

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

June 2021

NEW DRUG INFORMATION

- **Myfembree™ (relugolix 40mg, estradiol 1mg, and norethindrone acetate 0.5mg):** The U.S. Food and Drug Administration (FDA) has approved Pfizer's Myfembree (relugolix 40mg, estradiol 1mg, and norethindrone acetate 0.5mg), as a once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, with a treatment duration of up to 24 months. Uterine fibroids are the most common benign tumors in women of reproductive age and are estimated to affect 20 to 60% of women by the time they reach menopause. The approval of Myfembree is supported by efficacy and safety data from two Phase 3 clinical trials, LIBERTY 1 and LIBERTY 2 which demonstrated a 72.1% and 71.2% response rate respectively in menstrual blood loss at week 24. Additionally, the combination therapy preserved bone mass density in the women enrolled in the clinical trials. Myfembree has launched with a wholesale acquisition cost (WAC) of \$974.54 for a 28-day supply.¹
- **Lybalvi™ (olanzapine and samidorphan):** The FDA has approved Alkermes' Lybalvi for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes, as monotherapy or an adjunct to lithium or valproate. Lybalvi is a once-daily, oral atypical antipsychotic composed of olanzapine, an established antipsychotic agent, and samidorphan, a new chemical entity that is designed to mitigate weight gain associated with olanzapine. Lybalvi was approved based on Phase 3 ENLIGHTEN-2 study which demonstrated a lower mean percent weight gain from baseline compared to the olanzapine group and a lower proportion of patients who gained 10% or more of their baseline body weight at six months compared to the olanzapine group.² FDA's Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee met October 2020 to discuss Lybalvi, they voted 15–1, with one abstention, that the drug was effective and prevented weight gain. Weight gain remains a side effect of Lybalvi, and the weight gain profile is inferior to that of risperidone. The FDA panel was divided on whether a label warning would sufficiently capture Lybalvi's risks voting 11–6. Additional risks will be addressed in the warning label for patients with opioid withdrawal symptoms and opioid overdose due to how samidorphan works as an opioid antagonist. Alkermes expects to make Lybalvi available for patients in the fourth quarter of 2021 with pricing to follow.

- **Brexafemme® (ibrexafungerp tablets):** The FDA has approved Scynexis' Brexafemme for oral use in patients with vulvovaginal candidiasis (VVC), also known as vaginal yeast infection. Brexafemme is the first in class triterpenoid which are structurally distinct glucan synthase inhibitors. It has shown activity against *Aspergillus* and *Candida* as well as activity against multidrug-resistant (MDR) species *Candida auris* as well as *Pneumocystis*. Brexafemme's approval was based on two Phase 3 studies that demonstrated efficacy and favorable tolerability compared to placebo.³ Brexafemme is planning on launching in the second half of this year with pricing to follow.
- **Wegovy® (semaglutide 2.4mg):** The FDA approved Novo Nordisk's Wegovy for chronic weight management. Wegovy is indicated as an adjunct to diet and exercise for chronic weight management in adults with obesity (initial BMI \geq 30 kg/m²) or overweight (initial BMI \geq 27 kg/m²) with at least one weight-related comorbidity. Wegovy is a once-weekly subcutaneous injection. The approval is based on the results from the STEP Phase 3a clinical trial that demonstrated patients treated with Wegovy that did not have type 2 diabetes, lost an average weight loss of 17–18% of their weight (average of 34 pounds) which was sustained over 68 weeks. Compared to the placebo group where the average weight loss was about 2.5% or just under six pounds.⁴ In a trial of type 2 diabetes patients, the Wegovy arm lost 6.2% of initial body weight compared to placebo. Wegovy has launched with a WAC of \$1,297 a month, equivalent to Novo Nordisk's daily obesity drug Saxenda™ (liraglutide 3mg).
- **Tembexa® (brincidofovir):** The FDA has granted approval of Chimerix's Tembexa (brincidofovir) tablets and oral suspension approval for the treatment of smallpox for adult and pediatric patients, including neonates. Tembexa is a nucleotide analog lipid-conjugate designed to mimic a natural monoacyl phospholipid to achieve effective intracellular concentrations of the active antiviral metabolite, cidofovir diphosphate. Tembexa was approved under the FDA's animal rule using efficacy data in two lethal orthopoxvirus animal models of human smallpox disease. The rabbitpox model demonstrated Tembexa treatment resulted in statistically significant survival benefit versus placebo following delayed treatment after animals were infected with a lethal viral dose.⁵ Although smallpox was certified as eradicated in 1980 by the World Health Organization, it continues to be a potential global threat in today's interconnected world. Smallpox outbreaks killed several hundred million people throughout several centuries.⁶ Tembexa launch and pricing are pending.
- **Rezipres® (ephedrine hydrochloride injection):** The FDA approved Eton Pharmaceuticals' Rezipres for the treatment of clinically important hypotension occurring in the setting of anesthesia. Rezipres is a ready-to-use hospital injectable. Rezipres was approved via the 505(b)2 pathway using Exela Pharma's Akovaz as its reference product.⁷ Rezipres launch and pricing are pending.

