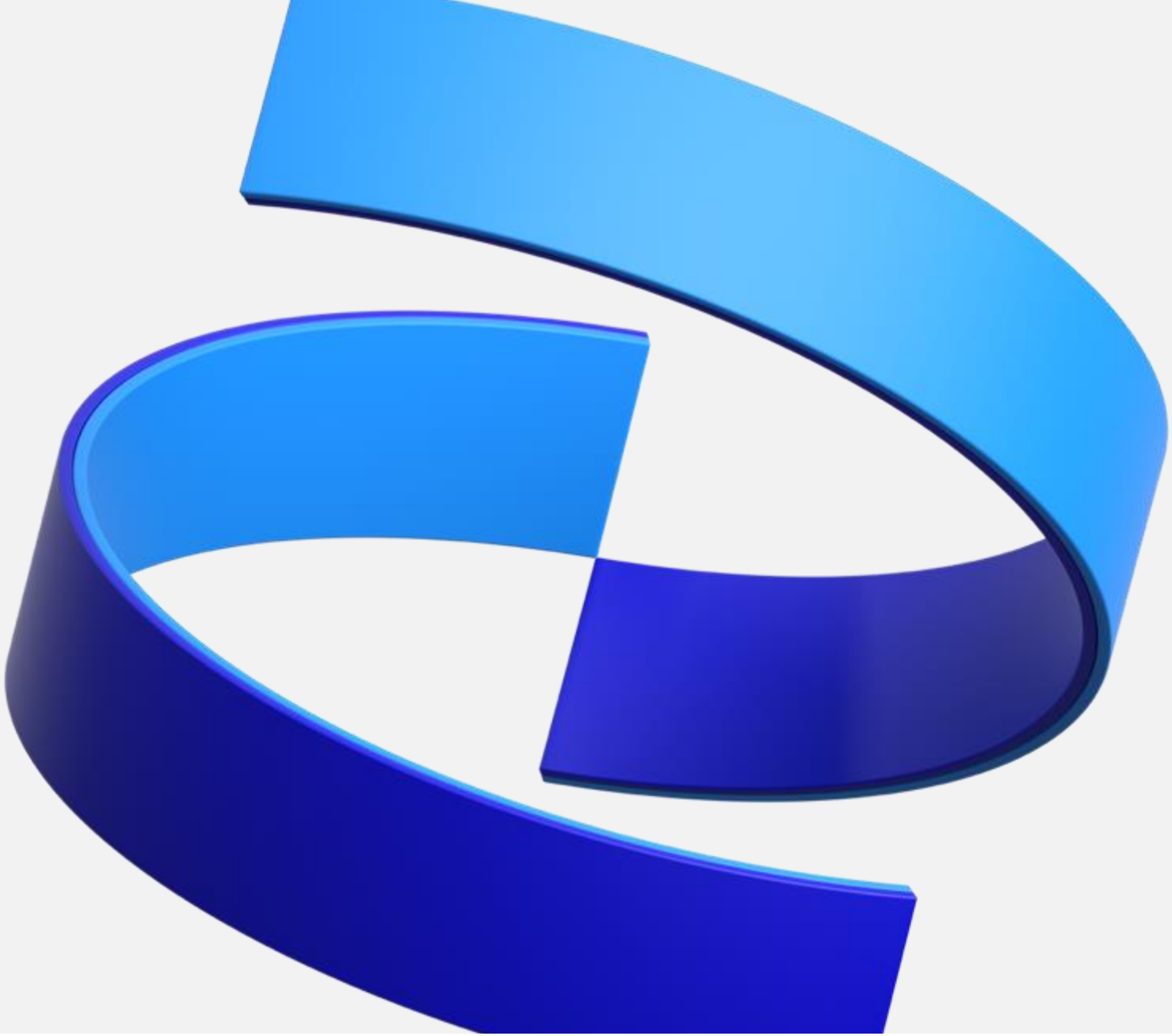
Pfizer Pipeline

Feb 8, 2022



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 Feb 8, 2022.

- 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.

