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Pharmacy Solutions

Pipeline Report

August 2020

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 these key themes and notable drugs:

- During the past quarter, the FDA has continued its accelerated pace of oncology approvals, with seven newly approved entities, including the first CAR-T therapy for the treatment of relapsed or refractory mantle cell lymphoma. Also approved was the first oral therapy, risdiplam, for the treatment of spinal muscular atrophy. This greatly expands available treatment options for a devastating disease which most adversely affects young children.

- Roctavian, the first gene therapy for hemophilia A, is due for FDA approval in the upcoming weeks. Ryoncil, proposed for the treatment of pediatric acute graft vs. host disease would be the first ever FDA-approved stem cell therapy with final approval expected the end of September.

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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Recent Specialty Drug Approvals

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Acaria Health (AH) Access Status	Comments	Cost (WAC)
ENDOCRINOLOGY						
Dojolvi *triheptanoin* oral liquid	· Ultragenyx	· Medium-length, odd-chain fatty acid replacement	6/30/20	AH has access	· For use as a source of calories and fatty acids for molecularly confirmed LC-FAOD. · Currently available therapies include avoidance of fasting, low-fat/high carbohydrate diets, carnitine and medium-chain triglyceride (MCT) oil, a medical food product.	$138,000/year
INFECTIOUS DISEASES						
LIPC-0118 *artesunate* intravenous infusion	· Amivas	· Malaria	5/26/20	Pending launch	· For the initial treatment of severe malaria in adult and pediatric patients. · This is a World Health Organization (WHO)-recommended first-line therapy.	Pending launch
Rukobia *fostemsavir* oral tablets	· GlaxoSmithKline · ViiV Healthcare	· Human immunodeficiency virus-1 (HIV-1) infection	7/2/20	AH has access	· For use in combination with other antiretrovirals (ARVs) for the treatment of heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance or safety considerations. · Due to its mechanism of action, there is no in-vitro cross-resistance to other classes of ARVs, which may help patients who have become resistant to most other medicines.	$93,000/year
MUSCULOSKELETAL CONDITIONS						
Evrysdi *risdiplam* oral solution	· PTC Therapeutics · Roche	· Spinal muscular atrophy (SMA)	8/7/20	Limited access	· Approved for the treatment of SMA Types 1, 2, and 3. · Is the first daily oral therapy approved for SMA. · Will compete with Spinraza and Zolgensma.	Pending launch
Viltepso *viltolarsen* intravenous infusion	· NS Pharma	· Duchenne muscular dystrophy (DMD)	8/12/20	Pending launch	· Exon 53 skipping agent. · Antisense oligonucleotide. · For the treatment of DMD amenable to exon 53-skipping. · Will compete with Vyondys 53, with potentially better efficacy.	Pending launch
NEUROLOGY						
Fintepla *fenfluramine* oral solution	· Zogenix	· Dravet syndrome	6/25/20	AH has access	· For the treatment of patients 2 years of age and older. · Fintepla was studied as an adjunct to existing therapies such as off-label valproate and clobazam (Onfi). · Epidiolex and Diacomit are also FDA-approved. · Fintepla was approved with a Black Box Warning re: valvular heart disease and pulmonary arterial hypertension.	Pending launch

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Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Acaria Health (AH) Access Status	Comments	Cost (WAC)
ONCOLOGY						
Retevmo *selpercatinib* oral capsules	· Loxo Oncology · Lilly	· Non-small cell lung cancer (NSCLC) · Thyroid cancer	5/8/20	Limited access	· For adult patients with metastatic RET fusion-positive NSCLC, and for adult and pediatric patients 12 years of age and older with either advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy or thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).	$250,000/year
Qinlock *ripretinib* oral tablets	· Deciphera	· Gastrointestinal stromal tumor (GIST)	5/15/20	Limited access	· For adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.	$390,000/ year
Zepzelca *lurbinectedin* intravenous infusion	· PharmaMar	· Small cell lung cancer (SCLC)	6/15/20	Limited access	· For adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.	$225,000/year
Inqovi *cedazuridine + decitabine* oral tablets	· Astex Pharmaceuticals	· Myelodysplastic syndromes (MDS)	7/7/20	Pending launch	· For adult patients with previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]), and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. · By inhibiting cytidine deaminase in the gut and the liver, Inqovi allows for oral delivery of decitabine at exposures which emulate exposures achieved with the approved intravenous form of decitabine administered over 5 days.	Pending launch
Tecartus *brexucabtagene autoleucel* intravenous infusion	· Gilead	· Mantle cell lymphoma (MCL)	7/24/20	Limited access	· For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). · This is the first CAR-T therapy to be FDA-approved for this indication. · The product labeling includes a Black Box Warning re: cytokine release syndrome and neurologic toxicities.	$373,000/year
Monjuvi *tafasitamab-cxix* intravenous infusion	· MorphoSys	· Diffuse large B-cell lympho-ma (DLBCL)	7/31/20	Pending launch	· For use in combination with lenalidomide for the treatment of adult patients with relapsed/refractory disease who are not eligible for high-dose chemotherapy and autologous stem-cell transplantation.	Pending launch
Blenrep *belantamab ma-fodotin-blmf* intravenous infusion	· GlaxoSmithKline	· Multiple myeloma	8/5/20	Pending launch	· For patients who have failed at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. · Approved with a Black Box Warning re: ocular toxicity.	$281,000/year

