

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

December 2020

NEW DRUG INFORMATION

- **Xofluza™ (baloxavir marboxil) oral suspension:** The U.S. Food and Drug Administration (FDA) approved Roche's Xofluza for post-exposure prophylaxis of influenza in persons 12 years of age and older, following contact with an individual who has influenza. Additionally, Xofluza is indicated for treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or at high risk of developing influenza-related complications. Xofluza's new formulation is a 2mg/mL oral suspension that is administered as a one-time dose and will be available for children ages 1 to less than 12 years of age or those who have difficulty swallowing. Xofluza is already approved as a 20 and 40mg tablet. Xofluza's approval was based on a placebo-controlled study that evaluated the prevention of influenza. Xofluza demonstrated a statistically significant 13% reduction in influenza transmission compared to placebo.¹ Xofluza oral suspension launch and pricing are pending.
- **Thyquidity™ (levothyroxine sodium) oral solution:** The FDA has approved Regulance's Thyquidity as replacement therapy in primary, secondary, and tertiary congenital or acquired hypothyroidism as well as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. Thyquidity was approved via the 505(b)2 pathway based on the safety and efficacy of Synthroid.² Thyquidity launch and pricing are pending.
- **Hetlioz LQ™ (tasimelteon):** Vanda Pharmaceuticals' Hetlioz LQ has been approved by the FDA for nighttime sleep disturbances associated with Smith-Magenis syndrome (SMS). SMS is a rare neurodevelopmental disorder where the patients have "inverted" circadian rhythm. It is available in two formulations: a liquid suspension for children and a capsule for adults. Approval is based on a single placebo-controlled efficacy study of Hetlioz LQ. Hetlioz LQ resulted in statistically significant improvement in the 50% worst nights' sleep quality.³ Hetlioz capsules and Hetlioz LQ oral suspension are not substitutable. Hetlioz capsules for adults will be immediately available; Hetlioz LQ liquid formulation for children will be available in the first quarter of 2021 with pricing to follow.
- **Klisyri® (tirbanibulin):** The FDA approved Athenex's Klisyri for the topical treatment of actinic keratosis (AK) on the face or scalp. AK is a pre-cancerous skin lesion and the second most common diagnosis made by dermatologist in the United States. Left untreated, 10 – 15% of AK lesions will develop into skin cancers. Klisyri is a first-in-class microtubule inhibitor that is a 1% ointment (10mg/g) that is applied once daily for five days. Klisyri was approved based on two Phase 3 clinical trials that demonstrated complete clearance of actinic keratosis lesions at day 57 when compared to vehicle.⁴ Klisyri achieved a significantly higher number of patients with complete (100%) clearance of AK lesions in the treated area compared to vehicle (44% vs. 5% in study 1 and 54% vs. 13% in study 2). Athenex is expected to launch Klisyri by the first quarter of 2021 with pricing to follow.

GENERIC DRUG INFORMATION

- **Ofirmev® (acetaminophen inj, 10mg/mL):** Auromedics Pharma launched their generic version of Mallinckrodt Hospital's Ofirmex to reduce fever, or to treat mild to moderate pain. Ofirmev generated \$379 million in U.S. annual sales in 2019. Multiple manufacturers are set to launch this year.
- **Alinia® (nitazoxanide) tablet:** Rising Pharmaceuticals launched their generic version of Romark Pharmaceuticals' Alinia as an antiprotozoal indicated for the treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum. Alinia generated \$70 million in U.S. annual sales in 2019.
- **Sklice® (ivermectin lotion):** Taro launched their generic version of Arbor Pharmaceuticals Sklice lotion as a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older. Sklice generated \$35 million in U.S. annual sales in 2019.
- **Entereg® (alvimopan):** Actavis Pharma launched their generic version of Merck Sharp & Dohme's Entereg as a peripherally acting μ -opioid receptor antagonist indicated to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. Entereg generated \$107 million in U.S. annual sales in 2019.
- **Saphris® (asenapine maleate):** Breckenridge launched their generic version of Allergan's Saphris for the treatment of bipolar disorder and schizophrenia. Multiple manufacturers are set to launch before the end of the year. Saphris generated \$255 million in U.S. annual sales in 2019.

