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Pharmacy Solutions

Pipeline Report

May 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:

- Despite the FDA's recent intense focus on COVID-19-related activities, oncology drug pipeline is one therapeutic area which remains vibrant in the immediate term. This is evidenced by the consistent rate of FDA approvals, as well as acceptance of New Drug and Biologic License Applications for review. In fact, multiple oncology agents were FDA-approved several months ahead of schedule, underscoring the urgency with which the FDA continues to act on oncologic agents.

- Several pipeline agents on this quarterly report are worth highlighting as possible new alternatives in high-cost disease states with few therapeutic options. These agents include *viltolarsen* in the treatment of Duchenne muscular dystrophy (DMD), *fostemsavir* in the treatment of heavily treatment-experienced adult patients with HIV, and *roxadustat* which offers the first oral alternative to injectable agents such as Aranesp, Epogen and Procrit, for the treatment of anemia associated with chronic kidney disease.

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	Indication(s)	FDA Approval Date	AcariaHealth (AH) Access Status	Comments	Cost (AWP Package Price)
ENDOCRINOLOGY						
Isturisa *osilodrostat* oral tablets	· Novartis	· Cushing's disease	3/6/2020	Pending launch	· For the treatment of adults who either cannot undergo pituitary gland surgery or have undergone the surgery but still have the disease.	$410,400/ year
NEUROLOGY						
Vyepti *eptinezumab-jjmr* intravenous infusion	· Alder BioPharmaceuticals	· Migraine headaches	2/21/2020	Limited access	· Efficacy demonstrated for both episodic and chronic migraines. · 30-minute infusion once every 12 weeks.	$7,176/ year
Zeposia *ozanimod* oral capsules	· Celgene	· Relapsing forms of multiple sclerosis (MS)	3/25/2020	Pending launch	· Same mechanism of action as Gilenya, but potentially less cardiac adverse effects.	Pending launch
ONCOLOGY						
Sarclisa *isatuximab-irfc* intravenous infusion	· Sanofi	· Muliple myeloma	3/2/2020	Limited access	· Proposed for use in combination with pomalidomide and dexamethasone for third-line treatment. · Same mechanism of action and indication as Darzalex.	$141,960/ year
Koselugo *selumetinib* oral capsules	· AstraZeneca · Merck	· Neurofibromatosis type 1 (NF1) with plexiform neurofibromas (PN)	4/10/2020	Limited access	· Approved for the treatment of pediatric patients aged two years and older with symptomatic, inoperable PNs.	$156,960/ year
Jelmyto *mitomycin* pyelocalyceal instillation gel	· UroGen Pharmaceuticals	· Urothelial carcinoma	4/15/2020	Pending launch	· Is the only FDA-approved non-surgical treatment for this indication, for the treatment of low-grade upper tract disease that is unamenable to endoscopic resection or with contraindication to nephroureterectomy.	$363,392/ 14-month course of therapy
Pemazyre *pemigatinib* oral tablets	· Incyte	· Cholangiocarcinoma	4/17/2020	Limited access	· For the treatment of locally advanced/metastatic or surgically unresectable disease with FGFR-2 translocation in patients who failed previous therapy.	$285,600/ year
Tukysa *tucatinib* oral tablets	· Cascadian Therapeutics	· Breast cancer	4/17/2020	AH has access	· Approved for use in combination with trastuzumab and capecitabine for patients who have received one or more prior anti-HER2-based regimens in the metastatic setting. · Showed efficacy in patients both with or without brain metastases.	$266,400/ year
Trodelvy *sacituzumab govitecan-hziy* intravenous infusion	· Immunomedics	· Triple negative breast cancer (TNBC)	4/22/2020	Limited access	· Antibody-drug conjugate (ADC). · Impressive clinical activity seen in a refractory setting. · Is the first and only ADC approved for the treatment of metastatic TNBC.	$251,160/ year
Tabrecta *capmatinib* oral tablets	· Novartis	· Non-small cell lung cancer (NSCLC)	5/6/2020	Pending launch	· Approved for both first-line and previously treated patients with metastatic MET exon 14 skipping (METex14) mutated disease. · The MET mutation is seen in an estimated 3% - 4% of all patients with NSCLC.	Pending launch

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Recent Non-Specialty Drug Approvals

