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Pharmacy Solutions

Pipeline Report

February 2021

This quarterly at-a-glance publication is developed by our Clinical Pharmacy Drug Information team to increase your understanding of the drug pipeline, ensuring you're equipped with insights to prepare for shifts in pharmacy benefit management. In this issue, you'll learn more about key themes and notable drugs referenced in the following points.

- **Veklury** is currently the only agent that is FDA-approved for the treatment of COVID-19. Three additional therapeutics and two vaccines have been granted Emergency Use Authorization (EUA), and at least three more vaccines are expected to receive an EUA in the relatively near future.
- The previous quarter noted the approval of several breakthrough therapies for rare or ultra-rare conditions, which previously had no available FDA-approved treatments — **Zokinvy** for Hutchinson-Gilford progeria syndrome and progeroid laminopathies, **Oxlumo** for primary hyperoxaluria type 1, and **Imcivree** for genetically mediated obesity.
- Other notable approvals include: **Lupkynis** — the first oral therapy approved for lupus nephritis; **Orladeyo** — the first oral therapy approved as prophylaxis of hereditary angioedema attacks; **Cabenuva** – the first long-acting injectable antiretroviral therapy intended as maintenance treatment of HIV; and **Breyanzi** — the third CAR-T therapy to market for treatment of large B-cell lymphomas, with a favorable adverse effect profile relative to the two previously approved agents **Kymriah** and **Yescarta**.
- Other potentially impactful FDA approvals are on the horizon, including *teplizumab* which would be the first disease-modifying therapy for delaying the onset of type 1 diabetes in high-risk patients, *arimoclomol* as the first approved therapy for Niemann-Pick disease type C, and *casimersen* as the first treatment for Duchenne muscular dystrophy that has mutations amenable to exon 45 skipping. Meanwhile, the FDA's three-month delay on the approval decision for *aducanumab* for mild or prodromal Alzheimer's disease hints at the willingness to continue its review of the drug, providing hope for the therapy to ultimately be approved.

To prepare this report, our team accesses a wide range of clinical resources. This information is then analyzed, resulting in updates across multiple disease states including recent and anticipated drug approvals, key changes in the biosimilar agent landscape, and notes on recent and anticipated generic product launches. Our pipeline report is just one of many ways we're committed to providing helpful tools and resources to our clients and partners. We look forward to sharing more updates with you in the months ahead.

Ross Hoffman, MD

To provide comments, feedback or requests for report enhancements, please email us at Communications@EnvolveHealth.com.

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COVID-19

FDA-APPROVED AGENTS					
Drug Name	**Manufacturer(s)**	**FDA Approval Date**	**Therapeutic Class**	**Comments**	**Cost (WAC)**
Veklury *remdesivir* intravenous infusion	Gilead	10/22/20	Treatment - antiviral	• Indicated for the treatment of adults and pediatric patients ≥ 12 years old and weighing ≥ 40 kg requiring hospitalization for COVID-19 • Veklury should only be administered in a hospital or healthcare setting capable of providing acute care comparable to inpatient hospital care	$520 for a 100 mg single dose vial $3,120 for a 5-day course $5,720 for a 10-day course
AGENTS GRANTED FDA EMERGENCY USE AUTHORIZATION (EUA)					
Drug Name	**Manufacturer(s)**	**EUA Approval Date**	**Therapeutic Class**	**Comments**	**Cost (WAC)**
Convalescent plasma intravenous infusion	U.S. Dept of Health and Human Services	Original: 8/23/20 Revised: 2/4/21	Treatment - blood product	• Current EUA is for the use of high titer convalescent plasma for the treatment of hospitalized patients early in the disease course and to those hospitalized patients who have impaired humoral immunity and cannot produce an adequate antibody response	Unknown at this time
LY-CoV555 *bamlanivimab* intravenous infusion	Eli Lilly	11/9/20	Treatment - monoclonal antibody	• EUA is for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are ≥ 12 years old and weighing ≥ 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization • **Outpatient only - no cost to patients, although healthcare facilities may charge fees related to administration**	$1,250 single dose infusion $309.60 administration cost
Olumiant *baricitinib* oral tablet	Eli Lilly	11/19/20	Treatment - acute respiratory distress syndrome (ARDS)	• EUA for use in combination with Gilead's Veklury (remdesivir) for treating hospitalized patients with COVID-19 infection in patients aged two years or older, with suspected or laboratory confirmed COVID-19 requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation • **4 mg once daily for 14 days or until hospital discharge**	$2,553 for 14-day course $91.17 per 2 mg tablet