+Specialty medication

NEW MOLECULAR ENTITY APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
tirbanibulin	Klisryi®	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
rimegepant	Nurtec ODT™	Biohaven	Acute migraine	February 2020
eptinezumab-jjmr	Vyepti™	Adler BioPharmaceuticals	Migraine prevention	February 2020
amisulpride	Barhemsys®	Acacia Pharma	Post-operative nausea & vomiting	February 2020
bempedoic acid	Nexletol®	Esperion Therapeutics Inc	High cholesterol	February 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*
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
metoclopramide nasal spray	Gimoti™	Evoke Pharma	Diabetic gastroparesis	June 2020
insulin lispro-aabc	Lyumjev™	Lilly	Diabetes mellitus	June 2020
insulin glargine	Semglee™	Mylan and Biocon	Diabetes mellitus	June 2020
dolutegravir	Tivicay PD™	Viiv Healthcare	HIV-1	June 2020
minocycline topical foam	Zilxi™	Foamix Pharmaceuticals	Rosacea	June 2020
lactic acid, citric acid, and potassium bitartrate	Phexxi™	Evoform	Pregnancy prevention	May 2020
celecoxib oral solution	Elyxyb™	Promius Pharma	Acute migraine	May 2020
elagolix, estradiol and norethindrone acetate	Oriahnn™	AbbVie/Neurocrine Biosciences	Menstrual bleeding associated with uterine leiomyomas	May 2020
progesterone	Milprosa™	Ferring Pharmaceuticals	Female infertility	April 2020
opicapone	Ongentys™	Neurocrine Biosciences	Parkinson's disease	April 2020
ferric pyrophosphate citrate	Triferic Avnu™	Rockwell Medical	Maintain hemoglobin in hemodialysis-dependent chronic kidney disease	March 2020
bimatoprost sustained-release (SR)	Durysta™	Allergan	Open-angle glaucoma or ocular hypertension	February 2020
bempedoic acid/ezetimibe	Nexlizet™	Esperion Therapeutics	High cholesterol	February 2020
semaglutide, oral tablet	Rybelsus™	Novo Nordisk	Diabetes	February 2020

continued

OTHER NEW PRODUCT APPROVALS IN THE PAST TWELVE MONTHS *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
ethinyl estradiol and levonorgestrel transdermal system	Twirla™	Agile Therapeutics	Pregnancy prevention	February 2020
meloxicam IV	Anjeso™	Baudax Bio	Pain	February 2020
lactitol	Pizensy™	Braintree Laboratories Inc.	Chronic idiopathic constipation	February 2020
empagliflozin, linagliptin and metformin XR	Trijardy XR™	Boehringer Ingelheim and Eli Lilly	Type 2 diabetes	January 2020
fidaxomicin	Difacid™	Merck	Clostridium difficile-associated diarrhea (CDAD)	January 2020
ferric derisomaltose	Monoferric™	Pharmacosmos	IV iron replacement product	January 2020
tazarotene	Arazlo™	Ortho Dermatologics	Acne vulgaris	January 2020
diazepam	Valtoco™	Neurelis	Seizures	January 2020