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Acaria Health (AH) Access Status	Comments	Cost (WAC)
OPHTHALMOLOGY						
Uplizna *inebilizumab-cdon* intravenous infusion	· MedImmune · AstraZeneca · Viela Bio	· Neuromyelitis optica spectrum disorder (NMOSD)	6/11/20	Limited access	· For adult patients who are anti-AQP4 antibody positive. · This product will compete with Soliris for the same indication. · Ultomiris is also being studied for this indication.	Year 1: $393,000 Year 2 and beyond: $262,000/year

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Recent Non-Specialty Drug Approvals

Drug Name	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC)
ANESTHESIA					
Byfavo *remimazolam* intravenous infusion	· Cosmo Technologies Ltd	· Procedural sedation	7/2/20	· For the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.	Pending launch
DERMATOLOGY					
Zilxi *minocycline* topical foam	· Foamix	· Rosacea	5/28/20	· For the treatment of inflammatory lesions of rosacea in adults. · First topical minocycline formulation to be approved for this indication.	$5,800/year
Xeglyze *abametapir* topical lotion	· Dr. Reddy's Labs	· Head lice	7/24/20	· For the topical treatment of head lice infestation in patients 6 months of age and older.	Pending launch
INFECTIOUS DISEASES					
Lampit *nifurtimox* oral tablets	· Bayer	· Chagas disease	8/6/20	· For use in pediatric patients for treatment of disease caused by Trypanosoma cruzi.	Pending launch
OPHTHALMOLOGY					
Upneeq *oxymetazoline* ophthalmic solution	· RVL Pharmaceuticals, Inc.	· Blepharoptosis	7/8/20	· For the treatment of acquired blepharoptosis (droopy eyelids) in adults · Once-daily formulation. · Standard of care is surgery for severe cases.	Pending launch
WOMEN'S HEALTH					
Phexxi *lactic acid, citric acid, potassium bitartrate* topical gel	· Evofem	· Pregnancy prevention	5/22/20	· For use by females as an on-demand method of contraception. · Maintains an acidic vaginal environment that is inhospitable to sperm.	$22/dose
Oriahnn *elagolix/estradiol/ norethindrone + elagolix* oral capsules	· AbbVie	· Uterine leiomyomas	5/29/20	· For the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. · The product labeling includes a Black Box Warning re: thrombolic disorders and vascular events.	$12,000/year

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
CARDIOVASCULAR					
inclisiran subcutaneous injection	· Novartis	· Hypercholesterolemia	· Proprotein convertase subtilisin/kexin type 9 (PCSK9) synthesis inhibitor	· Administered in the doctor's office as twice yearly dosing. · Would compete with the PCSK9 binding inhibitors for high cardiovascular risk patients who are already on maximized statin therapy.	12/1/20
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					
Roctavian* *valoctocogene roxaparvovec* intravenous infusion	· BioMarin	· 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.	8/21/20
AMT-061* *etranacogene dezaparvovec* intravenous infusion	· Uniqure	· 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.	2020-2021
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
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
DERMATOLOGY					
CAT354 *tralokinumab* subcutaneous injection	· Leo Pharma	· Atopic dermatitis	· IL-13 inhibitor	· Would compete with Dupixent for this indication. · Would be the 4th JAK inhibitor to be FDA-approved for the treatment of RA.	Q2 2021
ENDOCRINOLOGY					
Zokinvy *lonafarnib* oral therapy	· Merck · Eiger Biopharma	· Hutchinson-Gilford Progeria Syndrome (HGPS) · Progeroid laminopathies	· Farnesyltransferase inhibitor	· Progeria is an ultra-rare and fatal disease that causes premature aging in children. · There are currently no FDA approved therapies.	11/20/20

