulatory Designation – See Definitions in Backup



# Projects Discontinued from Development since January 30, 2018

New Molecular Entity

New Indication or Enhancement

| Compound Name            | Mechanism of Action                                | Indication   | Phase   |
|--------------------------|--|--|---------|
| Inlyta (axitinib)        | VEGF Tyrosine Kinase Inhibitor                     | Renal Cell Carcinoma Adjuvant  | Phase 3 |
| Xtandi (enzalutamide)    | Androgen receptor inhibitor                        | Hepatocellular Carcinoma   | Phase 2 |
| PF-04136309              | CCR2 (Chemokine receptor 2) Antagonist             | Pancreatic Cancer ( <b>ORPHAN - U.S.</b> )                                 | Phase 1 |
| PF-06423264              | acetyl-Coenzyme A carboxylase alpha+beta Inhibitor | Acne   | Phase 1 |
| * PF-06883541            | CD19 molecule Targeted Cytotoxicity CART           | Cancer (Biologic)  | Phase 1 |
| utumilumab (PF-05082566) | CD137 Agonist                                      | Cancer (Biologic)  | Phase 1 |
| utumilumab (PF-05082566) | CD137 Agonist                                      | Combo w/ Merck's Keytruda (PD-1, pembrolizumab) (Biologic)                 | Phase 1 |
| utumilumab (PF-05082566) | CD137 Agonist                                      | Combo w/ Kyowa Hakko Kirin's anti-CCR4 antibody (mogamulizumab) (Biologic) | Phase 1 |

\* Pursuant to a transaction between Pfizer and Allogene Therapeutics, Inc. (Allogene), on April 9, 2018, Allogene acquired from Pfizer the rights to PF-06883541 (CD19 molecule Targeted Cytotoxicity CART), which was a clinical asset previously licensed by Pfizer from Servier. As a result, this clinical asset is shown as discontinued from Phase 1 of Pfizer's pipeline.

Indicates Regulatory Designation – See Definitions in Backup



# 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 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.