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PIPELINE WATCH

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
testosterone undecanoate	Tlando™	Lipocine	Hormonal therapy replacement	Tentative approval
AR19	N/A	Arbor Pharmaceuticals	ADHD	November 2020
daxibotulinumtoxinA	N/A	Revance Therapeutics	Frown lines	November 2020
vibegron	N/A	Sumitomo Pharmaceuticals Co.	Overactive bladder	December 2020
ansofaxine (LY-03005)	N/A	Luye Pharma Group, Ltd	Major depression disorder	December 2020
arbaclofen, extended-release	Ontinua XR™	Osmotica	Spasticity associated with MS	December 2020
vericiguat	N/A	Merck	Heart failure	January 2021
taurolidine, heparin and citrate	Defencath™	CorMedix Inc.	Catheter-related bloodstream infections	February 2021
KP415	N/A	KemPharm	ADHD	March 2021
dasiglucagon HypoPal Rescue Pen	N/A	Zealand Pharma	Hypoglycemia	March 2021
budesonide oral suspension	Eohilia™	Takeda	Localized esophageal inflammation	April 2021
estetrol and drospirenone (E4/DRSP)	N/A	Mayne Pharma, Mithra Pharmaceuticals	Pregnancy prevention	April 2021
benzoyl peroxide	Epsolay™	Sol-Gel Technologies	Rosacea	April 2021
tenapanor	N/A	Ardelyx	Serum phosphorus	April 2021
HTX-011 (bupivacaine and meloxicam)	N/A	Heron Therapeutics	Postoperative pain	May 2021
ET-104 (zonisamide oral suspension)	N/A	Eton Pharmaceuticals	Anticonvulsant	May 2021
relugolix, estradiol and norethindrone	N/A	Myovant (Sumitomo Dainippon)	Heavy menstrual bleeding	June 2021
ibrexafungerp	N/A	Scynexis	Antifungal	June 2021
cyclosporine ophthalmic emulsion	N/A	Santen	Vernal keratoconjunctivitis	June 2021
sulopenem etzadroxil and probenecid	N/A	Iteum Therapeutics	Urinary tract infections	July 2021
benzoyl peroxide and tretinoin	Twynéo®	Sol-Gel Technologies	Acne vulgaris	August 2021
ET-101 (topiramate oral solution)	N/A	Eton Pharmaceuticals and Tulex Pharmaceuticals	Seizures	August 2021
INP104 (dihydroergotamine mesylate, DHE)	N/A	Impel Neuropharma	Migraine	September 2021
finerenone	N/A	Bayer	Chronic kidney disease (CKD) and type 2 diabetes	November 2021
vaccine, hepatitis B	N/A	VBI Vaccines	Hepatitis B virus	December 2021

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

GENERIC NAME	BRAND NAME	BRAND MANUFACTURER	INDICATION(S)	DATE APPROVED*
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	2020
efavirenz; emtricitabine; tenofovir disoproxil fumarate	Atripla®	Gilead	HIV	2020
ciprofloxacin/dexamethasone otic susp	Ciprodex®	Novartis	Ear infections	August 2020
tolvaptan ⁺	Samsca®	Otsuka America	Hypervolemic hyponatremia	May 2020
albuterol sulfate	Proventil® HFA/ ProAir® HFA	Merck/Teva	Asthma/COPD	March 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

OTHER FIRST GENERIC LAUNCHES IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
alvimopan	Entereg®	Merck Sharp & Dohme	Gastrointestinal recovery	December 2020
nitazoxanide	Alinia®	Romark Pharmaceuticals	Certain forms of diarrhea	December 2020
norethindrone/ethinyl estradiol/fe cap, 1mg-20mcg	Taytulla®	Allergan	Oral contraceptive	November 2020
timolol pf ophth soln, 0.5%	Timoptic® Ocudose	Bausch Health	Ocular hypertension or open-angle glaucoma	November 2020
rufinamide oral susp	Banzel®	Eisai	Lennox-Gastaut syndrome seizures	November 2020
tavorole 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