GENERIC DRUG INFORMATION

- **Thiola® (tiopronin):** Teva launched their generic version of Travele Therapeutics' Thiola indicated in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone. Thiola generated less than \$10 million in U.S. annual sales in 2020.
- **Bepreve® (bepotastine besilate):** Mylan launched their generic version of Bausch Health's Bepreve for the treatment of conjunctivitis. Multiple manufacturers are set to launch in 2021. Bepreve generated \$38 million in U.S. annual sales in 2020.
- **Banzel® (rufinamide tablet):** Multiple manufacturers have launched their generic version of Eisai's Banzel for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in pediatric patients 1 year of age and older, and adults. Banzel generated \$302 million in U.S. annual sales in 2020.
- **Kaletra® (lopinavir-ritonavir):** Hetero launched their generic version of Abbvie's Kaletra for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older). Kaletra generated \$36 million in U.S. annual sales in 2020.

*Specialty medication

NEW MOLECULAR ENTITY APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
brincidofovir	Tembexa®	Chimerix	Smallpox	June 2021
ibrexafungerp	Brexafemme®	Scynexis	Antifungal	June 2021
olanzapine and samidorphan	Lybalvi®	Alkermes	Schizophrenia or bipolar I disorder	June 2021
estetrol and drospirenone (E4/DRSP)	Nextstellis™	Mayne Pharma, Mithra Pharmaceuticals	Pregnancy prevention	April 2021
viloxazine hydrochloride	Qelbree™	Supernus Pharmaceuticals	ADHD	April 2021
oritavancin	Kimyrsa™	Melinta Therapeutics	Acute bacterial skin and skin structure infections (ABSSSI)	March 2021
serdexmethylphenidate and dexamethylphenidate	Azstarys™	KemPharm	ADHD	March 2021
cabotegravir	Vocabria™	VIIV Healthcare	HIV-1 infection	January 2021
cabotegravir and rilpivirine	Cabenuva™	VIIV Healthcare	HIV-1 infection	January 2021
vericiguat	Verquvo™	Merck	Heart failure	January 2021
vibegron	Gemtesa™	Sumitomo Pharmaceuticals Co.	Overactive bladder	December 2020
tirbanibulin	Klisyri®	Athenex and Almirall	Actinic keratosis	December 2020
clascoterone	Winlevi™	Cassiopea SPA	Acne	August 2020
fostemsavir	Rukobia™	Viiv Healthcare	HIV	August 2020
oliceridine	Olinvyk™	Trevena	Pain	August 2020
nifurtimox	Lampit™	Bayer	Pediatric Chagas disease	August 2020
abametapir	Xeglyze™	Hatchtech	Head lice treatment	July 2020
remimazolam	Byfavo™	Acacia Pharma	Procedure sedation	July 2020

*Date indicates FDA approval date only. The product launch and marketing dates are determined by the approved product's manufacturer.