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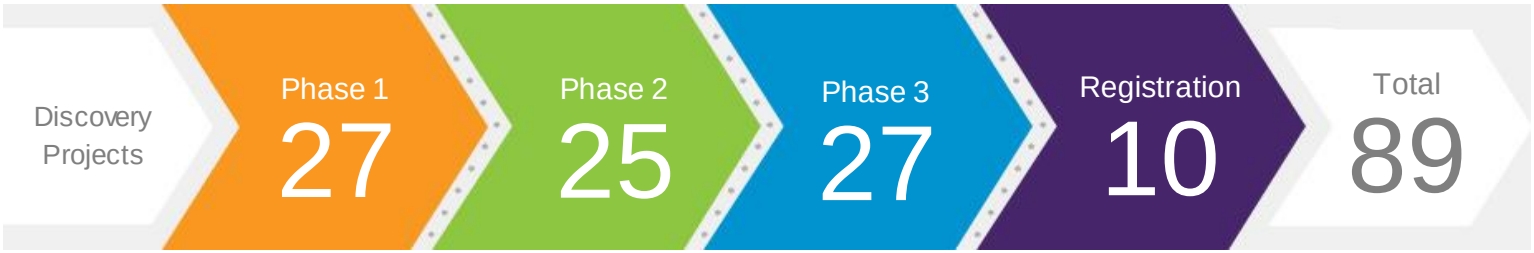


Pfizer Pipeline Snapshot as of February 8, 2022

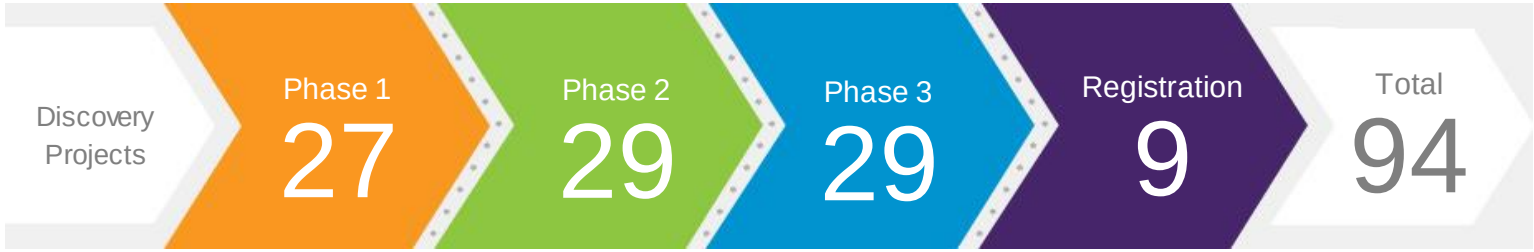
Pipeline represents progress of R&D programs as of February 8, 2022

- 8 programs advanced or are new
- 8 programs discontinued since last update
- Included are 59 NMEs, 30 additional indications

Recent Approvals

- XELJANZ® (tofacitinib) for the treatment of adults with active ankylosing spondylitis (AS) (U.S.; E.U.)
- Cibinqo® (abrocitinib) for the treatment of moderate-to-severe atopic dermatitis (AD) in adults (U.S; E.U.)
- LORVIQUA® (lorlatinib) for the treatment of adult patients with ALK- positive advanced NSCLC previously not treated with an ALK inhibitor (E.U.)

*- COMIRNATY® Booster (Pfizer/BioNTech COVID-19 vaccine) expanded Emergency Use Authorization (EUA) from FDA on Dec 9, 2021 to include individuals 16 years of age and older and on Jan 3, 2022 to include individuals 12 years of age and older (U.S.)
- COMIRNATY® received conditional marketing authorization (CMA) from the EMA on Nov 25, 2021 for children aged 5 to 11 years (E.U.)
- PAXLOVID™ (nirmatrelvir [PF-07321332] and ritonavir) received EUA from FDA on Dec 22, 2021 for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg [88 lbs]) and who are at high risk for progression to severe COVID-19 (U.S.) and CMA from EMA on Jan 28, 2022 for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19 (E.U.)



Pfizer Pipeline Snapshot as of November 2, 2021

Pipeline represents progress of R&D programs as of November 2, 2021

- 13 programs advanced or are new
- 16 programs discontinued since last update
- Included are 59 NMEs, 35 additional indications

Recent Approvals

- TICOVAC™ (tick-borne encephalitis (TBE) vaccine) for active immunization to prevent TBE in individuals 1 year of age and older (U.S.)
- COMIRNATY® (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 16 years of age and older. COMIRNATY is the first COVID-19 vaccine to be granted approval by the FDA (U.S.)