Drug Name	Manufacturer	Indication(s)	FDA Approval Date	Comments	Cost (AWP Package Price)
CARDIOVASCULAR					
Nexletol *bempedoic acid* oral tablets	· Esperion Therapeutics, Inc.	· Hypercholesterolemia	2/21/2020	· For use in combination with maximally tolerated statin therapy. · Not as potent as Praluent and Repatha, but considerably less expensive.	$4,818/ year
Nexlizet *bempedoic acid /ezetimibe* oral tablets	· Esperion Therapeutics, Inc.	· Hypercholesterolemia	2/26/2020	· For use in combination with maximally tolerated statin therapy. · Not as potent as Praluent and Repatha, but considerably less expensive.	Pending launch
GASTROINTESTINAL					
Pizensy *lactitol* oral solution	· Braintree labs	· Chronic idiopathic constipation	2/12/2020	· Once daily dosing. · Mixed with 4-8 oz of fluid (water, juice, coffee, etc.).	Pending launch
Barhemsys *amisulpride* intravenous infusion	· Acacia	· Post-operative nausea and vomiting	2/26/2020	· Approved for use as both treatment and prophylaxis.	Pending launch
NEUROLOGY					
Nurtec ODT *rimegepant* oral tablets	· Biohaven	· Migraine headaches	2/27/2020	· Will compete with generically available oral triptans for the same indication.	$12,240/ year
Ongentys *opicapone* oral capsules	· Neurocrine Biosciences	· Parkinson's disease (PD)	4/24/2020	· Once daily dosing. · Intended as adjunct to levodopa therapy in patients experiencing "off" episodes.	Pending launch

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Drug Name	Manufacturer	Indication(s)	Mechanism of Action	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.	2020
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.	12/1/2020
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.	8/21/2020
AMT-061 *etranacogene dezaparvovec* intravenous infusion	· Uniqure	· Hemophilia B	· Gene therapy	· 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	· 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
ENDOCRINOLOGY					
UX 007 *triheptanoin* oral liquid	· Ultragenyx	· Long-chain fatty acid oxidative disorder	· Fatty acid replacement therapy	· Currently available therapies include avoidance of fasting, low-fat/high carbohydrate diets, carnitine and medium-chain triglyceride (MCT) oil, a medical food product.	7/31/2020
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.	12/3/2020
HEPATOLOGY					
OCA *obeticholic acid* oral tablets	· Intercept	· Non-alcoholic hepatosteatosis (NASH)	· Farnesoid X-activated receptor agonist	· New indication for Ocaliva. · Would be the first FDA-approved pharmacologic therapy for NASH.	6/26/2020

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Drug Name	Manufacturer	Indication(s)	Mechanism of Action	Comments	Anticipated Approval Date
IMMUOLOGY					
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.	9/30/2020
INFECTIOUS DISEASE					
BMS663068 *fostemsavir* oral tablets	· ViiV Healthcare	· Human immunodeficiency virus (HIV)	· Viral attachment inhibitor	· Proposed for the treatment of heavily treatment-experienced adult patients.	8/9/2020
MUSCULOSKELETAL CONDITIONS					
RG7916 *risdiplam* oral therapy	· PTC Therapeutics · Roche	· Spinal muscular atrophy (SMA)	· SMN2 gene splicer	· Proposed for the treatment of SMA Types 1, 2, and 3. · Would be the first daily oral therapy approved for SMA. · Potential competitor to Spinraza and Zolgensma.	8/24/2020
NS-065 *viltolarsen* intravenous infusion	· NS Pharma	· Duchenne muscular dystrophy (DMD)	· Exon 53 skipping agent · Antisense oligonucleotide	· Proposed for the treatment of DMD amenable to exon 53-skipping. · Would compete with Vyondys 53, with potentially better efficacy.	Q3 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
NEPHROLOGY/HEMATOLOGY					
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.	12/20/2020
ONCOLOGY					
Instiladrin *nadofaragene firadenovec* intravesical injection	· Ferring Pharmaceuticals	· Non-muscle invasive bladder cancer	· Gene therapy	· Proposed for BCG-refractory disease. · Treatment is applied once every 12 weeks.	5/25/2020