OTHER NEW PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
ephedrine injection	Rezipres®	Eton Pharmaceuticals	Hypotension	June 2021
semaglutide	Wegovy™	Novo Nordisk	Chronic weight management	June 2021
relugolix, estradiol and norethindrone	Myfembree™	Myovant (Sumitomo Dainippon)	Heavy menstrual bleeding	June 2021
bupivacaine and meloxicam extended-release solution	Zynrelef™	Heron Therapeutics	Postoperative pain	May 2021
naloxone hydrochloride nasal spray	Kloxxado™	Hikma Pharmaceuticals	Emergency treatment of known or suspected opioid overdose	April 2021
mirabegron for extended-release oral suspension	Myrbetriq™ Granules	Astellas	Neurogenic detrusor overactivity (NDO)	March 2021
ezetimibe and rosuvastatin	Roszet™	Althera Pharmaceuticals	Hyperlipidemia	March 2021
dasiglucagon HypoPal Rescue Pen	Zegalogue™	Zealand Pharma	Hypoglycemia	March 2021
bupivacaine solution for infiltration	Posimir™	Durect Corporation	Post-surgical pain	February 2021
testosterone undecanoate	Tlando™	Lipocine	Hormonal therapy replacement	Tentative approval December 2020
tasimelteon	Hetlioz LQ™	Vanda Pharmaceuticals	Sleep disorders	December 2020
levothyroxine sodium	Thyquidity™	Reguliance	Hypothyroidism	November 2020
baloxavir marboxil oral suspension	Xofluza™	Roche	Influenza	November 2020
fosphenytoin sodium	Sesquient™	Sedor Pharmaceuticals	Status epilepticus	November 2020
sodium sulfate, magnesium sulfate, and potassium chloride tablets	Sutab®	Sebela Pharmaceuticals	Colonoscopy preparation	November 2020
loteprednol etabonate 0.25%	Eysuvis™	Kala Pharmaceuticals	Dry eyes	October 2020
bupivacaine hydrochloride collagen-matrix implants	Xaracoll™	Innocoll Holdings Limited	Postsurgical pain	August 2020
calcipotriene 0.005% and betamethasone 0.064% cream	Wynzora™	MC2 Therapeutics	Plaque psoriasis	July 2020
budesonide/glycolpyrrolonium/formoterol fumarate	Breztri™ Aerosphere	AstraZeneca	COPD	July 2020
oxymetazoline ophthalmic solution 0.1%	Upneeq™	Vertical Pharmaceuticals (Osmotica)	Acquired blepharoptosis (droopy eyelid)	July 2020

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PIPELINE WATCH

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
daxibotulinumtoxinA	N/A	Revance Therapeutics	Frown lines	Delayed
ansofaxine (LY-03005)	N/A	Luye Pharma Group, Ltd	Major depression disorder	Delayed
budesonide oral suspension	Eohilia™	Takeda	Localized esophageal inflammation	Delayed
benzoyl peroxide	Epsolay™	Sol-Gel Technologies	Rosacea	Delayed
ET-104 (zonisamide oral suspension)	N/A	Azurity Pharmaceuticals	Anticonvulsant	Delayed
cyclosporine ophthalmic emulsion	N/A	Santen	Vernal keratoconjunctivitis	June 2021
tenapanor	N/A	Ardelyx	Serum phosphorus	July 2021
sulopenem etzadroxil and probenecid	N/A	Iterum Therapeutics	Urinary tract infections	July 2021
finerenone	N/A	Bayer	Chronic kidney disease (CKD) and type 2 diabetes	July 2021
benzoyl peroxide and tretinoin	Twynéo®	Sol-Gel Technologies	Acne vulgaris	August 2021
ET-101 (topiramate oral solution)	N/A	Azurity Pharmaceuticals	Seizures	August 2021
AXS-05 (dextromethorphan and bupropion)	N/A	Axsome Therapeutics	Major depressive disorder	August 2021
difelikefalin	Korsuva®	Cara Therapeutics	Chronic kidney disease-associated pruritis (CKD-aP) in hemodialysis patients	August 2021
cantharidin 0.7% topical solution	Ycanth®	Verrica Pharmaceuticals	Molluscum contagiosum	September 2021
dihydroergotamine mesylate, DHE	Trudhesa®	Impel Neuropharma	Migraine	September 2021
reltecimod	N/A	Atox Bio	Necrotizing soft tissue infection	September 2021
atogepant	N/A	AbbVie	Preventive treatment of migraine	September 2021
testosterone undecanoate	Kyzatrex®	Marius Pharmaceuticals	Hypogonadism	October 2021
OC-01 (varenicline nasal spray)	N/A	Oyster Point Pharma	Dry eye disease	October 2021
phenylephrine and tropicamide ophthalmic solution	MydCombi®	Eyenovia	Mydriasis in the eye care practitioner's office	October 2021
triamcinolone acetonide	Xipere®	Clearside Biomedical and Bausch + Lomb	Macular edema associated with uveitis	October 2021
naloxone pre-filled syringe	Zimhi®	Adamas Pharma	Opioid overdose	November 2021
omidenepeg isopropyl	N/A	Santen and Ube Industries	Glaucoma	November 2021
maribavir	N/A	Takeda	Cytomegalovirus (CMV) infection	November 2021
tadalafil/finasteride	Tadfin™	Veru	Benign prostatic hyperplasia	December 2021
AGN-190584 (pilocarpine 1.25% ophthalmic solution)	N/A	Allergan	Presbyopia	December 2021
dextroamphetamine transdermal system (ATS)	N/A	Noven Therapeutics	ADHD	December 2021
E-58425 (tramadol 44mg and celecoxib 56mg tablet)	N/A	Esteve Pharmaceuticals and Kowa Pharmaceuticals America	Pain	December 2021
gefapixant	N/A	Merck	Chronic cough	December 2021

continued

PIPELINE WATCH *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
BXCL501 (dexmedetomidine orally dissolving film)	N/A	BioXcel Therapeutics	Schizophrenia and bipolar disorders	January 2022
daridorexant	N/A	Idorsia	Insomnia	January 2022
letibotulinumtoxinA	N/A	Hugel America	Frown lines	March 2022