* COMIRNATY® Booster (Pfizer/BioNTech COVID-19 vaccine) received Emergency Use Authorization (EUA) from FDA on Sep 22, 2021 for individuals 65 years of age and older, and individuals ages 18 through 64 within certain high-risk groups; received conditional marketing authorization from the EMA on Oct 5, 2021 for 18 years of age and older.
COMIRNATY® received EUA from FDA (U.S.) for 5 to 11 years old age group on Oct 29, 2021

Inflammation and Immunology

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Alopecia Areata (BREAKTHROUGH)	Phase 3	New Molecular Entity
Dekavil*	IL-10	Rheumatoid Arthritis (Biologic)	Phase 2	New Molecular Entity
PF-06480605	TNFSF15 Blocker	Ulcerative Colitis (Biologic)	Phase 2	New Molecular Entity
ritlecitinib +/- PF-06650833; ritlecitinib + tofacitinib	JAK3/TEC Inhibitor IRAK4 Inhibitor JAK Inhibitor	Rheumatoid Arthritis	Phase 2	New Molecular Entity
PF-06650833	IRAK4 Inhibitor	Hidradenitis Suppurativa	Phase 2	Product Enhancement
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Ulcerative Colitis	Phase 2	Product Enhancement
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Crohn's Disease	Phase 2	Product Enhancement
ritlecitinib (PF-06651600)	JAK3/TEC Inhibitor	Vitiligo	Phase 2	Product Enhancement
Eucrisa (crisaborole)	PDE4 Inhibitor	Stasis Dermatitis	Phase 2	Product Enhancement
PF-06823859	interferon, beta 1, fibroblast (IFNB1) Blocker	Dermatomyositis (Biologic) (ORPHAN - U.S., E.U., PRIME - E.U.)	Phase 2	New Molecular Entity
PF-07038124	Topical PDE4 Inhibitor	Atopic Dermatitis and Psoriasis	Phase 2	New Molecular Entity
PF-06835375	Chemokine Inhibitor	Lupus (Biologic)	Phase 1	New Molecular Entity
PF-07054894	CCR6 Antagonist	Inflammatory Bowel Disease	Phase 1	New Molecular Entity
PF-07242813	CD1a inhibitor	Atopic Dermatitis (Biologic)	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

*Clinical trial to be conducted by Philogen S.p.A

Internal Medicine (1 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Myfembree	Oral GnRH receptor antagonist	Combination with estradiol and norethindrone acetate for Endometriosis (U.S.)	Registration	Product Enhancement
►Rimegepant	CGRP receptor antagonist	Acute migraine (E.U.)	Registration	New Molecular Entity
►Rimegepant	CGRP receptor antagonist	Migraine prevention (E.U.)	Registration	Product Enhancement
Myfembree	Oral GnRH receptor antagonist	Combination with estradiol and norethindrone acetate for contraceptive efficacy	Phase 3	Product Enhancement
ervogastat (PF-06865571)	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 2	New Molecular Entity
ervogastat (PF-06865571) + clesacostat (PF-05221304)	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor; Acetyl CoA-Carboxylase (ACC) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 2	New Molecular Entity
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Diabetes Mellitus-Type 2	Phase 2	New Molecular Entity
danuglipron (PF-06882961)	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Obesity	Phase 2	Product Enhancement

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- Regulatory Designations – See Definitions in Backup

Internal Medicine (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
PF-06946860	Growth Differentiation Factor 15 (GDF15) Monoclonal Antibody	Cachexia (Biologic)	Phase 1	New Molecular Entity
PF-07081532	Glucagon-like peptide 1 receptor (GLP-1R) Agonist	Diabetes Mellitus-Type 2 and Obesity	Phase 1	New Molecular Entity
danuglipron (PF-06882961) + PF-06865571	Glucagon-like peptide 1 receptor (GLP-1R) Agonist; Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 1	New Molecular Entity
PF-07258669	Melanocortin-4 receptor (MC4R) Antagonist	Geriatric Anorexia	Phase 1	New Molecular Entity
PF-07202954	Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor	Non-alcoholic Steatohepatitis (NASH) with Liver Fibrosis	Phase 1	New Molecular Entity