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Drug Name	Manufacturer(s)	EUA Approval Date	Therapeutic Class	Comments	Cost (WAC)
REGN-COV2 *casirivimab + imdevimab* intravenous infusion	Regeneron	11/21/20	Treatment - monoclonal antibody	· EUA is for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are ≥ 12 years old and weighing ≥ 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization • **Outpatient only - no cost to patients, although healthcare facilities may charge fees related to administration**	$1,500 single dose infusion $309.60 administration cost
BNT162b2 *tozinameran* intradermal injection	Pfizer	12/11/20	Vaccine	· mRNA vaccine that expresses SARS-CoV2 spike protein • **No cost to patients**	$19.50 per dose*
mRNA 1273 intradermal injection	Moderna	12/18/20	Vaccine	· mRNA vaccine that expresses SARS-CoV2 spike protein • **No cost to patients**	$32-37 per dose*
LY-CoV555 + LY-CoV016 *bamlanivimab + etesivimab* intravenous infusion	Eli Lilly	2/9/21	Treatment - monoclonal antibody	· EUA is for the emergency use of bamlanivimab and etesevimab administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (≥ 12 years of age and weighing ≥ 40 kg) with positive results of direct SARS-CoV2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization • **Outpatient only - no cost to patients, although healthcare facilities may charge fees related to administration**	*bamlanivimab*: $1,250 single dose infusion *etesevimab*: pending launch $309.60 administration cost
PIPELINE AGENTS					
Drug Name	**Manufacturer(s)**	**Anticipated Date of EUA or FDA Approval**	**Therapeutic Class**	**Comments**	**Cost (WAC)**
Ad26.COV2-S intradermal injection	J&J/Janssen	2/26/21	Vaccine	· Non-replicating adenovirus 26-vector dsDNA expressing SARS-CoV-2 spike protein • **No cost to patients**	Projected $10 per dose*

***Initially, the federal government will supply the vaccine at no cost to providers.**

Drug Name	Manufacturer(s)	Anticipated Date of EUA or FDA Approval	Therapeutic Class	Comments	Cost (WAC)
AZD 1222 intradermal injection	AstraZeneca	Q1 2021	Vaccine	· Non-replicating chimpanzee adenovirus-vector dsDNA expressing SARS-CoV-2 spike protein • **No cost to patients**	Projected $3 per dose*
NVX-CoV2373 intradermal injection	Novavax	Q2 2021	Vaccine	· SARS-CoV-2 spike glycoprotein nanoparticle + adjuvant vaccine • **No cost to patients**	Projected $16 per dose*

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	AcariaHealth and PANTHERx Access Status	Comments	Cost (WAC)
CARDIOVASCULAR						
Evkeeza *evinacumab-dgnb* intravenous infusion	Regeneron	Homozygous familial hypercholesterolemia (HoFH)	2/11/21	Pending	• Approved for use as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients aged ≥ 12 years • Administered as monthly intravenous infusions • Repatha, Juxtapid, and Kynamro are also FDA-approved for HoFH	$450,000/year
ENDOCRINOLOGY						
Zokinvy *lonafarnib* oral capsule	Merck	Hutchinson-Gilford progeria syndrome Progeroid laminopathies	11/20/20	Pending	• Approved for use in patients ≥ 12 months of age with a body surface area of ≥ 0.39 m^2 for either Hutchinson-Gilford progeria syndrome, or for processing-deficient Progeroid laminopathies with either: heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations • Progeria is an ultra-rare and fatal disease that causes premature aging in children • There are currently no other FDA approved therapies • Projected impact: cost increase	$785,000-$1,300,000/year
Oxlumo *lumasiran* subcutaneous injection	Alnylam	Primary hyperoxaluria type 1	11/23/20	AcariaHealth: limited access PANTHERx: has access	• Administered as monthly injections • Current treatment options for advanced disease are very limited, and include frequent renal dialysis or combined organ transplantation of liver and kidneys • Vitamin B6 has been used as an off-label therapy • Projected impact: cost increase	15 kg child: $440,000/year 70 kg adult: $1,320,000/year

Continued

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	AcariaHealth and PANTHERx Access Status	Comments	Cost (WAC)
Imcivree *setmelanotide* subcutaneous injection	Rhythm Pharmaceuticals	Pro-opiomelanocortin (POMC) Proprotein convertase subtilisin/ kexin type 1 (PCSK1) Leptin receptor (LEPR) deficiency obesity	11/25/20	AcariaHealth: limited access PANTHERx: has access	• Approved for use in patient ≥ 6 years of age • POMC and LEPR deficiency obesities are ultra-rare disorders • There are approximately 100 to 500 patients in the U.S. with POMC deficiency obesity and approximately 500 to 2,000 patients in the U.S. with LEPR deficiency obesity • There are no approved therapies for these two conditions • Projected impact: cost increase	$119,000-$356,000/year
Orladeyo *berotralstat* oral capsules	BioCryst	Hereditary angioedema (HAE)	12/3/20	Limited access	• Once daily oral prophylaxis therapy approved for patients ≥ 12 years of age • All other HAE therapies are IV or SC injections • High demand for this more convenient, less invasive dosage form is anticipated • Projected impact: cost replacement of existing therapies	$486,000/year
HEMATOLOGY						
Cosela *trilaciclib* intravenous infusion	G1 Therapeutics Boehringer Ingelheim	Cyclin dependent kinases (CDK4/CDK6) inhibitor	2/12/21	Pending	• Approved to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC)	Pending launch