FIRST GENERIC LAUNCHES OF TOP SELLING BRAND NAME DRUGS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	BRAND MANUFACTURER	INDICATION(S)	DATE APPROVED*
rufinamide	Banzel®	Eisai	Seizures associated with Lennox-Gastaut Syndrome	June 2021
isotretinoin	Absorica®	Ranbaxy	Acne	May 2021
brinzolamide	Azopt® ophth susp 1%	Novartis	Glaucoma or ocular hypertension	March 2021
droxidopa	Northera®	H. Lundbeck A/S	Parkinson's disease	February 2021
loteprednol ophth gel, 0.5%	Lotemax ophth gel® 0.5%	Bausch	Post-operative inflammation	February 2021
glucagon (rdna) for inj kit	Glucagon Emergency Kit®	Lilly	Hypoglycemia	January 2021
abiraterone	Zytiga®	Janssen Biotech	Prostate cancer	December 2020
asenapine maleate	Saphris®	Allergan	Bipolar disorder	December 2020
ivermectin lotion	Sklice®	Arbor Pharmaceuticals	Lice	December 2020
acetaminophen	Ofirmev®	Mallinckrodt	Pain	November 2020
icosapent ethyl	Vascepa®	Amarin	Dyslipidemia	November 2020
emtricitabine; tenofovir disoproxil fumarate	Truvada®	Gilead	HIV	September 2020
efavirenz; emtricitabine; tenofovir disoproxil fumarate	Atripla®	Gilead	HIV	September 2020
ciprofloxacin/dexamethasone otic susp	Ciprodex®	Novartis	Ear infections	August 2020

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+Specialty medication

OTHER FIRST GENERIC LAUNCHES IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
lopinavir, ritonavir	Kaletra®	AbbVie	HIV	June 2021
bepotastine ophth soln, 1.5%	Bepreve®	Bausch Health	Allergic conjunctivitis	June 2021
tiopronin tab	Thiola®	Traverse Therapeutics	Prevention of cystine stone formation	May 2021
pregabalin	Lyrica CR®	Pfizer	Neurological pain	April 2021
hydrocodone bitartrate	Hysingla ER®	Purdue	Pain	March 2021
topiramate	Qudexy XR®	Upsher-Smith	Epilepsy	February 2021
foscarnet	Foscavir®	Novaplus/Hospira	CMV retinitis and mucocutaneous acyclovir resistant HSV infections	February 2021
imiquimod cream, 3.75%	Zyclara®	Bausch Health	Actinic keratosis and genital warts	February 2021
epoprostenol for inj	Veletri®	Actelion Pharmaceuticals	Pulmonary arterial hypertension	January 2021