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- Regulatory Designations – See Definitions in Backup

Oncology (1 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
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 (Biologic)	Phase 3	New Molecular Entity
Talzenna (talazoparib)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for 1st Line Metastatic Castration Resistant Prostate Cancer	Phase 3	Product Enhancement
Talzenna (talazoparib)	PARP inhibitor	Combo w/ Xtandi (enzalutamide) for DDR-deficient Metastatic Castration Sensitive Prostate Cancer	Phase 3	Product Enhancement
Xtandi (enzalutamide)	Androgen receptor inhibitor	Non-metastatic High-Risk Castration Sensitive Prostate Cancer	Phase 3	Product Enhancement
Braftovi (encorafinib) + Erbitux® (cetuximab)	*BRAF* kinase inhibitor and anti EGFR	1st line BRAF-mutant Metastatic Colorectal Cancer	Phase 3	Product Enhancement
Braftovi (encorafinib) + Mektovi (binimetinib) + Keytruda® (pembrolizumab)	*BRAF* kinase inhibitor and MEK inhibitor and anti PD-1	BRAF-mutant Metastatic or Unresectable Locally Advanced Melanoma	Phase 3	Product Enhancement
Elranatamab	BCMA-CD3 Bispecific Antibody	Multiple Myeloma Double-Class Exposed (Biologic)	Phase 3	New Molecular Entity
Braftovi (encorafinib) + Mektovi (binimetinib)	*BRAF* kinase inhibitor and MEK inhibitor	1st line and 2nd line BRAF-mutant Metastatic Non-Small Cell Lung Cancer	Phase 2	Product Enhancement
ARV-471	ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer	Phase 2	New Molecular Entity

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- Regulatory Designations – See Definitions in Backup
- Erbitux® is a registered trademark of ImClone LLC
- Keytruda® is a registered trademark of Merck Sharp & Dohme Corp.
- PROTAC® is a registered U.S. trademark of Arvinas.

Pfizer

Oncology (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Elranatamab	BCMA-CD3 Bispecific Antibody	Multiple Myeloma Triple-Class Refractory (Biologic)	Phase 2	Product Enhancement
►PF-07901801 (TTI-622)	CD47-SIRPα Fusion Protein	Hematological malignancies (Biologic)	Phase 2	New Molecular Entity
PF-06647020	protein tyrosine kinase 7 (PTK7) Targeted Cytotoxicity	Cancer (Biologic)	Phase 1	New Molecular Entity
PF-06821497	EZH2 Inhibitor	Prostate Cancer	Phase 1	New Molecular Entity
PF-06873600	CDK 2,4,6 Inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07062119	GUCY2c CD3 Bispecific Antibody	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-06940434	Integrin alpha-V/beta-8 Antagonist	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07209960	interleukin 15 (IL15) Activator	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
PF-07220060	CDK4 Inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07265807	AXL/MERTK Inhibitor	Solid Tumors	Phase 1	New Molecular Entity
PF-07104091	CDK2 Inhibitor	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07248144	KAT6A Epigenetic modifier	Breast Cancer Metastatic	Phase 1	New Molecular Entity
PF-07284890	*BRAF* BP kinase Inhibitor	Melanoma	Phase 1	New Molecular Entity
PF-07284892	SHP2 tyrosine phosphatase Inhibitor	Cancer	Phase 1	New Molecular Entity
Ibrance + ARV-471	CDK 4,6 kinase inhibitor ER-targeting PROTAC® protein degrader	ER+/HER2- Metastatic Breast Cancer	Phase 1	Product Enhancement
PF-07257876	CD47xPDL1 Bispecific	NSCLC (Biologic)	Phase 1	New Molecular Entity
►PF-07263689	OBIR-2 Therapeutic Vaccine	Solid Tumors (Biologic)	Phase 1	New Molecular Entity
►PF-07260437	B7H4-CD3 Bispecific	Breast Cancer Metastatic (Biologic)	Phase 1	New Molecular Entity

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- PROTAC® is a registered U.S. trademark of Arvinas.