Continued

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	AcariaHealth and PANTHERx Access Status	Comments	Cost (WAC)
IMMUNOLOGY						
Lupkynis *voclosporin* oral capsule	Aurinia	Lupus nephritis	1/22/21	AcariaHealth: limited access PANTHERx: has access	· Is a structural analog of cyclosporine A, developed to potentially offer some advantage over legacy CNIs, such as improved tolerability and no need for therapeutic drug level monitoring · Would compete with Benlysta for patients with severe or refractory disease · Prescribing Information includes black box warnings for malignancies and serious infections · Projected impact: incremental cost increase	$146,000/year
INFECTIOUS DISEASES						
Ebanga *ansuvimab-zykl* intravenous infusion	Ridgeback Biotherapeutics LP	Zaire ebolavirus infection	12/21/20	Limited access	· Approved for treatment in both adults and children · Projected impact: minimal cost increase	Pending launch
Cabenuva *cabotegravir + rilpivirine* long-acting intramuscular injection	ViiV Healthcare Janssen	HIV-1 infection	1/21/21	Pending	· Approved for treatment of adults whose viral load is suppressed (HIV-1 RNA < 50 copies/mL) on a stable regimen, with no history of treatment failure, and with no known or suspected resistance to either cabotegravir or rilpivirine · Once monthly injections after a 4-week oral lead-in period · Projected impact: cost replacement of existing therapies	$48,000/year

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Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	AcariaHealth and PANTHERx Access Status	Comments	Cost (WAC)
ONCOLOGY						
Danyelza *naxitamab-gqgk* intravenous infusion	YmAbs Therapeutics, Inc.	Neuroblastoma	11/25/20	AcariaHealth: has access PANTHERx: limited access	· Approved for use in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients ≥ 1 year of age and adult patients with relapsed or refractory high-risk disease in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy · Prescribing Information includes black box warnings for serious infusion-related reactions and neurotoxicity · Projected impact: incremental cost increase	15 kg child: Year 1: $735,000 Year 2 and beyond: $367,000/year
Margenza *margetuximab-cmkb* intravenous infusion	MacroGenics	Breast cancer	12/16/20	Pending	· Approved for use in combination with chemotherapy, for the treatment of adults with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease · Same mechanism of action as Herceptin · Prescribing Information includes black box warnings for left ventricular dysfunction and embryo-fetal toxicity · Projected impact: cost replacement of existing therapies	Pending launch
Orgovyx *relugolix* oral tablet	Myovant	Prostate cancer	12/18/20	Limited access	· Approved for the treatment of advanced disease · Will compete with injectable GnRH analog therapies such as Lupron · Projected impact: cost replacement of existing therapies	$28,000/year

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Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	AcariaHealth and PANTHERx Access Status	Comments	Cost (WAC)
Tepmetko *tepotinib* oral tablet	Merck EMD Serono	Non-small cell lung cancer (NSCLC)	2/3/21	Pending	• Same indication as Tabrecta • Approved for the treatment of metastatic disease with MET exon 14 skipping alterations • Estimated prevalence: 84% of all lung cancer cases are NSCLC MET exon 14 skipping alterations and MET amplifications are present in 3-4% of NSCLC patients and correlate with poor prognosis • Projected impact: cost replacement of existing therapies	$251,000/year
Ukoniq *umbralisib* oral tablet	TG Therapeutics	Marginal zone lymphoma (MZL) Follicular lymphoma (FL)	2/5/21	Pending	• Approved for the treatment of adults with relapsed or refractory MZL after ≥ 1 prior anti-CD20-based regimen, and for relapsed or refractory FL after ≥ 3 prior lines of systemic therapy • Similar indication as Imbruvica for MZL and Tazverik for FL • Estimated prevalence: MZL and FL account for approximately 8% and 20% of all non-Hodgkin lymphoma cases, respectively	$191,000/year
Breyanzi *lisocabtagene maraleucel* intravenous infusion	Bristol Myers Squibb	Large B-cell lymphomas	2/5/21	Pending	• Approved for the treatment of adults with relapsed or refractory large B-cell lymphoma after ≥ 2 lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B • Is the third CAR-T therapy to market for these indications, after Kymriah and Yescarta • Has demonstrated a favorable adverse effect profile relative to Kymriah and Yescarta, with lower incidences of cytokine release syndrome and neurotoxicity	$410,300/one-time therapy

