59 Selected Pharmaceuticals in Late Stage U.S. and E.U. Development or Registration as of October 19, 2021

Total Indications

Cardiovascular and Metabolism

Approved 8/21 US
XARELTO (rivaroxaban) [3]
Infrainguinal revascular PAD

Phase III US
Phase III EU
aprocitentan [2]
Difficult to treat hypertension

Filed 6/21 US
XARELTO (rivaroxaban) [3]
Pediatric VTE/CHD (Fontan)

Phase III US
XARELTO (rivaroxaban) [3]
COVID-19 MI (PREVENT-HD)

Immunology

Phase III US
Phase III EU
TREMFYA (guselkumab)
Crohn's Disease

Phase III US
TREMFYA (guselkumab)
Psoriatic Arthritis Structural Damage

Phase III US
Phase III EU
STELARA (ustekinumab)
Pediatric Crohn's Disease

Phase III US
Phase III EU
TREMFYA (guselkumab)
Pediatric Psoriasis

Phase III US
Phase III EU
SIMPONI (golimumab)
Pediatric Ulcerative Colitis

Phase III US
Phase III EU
STELARA (ustekinumab)
Pediatric Ulcerative Colitis

Phase III US
Phase III EU
TREMFYA (guselkumab)
Ulcerative Colitis Monotherapy

Phase II/III US
Phase II/III EU
nipocalimab
Warm Autoimmune Hemolytic Anemia

Infectious Diseases and Vaccines

Phase II US
Phase II EU
rilematovir (RSV Fusion)
Hematopoietic Stem Cell Transplantation patients

Approved 2/21 EUA
Approved 3/21 cMAA
VAC31518
Janssen COVID-19 Vaccine

Phase III US
Phase III EU
VAC18193
RSV Adult Vaccine

Phase III US
Approved 7/20 EU
VAC52150 [10]
Monovalent Ebola Virus Vaccine

Phase III US
Phase III EU
VAC52416
Multivalent ExPEC Vaccine

Phase III US
VAC31518
Janssen COVID-19 Vaccine Pediatrics

Phase III US
Phase III EU
VAC89220
HIV Px Vaccine

Phase III US
Phase III EU
rilematovir (RSV Fusion)
Respiratory Syncytial Virus Pediatric

Neuroscience

Approved 7/20 US
Approved 2/21 EU
SPRAVATO (esketamine)
Major Depressive Disorder with Acute Suicidal Ideation or Behavior (US) / Major Depressive Disorder in a Psychiatric Emergency (EU)

Phase III US
Phase III EU
seltorexant
Adjunctive treatment for major depressive disorder with insomnia symptoms

Approved 3/21 US
Approved 5/21 EU
PONVORY (ponesimod)
Relapsing forms of Multiple Sclerosis

Phase III US
Phase III EU
nipocalimab
Myasthenia Gravis

Approved 8/21 US
Filed 11/20 EU
INVEGA HAFYERA/BYANNLI (PP6M)
Treatment of Schizophrenia

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(2) aprocitentan developed in collaboration with Idorsia; (3) XARELTO co-developed with Bayer HealthCare; (5) DARZALEX licensed from Genmab A/S; (6) IMBRUVICA developed in collaboration with Pharmacyclics, LLC, an AbbVie company; (7) BALVERSA discovered in collaboration with Astex Pharmaceuticals, Inc.; (8) Niraparib licensed from Tesaro; (9) BCMA CAR-T licensed from Legend Biotech; (10) Monovalent Ebola Vaccine developed in collaboration with Bavarian Nordic A/S, and MVA-BN-Filo® is licensed-in from Bavarian Nordic A/S; (11) DUOBODY platform licensed from Genmab relates to several bispecific antibody programs (Amivantamab, Teclistamab , Talquetamab);

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Total Indications

Oncology

Approved 7/21 US
Approved 6/21 EU
DARZALEX (daratumumab) [5]
Relapsed Refractory Multiple Myeloma w/PomDex

Phase III US
Phase III EU
DARZALEX (daratumumab) [5]
Frontline multiple myeloma transplant ineligible in combination w/ bortezomib, lenalidomide and dexamethasone (CEPHEUS)