Rare Disease

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
somatrogon (PF-06836922)	Human Growth Hormone Agonist	Pediatric Growth Hormone Deficiency (Biologic) (ORPHAN – U.S., E.U.)	Registration	New Molecular Entity
PF-07265803	p38 Mitogen-Activated Protein Kinase Antagonist	Dilated Cardiomyopathy due To Lamin A/C Gene Mutation (ORPHAN - U.S.)	Phase 3	New Molecular Entity
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
giroctocogene fitelparvovec (PF-07055480)	Gene Therapy, coagulation factor VIII (F8)	Hemophilia (Biologic) (RMAT, 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	Product Enhancement
fordadistrogene movaparvovec (PF-06939926)	Gene Therapy, minidystrophin	Duchenne Muscular Dystrophy Ambulatory (Biologic) (FAST TRACK – U.S.; ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
marstacimab (PF-06741086)	Tissue Factor Pathway Inhibitor (TFPI)	Hemophilia (Biologic) (FAST TRACK – U.S.; ORPHAN - U.S., E.U.)	Phase 3	New Molecular Entity
PF-06730512	fusion protein containing SLIT ligand portion of ROBO2 receptor	Focal Segmental Glomerulosclerosis (FSGS); ROBO2-Fc (Biologic)	Phase 2	New Molecular Entity
recifercept	Soluble recombinant human fibroblast growth factor receptor 3 (FGFR3) decoy	Achondroplasia (Biologic) (ORPHAN - U.S., EU)	Phase 2	New Molecular Entity
PF-06755347	Immunomodulation	Chronic Inflammatory Demyelinating Polyneuropathy (ORPHAN-US); Primary Immune Thrombocytopenia (Biologic)	Phase 1	New Molecular Entity
PF-07209326	E-Selectin antagonist	Sickle Cell Disease (Biologic) (ORPHAN - U.S.)	Phase 1	New Molecular Entity

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- Regulatory Designations – See Definitions in Backup

Vaccines (1 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (FAST TRACK, U.S. – 12 to 15 years of age) (E.U. – 12 years of age and older)[1]	Registration	Product Enhancement
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection Booster (in collaboration with BioNTech) (FAST TRACK, U.S.; EU)[2]	Registration	Product Enhancement
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (FAST TRACK, U.S.; EU – 5 to 11 years of age)[3]	Registration	Product Enhancement
►Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (FAST TRACK, U.S – 6 months to 4 years of age)[4]	Registration	Product Enhancement
PF-06482077	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (adult) (E.U.)	Registration	New Molecular Entity
PF-06425090	Prophylactic Vaccine	Primary *Clostridioides difficile* infection (FAST TRACK)	Phase 3	New Molecular Entity
PF-06482077	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (pediatric) (BREAKTHROUGH, FAST TRACK)	Phase 3	Product Enhancement
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (maternal) (FAST TRACK)	Phase 3	New Molecular Entity
PF-06886992	Prophylactic Vaccine	Serogroups ABCWY Meningococcal Infections (adolescent and young adults)	Phase 3	New Molecular Entity
PF-06928316	Prophylactic Vaccine	Respiratory Syncytial Virus Infection (older adult)	Phase 3	Product Enhancement

1. Comirnaty (Pfizer/BioNTech COVID-19 vaccine) received Emergency Use Authorization (EUA) from FDA on Dec 11, 2020 and FDA BLA on Aug 23, 2021 for 16 years of age and older; received conditional marketing authorization (CMA) from the EMA on Dec 21, 2020 for 16 years of age and older. 12-15 years old age group received EUA from FDA on May 10, 2021 and conditional marketing authorization from the EMA on May 28, 2021.
2. COMIRNATY® Booster (Pfizer/BioNTech COVID-19 vaccine) expanded Emergency Use Authorization (EUA) from FDA on Dec 9, 2021 to include individuals 16 years of age and older and on Jan 3, 2022 to include individuals 12 years of age and older; received CMA from the EMA on Oct 5, 2021 for 18 years of age and older.
3. Comirnaty (Pfizer/BioNTech COVID-19 vaccine) received EUA from FDA on Oct 29, 2021 and CMA from EMA on Nov 25, 2021 for 5 to 11 years of age
4. In February 2022, following a request from the FDA, a rolling submission seeking to amend the Comirnaty EUA to include children 6 months through 4 years of age (6 months to <5 years of age) was initiated. This application is for authorization of the first two 3 µg doses of a planned three-dose primary series in this age group. Data on a third dose given at least 8 weeks after completion of the second dose are expected in the coming months and will be submitted to the FDA to support a potential expansion of this requested EUA