* 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
RM-493* *setmelanotide* subcutaneous injection	· Rhythm Pharmaceuticals	· Pro-opiomelanocortin (POMC) deficiency obesity and leptin receptor (LEPR) deficiency obesity	· Melanocortin agonist	· 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.	11/27/20
ALN-GO1 *lumasiran* subcutaneous injection	· Alnylam	· Primary hyperoxaluria Type 1 (PH1)	· RNAi therapeutic (gene silencing)	· 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. · Although some patients respond to Vitamin B6 supplementation, there are no approved pharmaceutical therapies for PH1.	12/3/20
BCX7353* *berotralstat* oral capsules	· BioCryst	· Hereditary angioedema (HAE)	· Selective inhibitor of plasma kallikrein	· Once daily oral therapy. · All other HAE therapies are IV or SC injections. · High demand for this more convenient, less invasive dosage form is anticipated.	12/3/20
HEMATOLOGY					
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.	2021
IMMUNOLOGY					
filgotinib oral capsule	· Gilead · Galapagos	· Rheumatoid arthritis (RA)	· JAK1-selective inhibitor	· Proposed for the treatment of moderate to severe disease. · Would be the 4th JAK inhibitor to be FDA-approved for the treatment of RA.	8/19/20
Ryoncil *remestemcel-L* intravenous infusion	· Mesoblast	· Acute graft vs. host disease	· Stem cell therapy	· IV infusion twice weekly for 4 consecutive weeks. · Among 50 patients who received ≥ 1 treatment infusion, the Day 100 mortality rate was 22%, in contrast to Day 100 mortality rates as high as 70% in historical controls.	9/30/20
BIVV009* *sutimlimab* intravenous infusion	· Sanofi	· Cold agglutinin disease (CAD)	· Complement pathway inhibitor	· Proposed for the treatment of hemolysis in patients with primary CAD. · Rituxan is used off-label for this indication.	11/13/20
Luveniq *voclosporin* oral capsule	· Aurinia	· Lupus nephritis	· Calcineurin inhibitor	· Voclosporin is a structural analog of cyclosporine A, developed to potentially offer a number of advantages over legacy calcineurin inhibitors.	1/22/21

* 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
MUSCULOSKELETAL CONDITIONS					
SRP-4045* *casimersen* intravenous infusion	· Sarepta Therapeutics	· Duchenne muscular dystrophy	· Antisense oligonucleotide	· Proposed for the treatment of patients with mutations amenable to exon 45 skipping.	2nd Half of 2020
GALGT2* *AAVrh74.MHCK.GALGT2* intra-arterial injection	· Sarepta	· Duchenne muscular dystrophy	· 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 it's too early to distinguish between the two agents' relative safety and efficacy profiles.	2020-2021
SRP-9001* *microdystrophin* intravenous infusion	· Sarepta	· Duchenne muscular dystrophy	· Gene therapy	· Targets exons 18 through 58 (~60-75% of DMD patients have mutations in these exons).	2020-2021
SGT-001* intravenous infusion	· Solid Biosciences	· Duchenne muscular dystrophy	· Gene therapy	· Development has been marred by safety issues and FDA-applied clinical trial holds, with thus far mediocre efficacy results.	2021-2022
NEPHROLOGY/HEMATOLOGY					
Terlivaz *terlipressin* intravenous infusion	· Mallinckrodt	· Hepatorenal syndrome (HRS) type 1	· Vasopressin analog	· HRS-1 is estimated to affect between 30,000 and 40,000 patients in the U.S. annually. · Norepinephrine, octreotide and midodrine are alternatives.	9/12/20
FG-4592 *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.	12/20/20
NEUROLOGY					
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.	3/7/21
ONCOLOGY					
CC-486 *azacitidine* oral therapy	· BMS · Celgene	· Acute myeloid leukemia (AML)	· DNA hypomethylating agent	· Proposed for the maintenance treatment of adult patients who achieved complete remission (CR) or CR with incomplete blood count recovery (CRi), following induction therapy with or without consolidation treatment, and who are not candidates for, or who choose not to proceed to, hematopoietic stem cell transplantation.	9/3/20