Phase III US
Phase III EU
IMBRUVICA (ibrutinib) [6]
Relapsed/refractory patients with Indolant Non-Hodgkins Lymphoma in combination with Bendamustine and Rituximab or R-CHOP; (SELENE)

Phase III US
Phase III EU
ERLEADA (apalutamide)
Localized prostate cancer

Phase II US
Phase II EU
BALVERSA (erdafitinib) [7]
Tumor Agnostic

Phase III US
Phase III EU
niraparib / abiraterone acetate
M1 Metastatic Castration-Sensitive Prostate Cancer in combination with abiraterone acetate and Prednisone

Phase III US
Phase III EU
ciltacabtagene autoleucel (BCMA CAR-T) [9]
Frontline Multiple Myeloma TNI

Phase III US
Phase III EU
amivantamab / lazertinib [11]
Non Small Cell Lung Cancer

Phase II US
Phase II EU
RIS/gemcitabine plus cetrelimab
Muscle non invasive bladder cancer

Approved 1/21 US
Approved 6/21 EU
DARZALEX (daratumumab) [5]
Amyloidosis (ANDROMEDA)

Phase III US
Phase III EU
DARZALEX (daratumumab) [5]
Frontline multiple myeloma transplant eligible in combination w/ bortezomib, lenalidomide and dexamethasone (PERSEUS)

Phase III US
Phase III EU
IMBRUVICA (ibrutinib) [6]
Frontline Chronic Lymphocytic Leukemia in combination with venetoclax (fixed duration) (GLOW)

Phase III US
Phase III EU
ERLEADA (apalutamide)
High risk prostate cancer (PROTEUS)

Phase II US
Phase II EU
BALVERSA (erdafitinib) [7]
Non muscle invasive bladder cancer

Filed 3/21 US
Filed 4/21 EU
ciltacabtagene autoleucel (BCMA CAR-T) [9]
Relapsed refractory multiple myeloma

Approved 5/21 US
Filed 1/21 US
RYBREVANT (amivantamab) [11]
Non Small Cell Lung Cancer

Phase II US
Phase II EU
teclistamab (BCMA/CD3) [11]
Relapsed refractory multiple myeloma

Phase III US
Phase III EU
RIS/gemcitabine plus cetrelimab
Non-muscle invasive bladder cancer

Phase III US
Phase III EU
DARZALEX (daratumumab) [5]
Smoldering multiple myeloma (SMM3001)

Phase III US
Phase III EU
IMBRUVICA (ibrutinib) [6]
Treatment naïve patients with Mantle Cell Lymphoma in combination with Bendamustine and Rituximab (SHINE)

Phase III US
Phase III EU
IMBRUVICA (ibrutinib) [6]
Relapsed/refractory patients with Mantle Cell Lymphoma in combination with venetoclax (SYMPATICO)

Approved 4/19 US
Phase III EU
BALVERSA (erdafitinib) [7]
Urothelial cancer

Phase III US
Phase III EU
niraparib [8]
L1 Prostate cancer metastatic castration-resistant in combination with abiraterone acetate and Prednisone

Phase III US
Phase III EU
ciltacabtagene autoleucel (BCMA CAR-T) [9]
Relapsed refractory multiple myeloma w/1-3 PL

Phase III US
Phase III EU
RYBREVANT (amivantamab) [11]
Frontline Non Small Cell Lung Cancer in combination with chemotherapy

Phase II US
Phase II EU
talquetamab (GPRC5D/CD3) [11]
Relapsed refractory multiple myeloma

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Total Indications

Pulmonary Hypertension

Phase III US
Phase III EU
OPSUMIT (macitentan)
Pediatric pulmonary arterial hypertension

Approved 7/21 US
UPTRAVI (selexipag)
Pulmonary arterial hypertension IV

Phase III US
Phase III EU
macitentan w/tadalafil FDC
Pulmonary arterial hypertension

Phase III US
Phase III EU
macitentan
Chronic thromboembolic pulmonary hypertension 75mg

Phase III US
Phase III EU
UPTRAVI (selexipag)
Chronic thromboembolic pulmonary hypertension

Phase III US
Phase III EU
macitentan
Pulmonary arterial hypertension 75mg

Phase III US
Phase III EU
UPTRAVI (selexipag)
Pediatric pulmonary arterial hypertension

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