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• Regulatory Designations – See Definitions in Backup

Vaccines (2 of 2)

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (children 2 to 4 years of age)	Phase 3	Product Enhancement
Comirnaty (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (infants 6 months to <24 months)	Phase 3	Product Enhancement
►Omicron variant (Covid-19 Vx)	Prophylactic mRNA Vaccine	COVID-19 Infection (in collaboration with BioNTech) (adults)	Phase 3	New Molecular Entity
PF-06842433	Prophylactic Vaccine	Invasive and Non-Invasive Pneumococcal infections (infants and children)	Phase 2	New Molecular Entity
PF-06760805	Prophylactic Vaccine	Invasive Group B Streptococcus Infection (maternal) (FAST TRACK)	Phase 2	New Molecular Entity
PF-07307405	Prophylactic Vaccine	Lyme disease (FAST TRACK)	Phase 2	New Molecular Entity
PF-06886992	Prophylactic Vaccine	Serogroups ABCWY Meningococcal Infections (infants)	Phase 2	Product Enhancement
PF-07252220	Prophylactic mRNA Vaccine	Influenza (adults)	Phase 1	New Molecular Entity

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- Regulatory Designations – See Definitions in Backup

Hospital (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 (high risk population) (FAST TRACK, U.S.; EU)*	Registration	New Molecular Entity
aztreonam-avibactam (PF-06947387)	Beta Lactam/Beta Lactamase Inhibitor	Treatment of infections caused by Gram-negative bacteria	Phase 3	New Molecular Entity
Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (standard risk population)	Phase 3	Product Enhancement
Paxlovid	SARS-CoV-2 3CL protease inhibitor (oral COVID-19 treatment)	COVID-19 Infection (post exposure prophylaxis)	Phase 3	Product Enhancement
Fosmanogepix (APX001)	Gwt1 inhibitor	Treatment of invasive fungal infections	Phase 2	New Molecular Entity

*PAXLOVID™ (nirmatrelvir [PF-07321332] and ritonavir) received EUA from FDA on Dec 22, 2021 for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg [88 lbs]) and who are at high risk for progression to severe COVID-19 (U.S.) and CMA from EMA on Jan 28, 2022 for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19