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
CARDIOVASCULAR DISEASE					
Verquvo *vericiguat* oral tablet	Merck Bayer	Heart failure (HF)	1/19/21	• Approved to reduce the risk of cardiovascular death and HF hospitalization following a hospitalization for HF or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction < 45% • Prescribing information includes a black box warning re: embryo-fetal toxicity	Pending launch
DERMATOLOGY					
Klisyri *tirbanibulin* topical ointment	Athenex, Inc.	Actinic keratosis	12/14/20	• For the topical treatment of the face or scalp • Five-day course of therapy	$990/5-day course of therapy
GENITOURINARY AGENTS					
Gemtesa *vibegron* oral tablet	Urovant Sciences	Overactive bladder (OAB)	12/23/20	• For the treatment of urge urinary incontinence, urgency and urinary frequency in adults • Once daily oral therapy • Multiple other agents exist for the treatment of OAB	$5,600/year

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
CARDIOVASCULAR					
Revascor* *rexlemestrocel-L* intramyocardial injection	Mesoblast	Chronic heart failure	Stem cell therapy	· Potentially large impacted population · Proposed for use in left ventricular systolic dysfunction · Would be reserved for use in patients who had failed multiple other therapies	2021
COAGULATION DISORDERS					
Ryplazim *plasminogen* intravenous infusion	Liminal BioSciences	Congenital plasminogen deficiency (C-PLGD)	Endogenous plasminogen analog	· There are currently no approved therapies for the treatment of C-PLGD, the estimated prevalence of which is ~1.6 of every 1,000,000 people	3/5/21
AMT-061* *etranacogene dezaparvovec* intravenous infusion	Uniqure CSL Behring	Hemophilia B	Gene therapy	· Proposed for the treatment of adults with severe disease (~40% of the total hemophilia B population) · Current standard of care is factor IX replacement therapy	2021-2022
SPK-8011* intravenous infusion	Spark Roche	Hemophilia A	Gene therapy	· Proposed for the treatment of adults with severe disease (~60% of the total hemophilia A population) · Current standard of care is factor VIII replacement therapy or Hemlibra	2021-2022
SB-525* *giroctocogene fitelparvovec* intravenous infusion	Sangamo BioSciences Inc Pfizer	Hemophilia A	Gene therapy	· Proposed for the treatment of adults with severe disease (~60% of the total hemophilia A population) · Current standard of care is factor VIII replacement therapy or Hemlibra	2021-2022

*** Expected to cost >$500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
DERMATOLOGY					
PF-04965842 *abrocitinib* oral tablet	Pfizer	Atopic dermatitis	Jnaus kinase 1 (JAK1) inhibitor	· Proposed for the treatment of moderate to severe disease in patients 12 years of age and older	4/1/21
CAT354 *tralokinumab* subcutaneous injection	Leo Pharma	Atopic dermatitis	IL-13 inhibitor	· Would compete with Dupixent for this indication	5/9/21
ENDOCRINOLOGY					
BBP-870 *fosdenopterin* intravenous infusion	BridgeBio Pharma	Molybdenum cofactor deficiency (MoCD) type A	cPMP substrate replacement therapy	· There are no FDA-approved therapies for MoCD type A, an ultra-rare condition due to an inborn error of metabolism · Infants are most affected, with rapid disease progression and a high infant mortality rate	3/29/21
PRX-102 *pegunigalsidase alfa* intravenous infusion	Protalix Biotherapeutics	Enzyme replacement therapy	Fabry disease	· Fabrazyme, dosed once every two weeks, is also FDA-approved for the treatment of Fabry disease · PRX-102 is being studied as once monthly dosing as well as once every two weeks · Estimated prevalence: 1 in 40,000 to 60,000 males (female prevalence is unknown)	4/27/21
NeoGAA* *avalglucosidase alfa* intravenous infusion	Genzyme Sanofi	Pompe disease	Enzyme replacement therapy	· Has been designed for enhanced receptor targeting and enzyme uptake through greater affinity for the M6P receptors on muscle cells, with the aim of enhancing glycogen clearance and improving on the clinical efficacy achieved with Lumizyme · Estimated prevalence: 50,000 people worldwide	5/18/21
BRX345 *arimoclomol* oral therapy	Orphazyme	Niemann-Pick type C disease (NPC)	Molecular chaperone activator	· There are no FDA-approved therapies for NPC, which has an estimated 500 cases diagnosed worldwide, and which affects ~1 in 120,000 newborns	6/17/21