continued

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

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
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
desonide	Desonate®	LEO Pharma Inc.	Dermatitis	June 2020
calcipotriene/ betamethasone susp	Taclonex®	LEO Pharma Inc.	Plaque psoriasis	May 2020
epinephrine injection	Adrenalin®	Par & Endo	Anaphylaxis reaction	May 2020
micafungin for injection	Mycamine®	Astellas	Fungal infection	April 2020
thiotepa for injection+	Tepadina®	Amneal Biosciences	Certain forms of cancer	April 2020
esomeprazole magnesium granules for oral suspension	Nexium®	AstraZeneca	GERD	April 2020
diazoxide suspension	Proglycem®	Teva	Hypoglycemia	March 2020
pyrimethamine	Daraprim®	Vyera Pharmaceuticals	Toxoplasmosis	March 2020
gadoterate meglumine	Clariscan®	Guerbet	Contrast agent	March 2020
everolimus+	Zortress®	Novartis	Transplant	March 2020
ziprasidone inj	Geodon®	Pfizer	Schizophrenia	March 2020
azelastine/fluticasone	Dymista®	Mylan Specialty	Seasonal allergic rhinitis	March 2020
naproxen/ esomeprazole DR	Vimovo®	Horizon Therapeutics USA	Arthritis	February 2020
phenobarbital inj	Phenobarbital inj®	Hikma	Seizures	February 2020
strontium-89 chloride inj	Metastron inj®	GE Health Care	Bone pain	February 2020
irinotecan inj+	Camptosar inj®	Pfizer	Colorectal cancer	February 2020
moxifloxacin oph soln	Moxeza®	Novartis	Conjunctivitis	February 2020
potassium chloride ER tab	K-tab®	Abbvie	Hypokalemia	January 2020
penicillamine tab	Depen Titratabs®	Meda Pharmaceuticals Mylan	Cystinuria hepatic encephalopathy, Wilson's disease	January 2020

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+Specialty medication

GENERICS OF TOP SELLING BRAND DRUGS POTENTIALLY AVAILABLE SOON

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
everolimus ⁺	Afinitor®	Novartis	Kidney cancer	2020
topiramate	Qudexy XR®	Upsher-Smith	Epilepsy	2020
levothyroxine sodium	Tirosint®	IBSA institut	Hypothyroidism	2020
varenicline Tartrate	Chantix®	Pfizer	Smoking cessation	2020
isotretinoin	Absorica®	Ranbaxy	Acne	2020
exenatide	Byetta®	AstraZeneca	Diabetes	2020
difluprednate	Durezol®	Alcon/Novartis	Eye inflammation	2020
cyclosporine	Restasis®	Allergan	Dry eye	2020
teriparatide ⁺	Forteo®	Lilly	Osteoporosis	2021
sucroferric oxyhydroxide	Velphoro®	Vifor Pharma	Kidney disease	2021
emtricitabine; tenofovir disoproxil fumarate	Truvada® (100mg/150mg, 133mg/200mg, 167mg/250mg)	Gilead	HIV	2021
fluticasone propionate	Flovent®	GSK	Respiratory	2021
lubiprostone	Amitiza®	Sucampo	Constipation	2021
droxidopa	Northera®	H. Lundbeck A/S	Parkinson's disease	2021
zolmitriptan nasal spray	Zomig®	AstraZeneca	Migraine	2021
pomalidomide ⁺	Pomalyst®	Celgene	Multiple myeloma	2021
formoterol fumarate	Perforomist®	Mylan	COPD	2021
etravirine	Intelence®	Janssen	HIV	2021
sunitinib malate ⁺	Sutent®	CPPI CV	Cancer	2021
nebivolol	Bystolic®	Allergan	Hypertension	2021
cabazitaxel ⁺	Jevtana Kit®	Sanofi	Prostate cancer	2021
arformoterol tartrate	Brovana®	Sunovion	COPD	2021
efinaconazole	Jublia®	Valeant	Fungal infection	2021
dabigatran	Pradaxa®	Boehringer Ingelheim Pharmaceuticals	Anticoagulant	2021

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

⁺ Specialty medication

REFERENCES

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3. <https://www.prnewswire.com/news-releases/fda-approves-hetlioz-tasimelteon-for-the-treatment-of-nighttime-sleep-disturbances-in-smith-magenis-syndrome-301183162.html>
4. <https://www.biospace.com/article/releases/athenex-announces-fda-approval-of-klisyri-tirbanibulin-for-the-treatment-of-actinic-keratosis-on-the-face-or-scalp>

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