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Upcoming Specialty Products

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
Rolontis *eflapegrastim* subcutaneous injection	· Spectrum Pharmaceuticals	· Chemotherapy-induced neutropenia	· 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.	10/24/20
JCAR017 *lisocabtagene maraleucel* intravenous infusion	· Juno Therapeutics	· Non-Hodgkin's lymphoma	· Chimeric antigen receptor T-cell (CART) therapy	· Would be third to market after Kymriah and Yescarta for this indication. · Has demonstrated a relatively favorable adverse effect profile.	11/16/20
Danyelza *naxitamab* intravenous infusion	· YmAbs Therapeutics, Inc.	· Neuroblastoma	· Anti-GD2 3F8 monoclonal antibody	· Proposed for the treatment of high risk neuroblastoma refractory to initial therapy or with incomplete response to salvage therapy in patients older than 12 months of age with persistent, refractory disease limited to bone marrow with or without evidence of concurrent bone involvement.	11/30/20
MGAH22 *margetuximab* intravenous infusion	· MacroGenics	· Breast cancer	· Anti-HER2 monoclonal antibody	· Proposed for the treatment of HER2-positive metastatic disease, in combination with chemotherapy. · Same mechanism of action as Herceptin.	12/18/20
relugolix oral tablet	· Myovant	· Prostate cancer	· GnRH receptor antagonist	· Would compete with injectable GnRH analog therapies such as Lupron.	12/20/20
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 100% overall response rate in the CARTITUDE-1 trial.	2nd Half of 2020
JNJ-68284528 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 100% overall response rate in the Phase I/II CARTITUDE-1 trial.	2020-2021
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
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
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

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

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Drug Name	Manufacturer	Indication(s)	Mechanism of Action	Comments	Anticipated Approval Date
OPHTHALMOLOGY					
RG6168 *satralizumab* subcutaneous injection	· Genentech	· Neuromyelitis optica and neuromyelitis optica spectrum disorders	· Anti-interleukin-6 receptor antibody	· Demonstrated benefit in both AQP4-positive and negative subjects. · Administered as a monthly subcutaneous injection after an initial loading phase. · Soliris and Uplizna are also FDA-approved.	8/15/20
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.	2020-2021

Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
CARDIOVASCULAR					
MK1242 *vericiguat* oral tablet	· Merck · Bayer	· Heart failure with reduced ejection fraction (HFrEF)	· Guanylate cyclase stimulator	· Proposed to reduce the risk of cardiovascular death and heart failure hospitalization following a worsening heart failure event in patients with symptomatic chronic HFrEF, in combination with other heart failure therapies.	1/20/21
DERMATOLOGY					
Winlevi *clascoterone* topical cream	· Cassiopea	· Acne vulgaris	· Dihydrotesterone antagonist	· Unlike oral hormonal therapies for acne, this therapy may be used in both male and female patients.	8/27/20
KX2-391 *tirbanibulin* topical ointment	· Athenex, Inc.	· Actinic keratosis	· Src kinase inhibition · Tubulin polymerization inhibition	· Five-day course of therapy.	12/30/20
KIDNEY DISEASE					
TRC101 *veverimer* oral suspension	· Tricida	· Metabolic acidosis in patients with chronic kidney disease (CKD)	· Non-absorbable hydrochloride-binding polymer agent	· Currently there are no FDA-approved chronic therapies for treating metabolic acidosis.	8/22/20
MUSCULOSKELETAL					
RN624 *tanezumab* subcutaneous injection	· Pfizer	· Osteoarthritis	· Nerve growth factor (NGF) inhibitor	· Subcutaneous administration by a health care provider once every eight weeks.	12/1/20
ONCOLOGY					
Pedmark *sodium thiosulfate* intravenous infusion	· Fennec Pharmaceuticals	· Chemotherapy-induced ototoxicity	· Antidote	· Proposed for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors.	8/10/20
OPHTHALMOLOGY					
Eysuvis *loteprednol etabonate 0.25%* ophthalmic suspension	· Kala Pharmaceuticals	· Dry eye disease	· Ophthalmic anti-inflammatory agent	· Proposed for the short-term (temporary) relief of the signs and symptoms of dry eye disease, including treatment of dry eye flares.	10/30/20
PSYCHIATRY					
SPN-812 *viloxazine* oral therapy	· Supernus Pharmaceuticals	· Attention deficit hyperactivity disorder (ADHD)	· Serotonin norepinephrine modulating agent (SNMA)	· Multiple other therapies for ADHD already exist.	11/8/20
LY03005 *ansofaxine* oral tablets	· Luye Pharma Group	· Major depressive disorder	· Serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI)	· Compared to traditional anti-depressants, SNDRI is proposed to help preserve patients' sexual function and produce a more rapid onset with higher efficacy.	12/26/20