*** Expected to cost >$500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
PRV-031 *teplizumab* intravenous infusion	Provention Bio, Inc.	Type 1 diabetes (T1D) prevention	Anti-CD3 monoclonal antibody	· Proposed for the delay or prevention of T1D in patients at high-risk of developing the disease · Administered as one two-week course of therapy · Has the potential to be the first disease-modifying therapy for T1D	7/2/21
A4250 *odevixibat* oral capsules	Albireo Pharma	Progressive familial intrahepatic cholestasis (PFIC)	Ileal bile acid transporter (IBAT) inhibitor	· There are no approved pharmacologic treatment options · PFIC is estimated to affect between one in every 50,000 to 100,000 children born worldwide and causes progressive, life-threatening liver disease · Moderate to severe pruritus is a common and problematic clinical presentation of PFIC that can severely diminish quality of life · Data on PFIC types 1, 2, and 3 were submitted to support use across a wide range of patients	7/20/21
BMN 111 *vosoritide* subcutaneous injection	BioMarin	Achondroplasia	C-type Natriuretic Peptide (CNP) analog	· Once daily injection proposed for use in children whose growth plates are still open (~25% of the achondroplasia population) · The worldwide incidence rate of achondroplasia is about one in 25,000 live births · There are no FDA-approved agents for achondroplasia	8/20/21
HEMATOLOGY					
Evrenzo *roxadustat* oral therapy	AstraZeneca Fibrogen	Anemia of chronic kidney disease	Hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI)	· Proposed for use in both dialysis- and non-dialysis-dependent CKD · Would compete with erythropoietin stimulating agents (ESAs, e.g., Procrit, Aranesp) · Appears to have less cardiovascular risk	3/20/21

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
APL-2* *pegcetacoplan* intravenous infusion	Apellis	Paroxysmal nocturnal hemoglobinuria (PNH)	C3 and C3b complement inhibition	· In the Phase 3 PEGASUS study, which met its primary endpoint, pegcetacoplan demonstrated superiority to Soliris with a statistically significant improvement in hemoglobin levels at 16 weeks, as well as higher normalization rates across key markers of hemolysis and clinically meaningful improvement in FACIT-fatigue score, with a comparable safety profile · Estimated prevalence: 0.5-1.5 per 1 million people	5/14/21
CCX168 *avacopan* oral therapy	ChemoCentryx	C5a complement protein receptor inhibitor	Anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV)	· Current therapies for ANCA-associated vasculitis typically include broad immunosuppression with daily doses of glucocorticoids such as prednisone or methylprednisone	7/7/21
LentiGlobin* *betibeglogene autotemcel* intravenous infusion	bluebird bio	Transfusion-dependent beta-thalassemia (TDT)	Gene therapy	· Demonstrated ability to dramatically decrease or terminate the need for chronic blood transfusions; · LentiGlobin is also being studied for the treatment of sickle cell disease - however, two of the clinical trials for this indication were temporarily suspended to allow for an investigation into whether two recently reported cases of cancer are related to the gene therapy. Implications for the product for sickle cell disease as well as for TDT could be serious if a link is found between LentiGlobin therapy and the onset of cancer	2022
IMMUNOLOGY					
KD025 *belumosudil* oral therapy	Kadmon Holdings	Chronic graft-vs-host disease (cGvHD)	Rho-associated coiled-coil kinase 2 (ROCK2) inhibitor	· Demonstrated overall response rates of 73% and 74% with belumosudil 200 mg QD and 200 mg BID, respectively. In a pivotal trial, was well tolerated	5/30/21
MUSCULOSKELETAL CONDITIONS					
Amondys 45* *casimersen* intravenous infusion	Sarepta Therapeutics	Duchenne muscular dystrophy (DMD)	Antisense oligonucleotide	· Proposed for the treatment of patients with mutations amenable to exon 45 skipping · Estimated prevalence: 1 in every 3,400 live male births · ~8% of DMD patients are amenable to exon 45 skipping	2/25/21

*** Expected to cost >$500,000 per member.**

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
GALGT2* *AAVrh74.MHCK. GALGT2* intra-arterial injection	Sarepta Therapeutics	DMD	Gene therapy	· Would compete with SRP-9001 gene therapy for those with mutations between exons 18 and 58 · SRP-9001 is further along in the pipeline process, but comparative safety and efficacy are undetermined	2021
SRP-9001* *microdystrophin* intravenous infusion	Sarepta Therapeutics	DMD	Gene therapy	· Targets exons 18 through 58 (~60-75% of DMD patients have mutations in these exons) · Topline results from a Phase 2 trial showed benefit on the biological endpoint of micro-dystrophin protein expression, but a functional benefit relative to placebo was not demonstrated	2021
PF-06939926* intravenous infusion	Pfizer	DMD	Gene therapy	· One-time treatment · Is the first DMD gene therapy candidate to start dosing in a Phase 3 trial · Has become the DMD gene therapy front-runner since SRP-9001 failed to demonstrate a functional benefit in a pivotal trial	2022
SGT-001* intravenous infusion	Solid Biosciences	DMD	Gene therapy	· Development has been marred by safety issues and FDA-applied clinical trial holds, with thus far mediocre efficacy results	2022
NEUROLOGY					
RG3477 *ponesimod* oral therapy	Janssen	Multiple sclerosis (MS)	Selective sphingosine-1-phosphate receptor 1 (S1P1) modulator	· Proposed for treatment of relapsing forms of MS · Will compete with other S1P1 modulators such as Gilenya, Mayzent, Zeposia · Estimated prevalence: 1 million people in the United States · Relapsing MS is the most common form of MS, affecting ~85% of patients	3/18/21
BIIB 037 *aducanumab* intravenous infusion	Biogen Eisai	Alzheimer's disease	Amyloid-binding monoclonal antibody	· Proposed as a treatment for prodromal or mild stages of Alzheimer's disease	6/7/21