continued

OTHER FIRST GENERIC LAUNCHES IN THE PAST TWELVE MONTHS *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
emtricitabine; tenofovir disoproxil fumarate	Truvada® (100mg/150mg, 133mg/200mg, 167mg/250mg)	Gilead	HIV	January 2021
levorphanol tab, 3 mg	Levorphanol®	Sentynl Therapeutics	Pain	January 2021
naproxen CR tab	Naprelan®	Almatica	Inflammation	January 2021
meloxicam capsule	Vivlodex®	Zyla Life Sciences	Osteoarthritis pain	December 2020
alvimopan	Entereg®	Merck Sharp & Dohme	Gastrointestinal recovery	December 2020
nitazoxanide	Alinia®	Romark Pharmaceuticals	Certain forms of diarrhea	December 2020
norethindrone/ethinyl estradiol/fe cap, 1 mg-20 mcg	Taytulla®	Allergan	Oral contraceptive	November 2020
timolol pf ophth soln, 0.5%	Timoptic® Ocusol	Bausch Health	Ocular hypertension or open-angle glaucoma	November 2020
rufinamide oral susp	Banzel®	Eisai	Lennox-Gastaut Syndrome seizures	November 2020
tavaborole topical soln	Kerydin®	Sandoz	Fungal infections	October 2020
methylphenidate ER 24hr	Aptensio XR®	Rhodes Pharmaceutical	Attention deficit hyperactivity disorder	October 2020
fosfomycin granules	Monurol®	Allergan	Urinary tract infection	October 2020
lapatinib tab*	Tykerb®	Novartis	HER2-positive breast cancer	October 2020
dimethyl fumarate DR cap starter pack*	Tecfidera® Starter Pack	Biogen Idec	Relapsing multiple sclerosis	October 2020
deferiprone tab*	Ferriprox®	Chiesi USA	Transfusional iron overload	September 2020
tobramycin neb soln	Bethkis®	Chiesi USA	Cystic fibrosis	September 2020
sapropterin tablets*	Kuvan® tablets	Biomarin Pharmaceuticals	Endocrine and nutritional disease	September 2020
sapropterin powder packets*	Kuvan® powder packets	Biomarin Pharmaceuticals	Endocrine and nutritional disease	September 2020
ascorbic acid; PEG; potassium chloride; sodium ascorbate; sodium chloride; sodium sulfate	Moviprep®	Salix Valeant	Osmotic laxative	September 2020
emtricitabine	Emtriva®	Gilead	HIV	September 2020
epinephrine nasal soln, 0.1%	Adrenalin nasal soln®	Par Sterile Products	Nasal decongestion	August 2020
efavirenz/lamivudine/tenofovir disoproxil fumarate tab	Symfi®	Mylan Specialty	HIV	August 2020
efavirenz/lamivudine/tenofovir disoproxil fumarate tab	Symfi Lo®	Mylan Specialty	HIV	August 2020
pantoprazole DR for oral susp	Protonix® oral susp	Pfizer	Gastroesophageal reflux disease	August 2020
deferasirox oral granules*	Jadenu Sprinkle®	Novartis	Chronic iron overload due to blood transfusion	August 2020
metyrosine	Demser®	Bausch Health	Pheochromocytoma	August 2020

*Date usually indicates FDA approval date. The product's launch date is determined by the manufacturer. Generic approvals that do not come to market within three months of approval are listed and dated when they enter the market.

*Specialty medication

GENERICS OF TOP SELLING BRAND DRUGS POTENTIALLY AVAILABLE SOON

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
levothyroxine sodium	Tirosint®	IBSA	Hypothyroidism	2021
formoterol fumarate	Perforomist®	Mylan	COPD	2021
varenicline tartrate	Chantix®	Pfizer	Smoking cessation	2021
sunitinib malate ⁺	Sutent®	CPPI CV	Cancer	2021
emtricitabine	Emtriva® oral solution	Gilead	HIV	2021
nebivolol	Bystolic®	Allergan	Hypertension	2021
cabazitaxel ⁺	Jevtana Kit®	Sanofi	Prostate cancer	2021
arformoterol tartrate	Brovana®	Sunovion	COPD	2021
fingolimod hydrochloride ⁺	Gilenya®	Novartis	Multiple sclerosis	2021
efinaconazole	Jublia®	Valeant	Fungal infection	2021
bupivacaine	Exparel®	Pacira	Anesthesia	2021
exenatide	Byetta®	AstraZeneca	Diabetes	2021
roflumilast	Daliresp®	AstraZeneca	COPD	2021
difluprednate	Durezol®	Alcon/Novartis	Eye inflammation	2021
aprepitant	Emend® oral suspension	Merck and Co	Nausea	2021
teriparatide ⁺	Forteo®	Lilly	Osteoporosis	2021
naloxone hydrochloride	Narcan® nasal spray	Adapt Pharma	Overdose	2021
zolmitriptan nasal spray	Zomig®	AstraZeneca	Migraine	2021
octreotide acetate ⁺	Sandostatin LAR®	Novartis	Endocrine gland disease	2021
fesoterodine fumarate	Toviaz®	Pfizer	Overactive bladder	2021
everolimus ⁺	Afinitor®	Novartis	Kidney cancer	2021–2022
etravirine	Intelence®	Janssen	HIV	2021–2022
lubiprostone	Amitiza®	Sucampo	Constipation	2021–2022
cyclosporine	Restasis®	Allergan	Dry eye	2021–2022
pomalidomide ⁺	Pomalyst®	Celgene	Multiple myeloma	2022
fluticasone propionate	Flovent®	GSK	Respiratory	2022
dabigatran	Pradaxa®	Boehringer Ingelheim Pharmaceuticals	Anticoagulant	2022
dabigatran	Pradaxa®	Boehringer Ingelheim Pharmaceuticals	Anticoagulant	2022

* Expected to market dates are predictions made by Prime based on industry information.

⁺ Specialty medication

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