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Upcoming Specialty Products

Drug Name	Manufacturer	Indication(s)	Mechanism of Action	Comments	Anticipated Approval Date
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
GSK2857916 *belantamab mafodotin* intravenous infusion	· GlaxoSmithKline	· Multiple myeloma	· Anti-B cell maturation antigen (BCMA) monoclonal antibody	· Proposed as monotherapy in patients who have failed at least three prior lines of therapy, including an anti-CD38 antibody and are refractory to a proteasome inhibitor and an immunomodulatory agent.	7/21/2020
KTE-X19 intravenous infusion	· Gilead	· Mantle cell lymphoma	· CAR-T therapy	· Proposed for the treatment of relapsed/refractory disease after at least five prior therapies. · Demonstrated an overall response rate of 93%, including 67% with complete response.	8/10/2020
ASTX727 *cedazuridine + decitabine* oral therapy	· Astex Pharmaceuticals	· Myelodysplastic syndrome (MDS)	· Cedazuridine · Cytidine deaminase inhibitor · Decitabine: DNA hypomethylating agent	· Proposed for the initial treatment of intermediate- and high-risk MDS including including chronic myelomonocytic leukemia. · Allows for oral delivery of decitabine at exposures which emulate exposures achieved with the IV form (Dacogen) administered over 5 days.	8/11/2020
DCC-2619 *ripretinib* oral tablets	· Deciphera	· Gastrointestinal stromal tumor (GIST)	· Pan-KIT and PDGFRα inhibitor	· Proposed as fourth-line treatment of patients who have received prior treatment with imatinib, sunitinib and regorafenib.	8/13/2020
Zepsyre *lurbinectedin* intravenous infusion	· PharmaMar	· Small cell lung cancer	· RNA polymerase II inhibitor	· Proposed for the treatment of patients whose disease has progressed after prior platinum-containing therapy.	8/16/2020
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.	8/19/2020
MOR208 *tafasitamab* intravenous infusion	· MorphoSys	· Diffuse large B-cell lymphoma (DLBCL)	· Fc-enhanced anti-CD19 monoclonal antibody	· Proposed 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.	8/30/2020
Rolontis *eflapegrastim* subcutaneous injection	· Spectrum Pharmaceuticals	· Chemotherapy-induced neutropenia	· Colony stimulating factor	· Long-acting agent dosed every 3 weeks. · Demonstrated non-inferiority to Neulasta.	10/24/2020
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.	11/16/2020
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

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Drug Name	Manufacturer	Indication(s)	Mechanism of Action	Comments	Anticipated Approval Date
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					
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.	5/31/2020
MEDI551 *inebilizumab* intravenous infusion	· MedImmune · AstraZeneca	· Neuromyelitis optica and neuromyelitis optica spectrum disorders	· Anti-CD19 monoclonal antibody	· Would compete with Soliris. · Ultomiris is also being studied for the same indication.	6/11/2020
MP0112 *abicipar pegol* intraocular injection	· Allergan	· Age-related macular degeneration	· Vascular endothelial growth factor (VEGF) inhibitor	· In two phase III trials, treatment with abicipar pegol given every 8 or 12 weeks was non-inferior to Lucentis given every 4 weeks.	7/9/2020
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

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Drug Name	Manufacturer	Indication(s)	Mechanism of Action	Comments	Anticipated Approval Date
ANESTHESIA					
CNS7056 *remimazolam* intravenous infusion	· Paion	· Sedation during gastrointestinal procedures	· Benzodiazepine derivative	· Rapid-acting, short-duration sedative.	7/5/2020
DERMATOLOGY					
VP-102 *cantharidin* topical solution	· Verrica Pharmaceuticals	· Molluscum contagiosum	· Vesicant and irritant	· Current therapies in use include cryotherapy, scraping or cantharidin obtained by provider offices from outside sources.	7/13/2020
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.	8/27/2020
KX2-391 *tirbanibulin* topical ointment	· Athenex, Inc.	· Actinic keratosis	· Src kinase inhibition · Tubulin polymerization inhibition	· Five-day course of therapy.	12/30/2020
IMMUNOLOGY					
Viaskin Peanut *peanut antigen* transdermal patch	· DBV Technologies	· Peanut hypersensitivity	· Epicutaneous desensitization therapy	· Proposed for treatment of children 4-11 years old. · Once daily patch. · Would compete with Palforzia.	8/5/2020
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.	8/22/2020
MUSCULOSKELETAL					
RN624 *tanezumab* subcutaneous injection	· Pfizer	· Osteoarthritis	· Nerve growth factor (NGF) inhibitor	· Subcutaneous administration by a health care provider once every eight weeks.	12/1/2020
NEUROLOGY					
Fintepla *fenfluramine* oral solution	· Zogenix	· Dravet syndrome	· Central serotonin enhancing agent	· Fintepla will likely be used as an adjunct to existing therapies such as off-label valproate and clobazam (Onfi). · Epidiolex is also FDA-approved.	6/25/2020
Qutenza *capsaicin* topical patch	· Averitas Pharmaceuticals	· Diabetic peripheral neuropathy	· Substance P depletion	· 8% topical patch.	7/13/2020