*** Expected to cost >$500,000 per member.**

Continued

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
Lenti-D* *elivaldogene tavalentivec* intravenous infusion	bluebird bio	Cerebral adrenoleukodystrophy (cALD)	Gene therapy	· Currently, the only therapeutic option for patients with CALD is allogeneic hematopoietic stem cell transplant (HSCT) · Beneficial effect has been reported if performed early in the course of cALD progression · In the U.S., newborn screening for ALD was added to the Recommended Universal Screening Panel in February 2016 and is currently active in 17 states, accounting for > 58% of U.S. newborns	Q4 2021
ONCOLOGY					
Yescarta *axicabtagene ciloleucel* intravenous infusion	Gilead	Follicular lymphoma (FL) Marginal zone lymphoma (MZL)	CAR-T therapy	· Proposed for the treatment of relapsed or refractory indolent non-Hodgkin lymphoma (NHL), including FL and MZL, after two or more prior lines of systemic therapy · FL is the most common form of indolent lymphoma and the second most common type of lymphoma globally · It accounts for approximately 22% of all lymphomas diagnosed worldwide · MZL is the third most common lymphoma, accounting for 8% to 12% of all B-cell NHLs	3/5/21
p1101 *ropeginterferon alfa-2b* subcutaneous injection	PharmaEssentia Corporation	Polycythemia vera (PV)	Monopegylated proline interferon	· Long-acting interferon formulation proposed for the treatment of PV in the absence of symptomatic splenomegaly	3/15/21
bb2121 idecabtagene vicleucel intravenous infusion	bluebird bio Bristol-Myers Squibb	Multiple myeloma	B-cell maturation antigen (BCMA)-targeted CAR-T cell therapy	· Similar proposed indication as, but apparently less robust efficacy than, JNJ-68284528, which demonstrated a 97% overall response rate in the CARTITUDE-1 trial	3/27/21

*** Expected to cost >$500,000 per member.**

Continued

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
Tivopath *tivozanib* oral therapy	AVEO Oncology	Renal cell carcinoma	Multi-kinase inhibitor Triple VEGF inhibitor	· Proposed for treatment of relapsed or refractory disease · Was more effective than Nexavar (sorafenib) in the TIVO-1 trial	3/31/21
TSR-042 *dostarlimab* intravenous infusion	Tesaro GlaxoSmithKline	Endometrial cancer	Anti-PD-1 monoclonal antibody	· Proposed for the treatment of recurrent or advanced disease that has progressed on or after a platinum-based regimen, including microsatellite instability high tumors	4/14/21
Lonca *loncastuximab tesirine* intravenous infusion	ADC Therapeutics	Diffuse large B-cell lymphoma (DLBCL)	Antibody-drug conjugate containing anti-CD19 monoclonal antibody	· Similar CD19-targeted mechanism of action as Monjuvi (tafasitamab-cxix), which is also FDA-approved for use in relapsed/refractory DLBCL	5/21/21
BBP831 *infigratinib* oral capsule	BridgeBio Pharma	Cholangiocarcinoma	Pan-fibroblast growth factor receptor (FGF-R) kinase inhibitor	· Proposed for use as second-line treatment of advanced or metastatic disease with FGFR2 genetic aberrations · FGFR2 genetic aberrations are present in approximately 15% to 20% of people who have this disease · Currently Pemazyre is the only other FDA-approved agent	6/1/21
OMS721 *narsoplimab* intravenous infusion	Omeros Corporation	Hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA)	Anti-MASP-2 monoclonal antibody	· Proposed for the treatment of patients with high-risk disease, specifically those patients who have persistent TMA despite modification of immunosuppressive therapy · Approximately 20,000 HSCT procedures are performed in the U.S. annually, and TMA is reported to occur in approximately 10% to 25% of HSCT patients	7/17/21
MGA012 *retifanlimab* intravenous infusion	Incyte	Squamous cell carcinoma of the anal canal (SCAC)	PD-1 inhibitor	· Proposed for the treatment of adults with locally advanced or metastatic disease who have progressed on, or who are intolerant of, platinum-based chemotherapy · Although SCAC is a rare disease, its incidence is thought to be increasing	7/25/21