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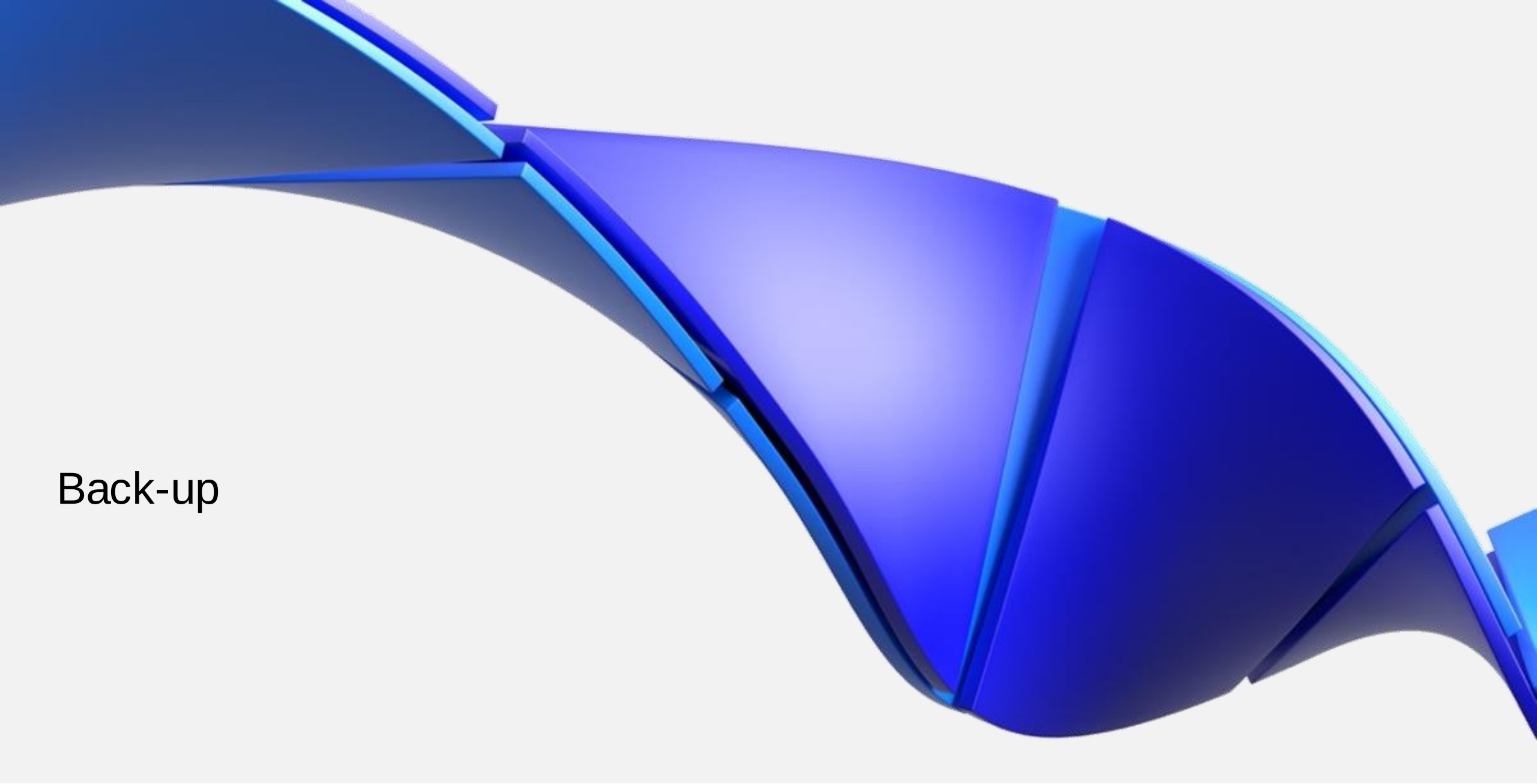
Programs Discontinued from Development since November 2, 2021

Compound Name	Mechanism of Action	Indication	Phase of Development	Submission Type
Bavencio (avelumab)	Anti PD-L1	1st Line Non-Small Cell Lung Cancer (Biologic)	Phase 3	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
Talzenna (talazoparib)	PARP inhibitor	2nd Line Metastatic Castration-Resistant Prostate Cancer	Phase 2	Product Enhancement
vupanorsen (PF-07285557)	Angiopoietin Like 3 (ANGPTL3) Antisense Oligonucleotide	Severe Hypertriglyceridemia, Cardiovascular Risk Reduction	Phase 2	New Molecular Entity
PF-07304814	SARS-CoV-2 3CL protease inhibitor (IV COVID-19 treatment)	COVID-19 Infection	Phase 2	New Molecular Entity
PF-07059013	Hemoglobin, Beta (HBB) Modulator	Sickle Cell Disease (ORPHAN - U.S.)	Phase 1	New Molecular Entity
PF-06939999	protein arginine methyltransferase 5 (PRMT5) Inhibitor	Solid Tumors	Phase 1	New Molecular Entity

*In the fourth quarter of 2021, enrollment was stopped in C4591015 Study (a Phase 2/3 placebo controlled randomized observer-blind study to evaluate the safety, tolerability, and immunogenicity of BNT162b2 against COVID-19 in healthy pregnant women 18 years of age and older). This study was developed prior to availability or recommendation for COVID-19 vaccination in pregnant women. The environment changed during 2021 and by September 2021, COVID-19 vaccines were recommended by applicable recommending bodies (e.g., ACIP in the U.S.) for pregnant women in all participating/planned countries, and as a result the enrollment rate declined significantly. With the declining enrollment, the study had insufficient sample size to assess the primary immunogenicity objective and continuation of this placebo controlled study could no longer be justified due to global recommendations. This proposal was shared with and agreed to by FDA and EMA.



Back-up

Regulatory Designations

- **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.) - 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** (E.U.) - 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 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.
- **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.