

Selected Pharmaceuticals in Late Stage U.S. and E.U. Development or Registration as of July 21, 2021

Cardiovascular and Metabolism

Filed 10/20 US **XARELTO (rivaroxaban)** ³
 Infrainguinal revascularized PAD

Phase III US **aprocitentan** ²
 Phase III EU 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 IIB/III US **TREMFYA (guselkumab)**
 Phase IIB/III EU Crohn's Disease

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

Phase IIB/III US **TREMFYA (guselkumab)**
 Phase IIB/III EU Ulcerative Colitis Monotherapy

Phase III US **TREMFYA (guselkumab)**
 Psoriatic Arthritis Structural Damage

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

Phase III US **nipocalimab**
 Phase III EU Warm Autoimmune Hemolytic Anemia

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

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

Infectious Diseases and Vaccines

Phase II US **rilematovir (RSV Fusion)**
 Phase II EU Hematopoietic Stem Cell Transplantation patients
 infected with Respiratory Syncytial Virus (FREESIA)

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

Phase III US **VAC89220**
 Phase III EU HIV Px Vaccine

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

Phase III US **VAC52416**
 Phase III EU Multivalent ExPEC Vaccine

Neuroscience

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

Filed 10/20 US **INVEGA HAFYERA (PP6M)**
 Filed 11/20 EU Treatment of Schizophrenia

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



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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);

Oncology

Approved 7/21 US Approved 6/21 EU	DARZALEX (daratumumab) ⁵ Relapsed Refractory Multiple Myeloma w/PomDex	Approved 1/21 US Approved 6/21 EU	DARZALEX (daratumumab) ⁵ Amyloidosis (ANDROMEDA)	Phase III US Phase III EU	DARZALEX (daratumumab) ⁵ Smoldering multiple myeloma (SMM3001)
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	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 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 Indolent Non-Hodgkins Lymphoma in combination with Bendamustine and Rituximab or R-CHOP; (SELENE)	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	IMBRUVICA (ibrutinib) ⁶ Relapsed/refractory patients with Mantle Cell Lymphoma in combination with venetoclax (SYMPATICO)
Phase III US Phase III EU	ERLEADA (apalutamide) Localized prostate cancer	Phase III US Phase III EU	ERLEADA (apalutamide) High risk prostate cancer (PROTEUS)	Approved 4/19 US Phase III EU	BALVERSA (erdafitinib) ⁷ Urothelial cancer
Phase II US Phase II EU	BALVERSA (erdafitinib) ⁷ Tumor Agnostic	Phase II US Phase II EU	BALVERSA (erdafitinib) ⁷ Non muscle invasive bladder 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	niraparib / abiraterone acetate M1 Metastatic Castration-Sensitive Prostate Cancer in combination with abiraterone acetate and Prednisone	Filed 3/21 US Filed 4/21 EU	ciltacabtagene autoleucel (BCMA CAR-T) ⁹ Relapsed refractory multiple myeloma	Phase III US Phase III EU	ciltacabtagene autoleucel (BCMA CAR-T) ⁹ Relapsed refractory multiple myeloma w/1-3 PL
Approved 5/21 US Filed 1/21 US	RYBREVANT (amivantamab) ¹¹ Non Small Cell Lung Cancer	Phase III US Phase III EU	RYBREVANT (amivantamab) ¹¹ Frontline Non Small Cell Lung Cancer in combination with chemotherapy	Phase III US Phase III EU	amivantamab / lazertinib ¹¹ Non Small Cell Lung Cancer
Phase II US Phase II EU	teclistamab (BCMA/CD3) ¹¹ Relapsed refractory multiple myeloma	Phase II US Phase II EU	talquetamab (GPRC5D/CD3) ¹¹ Relapsed refractory multiple myeloma	Phase II US Phase II EU	RIS/gemcitabine plus cetrelimab Muscle non invasive bladder cancer
Phase III US Phase III EU	RIS/gemcitabine plus cetrelimab Non-muscle invasive bladder cancer				



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Pulmonary Hypertension

Phase III US **OPSUMIT (macitentan)**

Phase III EU Fontan-palliated in adolescent (>12 years old) and adult patients

Phase III US **macitentan**

Phase III EU Pulmonary arterial hypertension 75mg

Phase III US **UPTRAVI (selexipag)**

Phase III EU Pediatric pulmonary arterial hypertension

Phase III US **OPSUMIT (macitentan)**

Phase III EU Pediatric pulmonary arterial hypertension

Filed 9/20 US **UPTRAVI (selexipag)**

Pulmonary arterial hypertension IV

Phase III US **macitentan w/tadalafil FDC**

Phase III EU Pulmonary arterial hypertension

Phase III US **macitentan**

Phase III EU Chronic thromboembolic pulmonary hypertension 75mg

Phase III US **UPTRAVI (selexipag)**

Phase III EU Chronic thromboembolic pulmonary hypertension



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