*** Expected to cost >$500,000 per member.**

Continued

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
Rolontis *eflapegrastim* subcutaneous injection	Spectrum Pharmaceuticals	Chemotherapy-induced neutropenia	Granulocyte colony stimulating factor	· Long-acting agent dosed every 3 weeks · Demonstrated non-inferiority to Neulasta · Is currently being studied with dosing on the same day as chemotherapy	1st Half of 2021
JNJ-68284528 *ciltacabtagene autoleucel* intravenous infusion	Janssen	Multiple myeloma	Anti-BCMA CAR-T therapy	· Proposed for the treatment of relapsed/refractory disease after at least three prior lines of therapy · Demonstrated a 97% overall response rate and 67% achieved a stringent complete response (sCR) at a median follow-up of 12.4 months in the Phase I/II CARTITUDE-1 trial	1st Half of 2021
Controlled IL-12* *Ad-RTS-hIL-12/ veledimex* intratumoral injection + oral therapy	Ziopharm Oncology	Recurrent glioblastoma	Gene therapy + oral activator agent	· Current standard of care is surgery, followed by radiation and chemotherapy (usually with temozolomide) · Would potentially be used after resection and radiation + temozolomide if progression or recurrence	2021-2022
OPHTHALMOLOGY					
NSR-REP1* subretinal injection	Nightstar	Choroideremia	Gene therapy	· Confirmation of diagnosis will be key, as clinical presentation of this disease is similar to other conditions	2021

*** Expected to cost >$500,000 per member.**

Continued

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
DERMATOLOGY					
NexoBrid *bromelain* topical gel	Teva MediWound	Burn wound debridement	Enzyme	· Proposed for debridement in adults with deep partial-thickness and/or full-thickness thermal burns	6/29/21
INFECTIOUS DISEASE					
brincidofovir oral therapy	Chimerix	Smallpox	Viral DNA polymerase inhibitor	· Is being developed as a potential medical countermeasure for smallpox in the event of a bioterror attack	4/7/21
SCY-078 *ibrexafungerp* intravenous infusion & oral therapy	Scynexis	Vulvovaginal candidiasis (VVC)	Glucan synthase inhibitor - triterpenoid	· Proposed for both treatment and prevention of recurrent VVC	6/1/21
MUSCULOSKELETAL					
RN624 *tanezumab* subcutaneous injection	Pfizer	Osteoarthritis	Nerve growth factor (NGF) inhibitor	· Subcutaneous administration by a health care provider once every eight weeks · Intended for use in patients who have experienced inadequate pain control with other analgesics	Q2 2021
NEPHROLOGY					
RDX5791 *tenapanor* oral therapy	Ardelyx	Chronic kidney disease (CKD)-related hyperphosphatemia	Sodium hydrogen exchanger 3 (NHE3) inhibitor	· Proposed for the control of serum phosphorus in adult patients with CKD on dialysis	4/29/21
BAY 94-8862 *finerenone* oral therapy	Bayer	Chronic kidney disease (CKD)	Nerve growth factor (NGF) inhibitor	· Proposed to reduce the risk of chronic kidney disease progression, kidney failure or kidney death in patients with Type 2 diabetes	7/12/21

Continued

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
PSYCHIATRY					
LY03005 *ansofaxine* oral tablets	Luye Pharma Group	Attention deficit hyperactivity disorder (ADHD)	Serotonin norepinephrine modulating agent (SNMA)	· Multiple other therapies for ADHD are currently available	Q1 2021
ALKS 3831 *olanzapine/ samidorphan* oral therapy	Alkermes	Schizophrenia and bipolar I disorder	Atypical antipsychotic/opioid receptor antagonist	· Once daily dosing · Designed to provide the efficacy of olanzapine while mitigating olanzapine-associated weight gain	6/1/21
WOMEN'S HEALTH					
Estelle *estetrol/drospirenone* oral therapy	Mithra Mayne Pharmaceuticals	Pregnancy prevention	Hormonal contraceptive	· Estetrol is a native estrogen with selective action in tissues · It has been observed to have minimal impact on liver cells and metabolic pathways, as well as on coagulation parameters	4/16/21
relugolix + estradiol + norethindrone oral tablet	Myovant	Uterine fibroids	GnRH receptor antagonist + hormone therapy	· Proposed for the treatment of women with heavy menstrual bleeding associated with uterine fibroids · Oriahnn (elagolix + estradiol + norethindrone) is FDA-approved for the same indication	6/1/21