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Drug Name	Manufacturer	Indication(s)	Mechanism of Action	Comments	Anticipated Approval Date
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.	8/10/2020
OPHTHALMOLOGY					
RVL-1201 *oxymetazoline* ophthalmic solution	· Vertical Pharmaceuticals	· Blepharoptosis	· Alpha-adrenergic receptor agonist	· Once-daily ophthalmic formulation. · Standard of care is surgery for severe cases.	7/16/2020
PSYCHIATRY					
SEP289 *dasotraline* oral tablet	· Sunovion	· Binge eating disorder	· Dopamine and norepinephrine reuptake inhibitor	· Once-daily dosing. · Same indication as Vyvanse.	5/14/2020
SPN-812 *viloxazine* oral therapy	· Supernus Pharmaceuticals	· Attention deficit hyperactivity disorder (ADHD)	· Serotonin norepinephrine modulating agent (SNMA)	· Multiple other therapies for ADHD already exist.	11/8/2020
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.	12/26/2020
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.	12/26/2020
WOMEN'S HEALTH					
Amphora *L-lactic acid, citric acid, and potassium bitartrate* topical therapy	· Evofem	· Pregnancy prevention	· Spermicide	· Maintains an acidic vaginal environment that is inhospitable to sperm.	5/25/2020

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Drug Name	Manufacturer	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
ENDOCRINOLOGY						
Basalog *insulin glargine* subcutaneous injection	· Mylan · Biocon	Lantus	· Diabetes mellitus	BLA is under FDA review (BsUFA date: 6/1/2020)	Yes - Basaglar, Toujeo	· Biosimilar to Lantus.
IMMUNOLOGY						
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, Truxima.
ONCOLOGY						
PF-06881894 *pegfilgrastim* subcutaneous injection	· Pfizer	Neulasta	· Chemotherapy-induced neutropenia	BLA is under FDA review (BsUFA date: 6/1/2020)	Yes - Fulphila	· Biosimilar to Neulasta.
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, 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, Zirabev.

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Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
naloxone hydrochloride	Evzio	· IJ Therapeutics	1/13/2020
ziprasidone mesylate	Geodon (injection)	· Gland Pharma	3/9/2020
everolimus	Zortress	· Hikma	3/13/2020
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
tolvaptan	Samsca	· Par · Endo	2020
abiraterone acetate	Zytiga (500 mg)	· Teva	2020
thalidomide	Thalomid	· Hikma, Lannett	2020
emtricitabine/tenofovir disoproxil fumarate	Truvada	· Teva	9/30/2020
efavirenz/emtricitabine/tenofovir disoproxil fumarate	Atripla	· Teva	9/30/2020
sapropterin dihydrochloride	Kuvan	· Par · Endo	10/1/2020
dimethyl fumarate	Tecfidera	· Graviti Pharmaceuticals · Macleods Pharmaceuticals · Mylan · Sandoz · Teva	2020-2021
sunitinib	Sutent	· Mylan	8/16/2021

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Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
dapsone	Aczone 7.5%	· Taro	1/2/2020
budesonide/ formoterol fumarate dihydrate	Symbicort	· Prasco	1/6/2020
calcipotriene	Sorilux	· Ayurax	1/17/2020
betamethasone dipropionate/ calcipotriene	Taclonex (topical suspension)	· Prasco	1/22/2020
hydrocodone bitartrate	Zohydro ER	· Alvogen	1/22/2020
Indomethacin	Tivorbex	· Ayurax	2/4/2020
ketorolac tromethamine	Sprix	· Prasco	2/7/2020
moxifloxacin hydrochloride	Moxeza	· Lupin	2/14/2020
esomeprazole magnesium/ naproxen	Vimovo	· Dr. Reddy's	2/27/2020
azelastine/ fluticasone propionate	Dymista	· Apotex	3/2/2020
esomeprazole magnesium	Nexium (packets for oral suspension)	· Cipla	3/24/2020
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER**	**ANTICIPATED LAUNCH DATE**
methylphenidate	Aptensio XR	· Actavis · Teva	2020
icosapent ethyl	Vascepa	· Apotex · Dr. Reddy's · Teva · West-Ward/Hikma	2020
acetaminophen	Ofirmev	· Sandoz · Wockhardt · Aurobindo · Custopharm	12/6/2020
lubiprostone	Amitiza (24 mcg capsule)	· Dr. Reddy's · Sun · Teva · Zydus	1/1/2021
nebivolol hydrochloride	Bystolic	· Hetero	9/17/2021

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