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Drug Name	Manufacturer(s)	Indication(s)	Mechanism of Action(s)	Comments	Anticipated Approval Date
UROLOGY					
MK-4618 *vibegron* oral therapy	· Urovant Sciences	· Overactive bladder	· β3-adrenergic agonist	· Once daily oral therapy. · Proposed for the treatment of patients with symptoms of urge urinary incontinence, urgency and urinary frequency.	12/26/20
WOMEN'S HEALTH					
E4/DRSP *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.	1st Half of 2021

Drug Name	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
IMMUNOLOGY						
Hulio *adalimumab-fkjp* subcutaneous injection	· Mylan · Kyowa Hakko Kirin	Humira	· Rheumatoid arthritis · Juvenile idiopathic arthritis (JIA) · Psoriatic arthritis · Ankylosing spondylitis · Adult Crohn's disease · Ulcerative colitis · Plaque psoriasis	FDA-approved	No	· Sixth biosimilar to Humira. · Approved for all of the same indications as Humira except: JIA in the 2-4 year age group, pediatric Crohn's, hidradenitis suppurativa and uveitis.
ABP 798 *rituximab* intravenous infusion	· Amgen · Allergan	Rituxan	· Rheumatoid arthritis	BLA is under FDA review (BsUFA date: 12/19/2020)	Yes - Ruxience, Truxima	· Another biosimilar to Rituxan, after Ruxience and Truxima.
ONCOLOGY						
Nyvepria *pegfilgrastim-apgf* subcutaneous injection	· Pfizer	Neulasta	· Neutropenia	FDA-approved	Yes - Fulphila	· Fourth biosimilar to Neulasta. · To decrease the incidence of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
SB8 *bevacizumab* intravenous infusion	· Samsung Bioepis · Merck	Avastin	· Breast cancer	BLA is under FDA review (BsUFA date: 9/19/2020)	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: 12/27/2020)	Yes - Mvasi, Zirabev	· Another biosimilar to Avastin, after Mvasi and Zirabev.
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

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
tolvaptan	Samsca (30 mg)	· Alkem · Ascend and Apotex	5/20/20
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
efavirenz/emtricitabine/tenofovir disoproxil fumarate	Atripla	· Teva	9/30/20
emtricitabine/tenofovir disoproxil fumarate	Truvada	· Teva	9/30/20
sapropterin dihydrochloride	Kuvan	· Par · Endo	10/1/20
asenapine	Saphris	· Alembic (Tentative) · Sigmapharm Laboratories (Tentative) · Breckenridge · Hikma	2nd Half of 2020
abiraterone acetate	Zytiga (500 mg)	· Teva	2020
thalidomide	Thalomid	· Hikma · Lannett	2020
dimethyl fumarate	Tecfidera	· Graviti Pharmaceuticals · Macleods Pharmaceuticals · Mylan · Sandoz · Teva	2020-2021

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
methylphenidate hydrochloride	Aptensio XR	· Rhodes (AG)	5/1/20
micafungin sodium	Mycamine	· Fresenius	5/8/20
desonide	Desonide	· Teresina Holdings	6/15/20
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
acetaminophen	Ofirmev	· Sandoz · Wockhardt · Aurobindo · Custopharm	12/6/20
varenicline tartrate	Chantix	· Actavis (Tentative) · Apotex (Tentative) · Mylan (Tentative) · Teva (Tentative) · Par · Endo	Q4 2020
icosapent ethyl	Vascepa	· Apotex · Dr. Reddy's · Teva · West-Ward · Hikma	2020
cyclosporine	Restasis	· Unknown	2020
ciprofloxacin/dexamethasone	Ciprodex	· Par · Endo	2020
lubiprostone	Amitiza (24 mcg capsule)	· Dr. Redady's · Sun · Teva · Zydus	1/1/21
nebivolol hydrochloride	Bystolic	· Hetero	9/17/21

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