Drug Name	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
ENDOCRINOLOGY						
MYL-1601D *insulin aspart* subcutaneous injection	Mylan Biocon	Novolog	Diabetes mellitus	BLA is under FDA review (BsUFA date: Q2 2021)	No	· First biosimilar application after reclassification of insulin products as biologic agents
HEMATOLOGY						
MSB11455 *pegfilgrastim* subcutaneous injection	Fresenius Kabi	Neulasta	Neutropenia	BLA is under FDA review (BsUFA date: 3/27/21)	Yes - Fulphila	· Another biosimilar to Neulasta, after Fulphila, Nyvepria, Udenyca and Ziextenzo
IMMUNOLOGY						
AVT02 *adalimumab* subcutaneous injection	Alvotech	Humira	Rheumatoid arthritis	BLA is under FDA review (BsUFA date: 9/1/21)	No	· Another biosimilar to Humira, after Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz
CHS-1420 *adalimumab* subcutaneous injection	Coherus BioSciences	Humira	Rheumatoid arthritis	BLA is under FDA review (BsUFA date: December 2021)	No	· Another biosimilar to Humira, after Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz; If approved, Coherus plans to launch this product in the U.S. on or after July 1, 2023, per the terms of an agreement with Humira manufacturer AbbVie
ONCOLOGY						
Aybintio *bevacizumab* intravenous infusion	Samsung Bioepis Merck	Avastin	Breast cancer	BLA is under FDA review (BsUFA date: 1/30/21)	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev
MYL-0401O *bevacizumab* intravenous infusion	Mylan Biocon	Avastin	Breast cancer	BLA is under FDA review (BsUFA date: 1st Half of 2021)	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev

Continued

Drug Name	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
BAT1706 *bevacizumab* intravenous infusion	Bio-Thera Solutions, Inc.	Avastin	Colorectal Non-small cell lung Cervical cancers Glioblastoma Renal cell carcinoma	BLA is under FDA review (BsUFA date: 11/27/21)	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev
Riabni *rituximab-arrx* intravenous infusion	Amgen Allergan	Rituxan	Non-Hodgkin's lymphoma Chronic lymphocytic leukemia Granulomatotsis with polyangiitis Microscopic polyangiitis	FDA-approved	Yes - Ruxience, Truxima	· Another biosimilar to Rituxan, after Ruxience and Truxima
OPHTHALMOLOGY						
SB11 *ranibizumab* intraocular injeciton	Samsung Bioepis	Lucentis	Macular degeneration Macular edema	BLA is under FDA review (BsUFA date: 9/18/21)	No	· Would be the first Lucentis biosimilar agent

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
rufinamide	Banzel (oral suspension)	Hikma	11/04/20
abiraterone acetate	Zytiga (500 mg)	Mylan	12/15/20
emtricitabine/tenofovir disoproxil fumarate	Truvada (100 mg/150 mg, 133 mg/200 mg, 167 mg/250 mg)	Amneal	1/20/21
epoprostenol sodium	Veletri	Sun Teva	1/26/21
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
glucagon	Glucagon	Amphastar Mylan Viatris	Q1 2021
etravirine	Intelence	Unknown	6/14/21
sunitinib malate	Sutent	Mylan Viatris	8/16/21
fingolimod	Gilenya (0.25 mg)	Teva	11/11/21
everolimus	Zortress (1 mg)	Unknown	2021
lopinavir/ritonavir	Kaletra (tablets)	Aurobindo Cipla Mylan Viatris Hetero Macleods Pharmaceuticals	2021
ritonavir	Norvir (capsules)	Hikma Mylan Viatris	2021

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
levothyroxine sodium	Tirosint	Lannett	11/03/20
*icosapent ethyl**	Vascepa	Hikma	11/05/20
micafungin sodium	Mycamine	Apotex	11/05/20
ethinyl estradiol/norethindrone acetate	Taytulla	Chemo Group	11/09/20
nitazoxanide	Alinia (tablet)	Rising Pharmaceuticals Inc.	11/27/20
acetaminophen	Ofirmev	Aurobindo	12/01/20
alvimopan	Entereg	Watson	12/01/20
ivermectin	Sklice	Taro	12/02/20
asenapine maleate	Saphris	Alembic Breckenridge Greenstone LLC Sigmapharm Laboratories	12/11/20
meloxicam	Vivlodex	Lupin	12/17/20
lubiprostone	Amitiza (8 mcg, 24 mcg capsule)	Par	1/04/21
zolmitriptan	Zomig (nasal spray, 2.5 mg/spray, 5 mg/spray)	Amneal Grunenthal Impax	1/21/21
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
droxidopa	Northera	Alkem Labs Teva Hikma Zydus Tasman Pharma Sun	2/18/21
miltefosine	Impavido	Unknown	3/19/21
enalapril maleate	Epaned	Bionpharma	4/30/21
formoterol fumarate	Perforomist	Teva	6/22/21
ferumoxytol	Feraheme	Sandoz	7/15/21

*** FDA-approved only for use as an adjunct to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia; current market availability is sporadic.**

Continued

GENERIC NAME	BRAND NAME	MANUFACTURER(S)	ANTICIPATED LAUNCH DATE
nebivolol hydrochloride	Bystolic	Alkem Labs Torrent Indchemie Health Specialties Actavis Teva Amerigen Pharmaceuticals Hetero Glenmark	9/17/21
arformoterol tartrate	Brovana	Teva Cipla Lupin	11/09/21
bepotastine besilate	Bepreve	Akorn Sandoz Micro Labs Apotex	2021
posaconazole	Noxafil (suspension)	Roxane Hikma Sandoz Par Endo	2021

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