

# Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

June 2020

## NEW DRUG INFORMATION

- **Elyxyb™ (celecoxib oral solution):** The U.S. Food and Drug Administration (FDA) approved Dr. Reddy's Elyxyb 25mg/mL oral solution for the treatment of acute migraine with or without aura in adults. Elyxyb gained approval via the 505(b)(2) pathway using Pfizer's Celebrex® (celecoxib) as its reference drug.<sup>1</sup> Launch and pricing pending.
- **Phexxi™ (L-lactic acid, citric acid, and potassium bitartrate):** The FDA has approved Evofem's Phexxi as a non-hormonal vaginal gel that restores vaginal pH levels to contraceptive levels (3.5 to 4.5) for prevention of pregnancy. Evofem gel is marketing Phexxi as a potential "on-demand" method of contraception for females. Phexxi's approval is based on the Phase 3 clinical trial, AMPOWER, which confirmed that cumulative pregnancy rate was 6.7% over seven cycles of use, which corresponds to a 93.3% efficacy rate for typical use.<sup>2</sup> Additionally Evofem is conducting clinical trials of Phexxi to prevent urogenital acquisition of Chlamydia trachomatis and Neisseria gonorrhoea in women. Evofem has launched Phexxi with a wholesale annual cost (WAC) of \$268 per box of 12 applicators.
- **Oriahnn™ (elagolix, estradiol and norethindrone acetate):** AbbVie/Neurocrine Biosciences' Oriahnn has been approved by the FDA for the management of heavy menstrual bleeding due to uterine fibroids in pre-menopausal women. Uterine fibroids are traditionally managed by surgery, Oriahnn allows patients an additional option for treatment. The FDA approved Oriahnn based on two Phase 3 clinical trials, ELARIS UF-I, and ELARIS UF-II, which met their primary endpoint of clinically meaningful reduction in bleeding, defined as the proportion of women who achieved both at least a 50% reduction in menstrual blood loss at final month of treatment and a total menstrual blood loss amount of less than 80mL, compared to placebo. Seven out of ten women no longer experienced heavy menstrual bleeding compared to one of ten women on placebo.<sup>3</sup> Additionally, Oriahnn showed a 50% reduction in heavy menstrual bleeding due to uterine fibroids within the first month of use. Active ingredient elagolix was previously approved at a lower dose in AbbVie's Orilissa® (elagolix) used for endometriosis pain. AbbVie has announced Oriahnn has launched with a WAC of \$907 per 28-day supply (56 capsules).

- **Tivicay PD™ (dolutegravir):** The FDA has approved Viiv Healthcare's Tivicay PD for the treatment of HIV-1 infection in pediatric patients at least four weeks old and weighing at least 3kg (6.61 pounds) in combination with other antiretroviral treatments. Tivicay PD is a dispersible tablet for oral suspension. It is not an interchangeable milligram dose with Tivicay tablets. Tivicay PD will be supplied as a 5mg dispersible tablet in strawberry cream flavor. It should be administered within 30 minutes of mixing. This approval additionally expanded Tivicay's indication to include treatment of patients four weeks and older; previously, Tivicay was approved for ages six years of age and above. The FDA approval is based on two ongoing studies, P1093 and ODYSSEY, which demonstrated safety, tolerability and dosing for pediatrics.<sup>4</sup> Launch and price pending.
- **Zilxi™ (minocycline) topical foam, 1.5%:** The FDA has approved Foamix Pharmaceuticals for treatment of inflammatory lesions of rosacea in adults. Rosacea is a diverse skin condition that most commonly presents with symptoms such as deep facial redness, spider veins and acne-like inflammatory lesions. Zilxi's approval was based off two clinical trials which measured the absolute change from baseline in inflammatory lesion counts at week 12 and the proportion of patients with treatment success at week 12, defined by Investigator Global Assessment (IGA). The first study demonstrated IGA treatment success in 52.1% of Zilxi-treated patients vs 43% vehicle-treated patients. The second study demonstrated IGA treatment success in 49.1% of Zilxi-treated patients vs 39% of vehicle-treated patients.<sup>5</sup> Additionally, Foamix Pharmaceuticals' Amzeeq® (minocycline) is available as a 4% topical foam for the treatment of moderate to severe acne vulgaris. Foamix Pharmaceuticals plans on launching Zilxi by 4th quarter 2020 with pricing to follow.

## GENERIC DRUG INFORMATION

- **Taclonex® (calcipotriene/betamethasone suspension):** Tolmar has launched their generic version of Leo Pharma Inc's Taclonex suspension for the treatment of plaque psoriasis. Taclonex generated \$56 million in U.S. annual sales in 2019.
- **Samsca® (tolvaptan)<sup>+</sup>:** Alkem Labs has launched their generic version of Otsuka America's Samsca tablets for treatment of hypervolemic and euvolemic hyponatremia. Alkem appears to be eligible for 180-day exclusivity for 60mg tablets. Multiple manufacturers are set to launch later in 2020. Samsca generated \$114 million in U.S. annual sales in 2019.
- **Desonate® (desonide):** Cintex has launched their generic version of LEO Pharma's Desonate gel for treatment of dermatitis or eczema. Desonate gel generated less than \$10 million in U.S. annual sales in 2019.

<sup>+</sup>Specialty medication

**NEW MOLECULAR ENTITY APPROVALS IN THE PAST TWELVE MONTHS**

<b>GENERIC NAME</b>	<b>BRAND NAME</b>	<b>MANUFACTURER</b>	<b>INDICATION(S)</b>	<b>DATE APPROVED*</b>
elagolix, estradiol and norethindrone acetate	Oriahnn™	AbbVie/ Neurocrine Biosciences	Menstrual bleeding associated with uterine leiomyomas	May 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 and vomiting	February 2020
bempedoic acid	Nexletol®	Esperion Therapeutics Inc	High cholesterol	February 2020
lumateperone	Caplyta®	Intra-Cellular Therapies	Schizophrenia	December 2019
lemborexant	Dayvigo®	Eisai/Prudue Pharma	Insomnia	December 2019
ubrogepant	Ubrelvy®	Allergan	Acute migraine	December 2019
cenobamate	Xcopri™	SK Biopharmaceuticals	Antiepileptic	November 2019
asenapine	Secuado™	Noven Pharmaceuticals	Schizophrenia	October 2019
lasmiditan	Reyvow®	Lilly	Acute migraine	October 2019
tenapanor	Ibsrela®	Ardelyx	IBS-C	September 2019
istradefylline	Nourianz™	Kyowa Kirin's	Parkinson's disease 'off' episodes	September 2019
pitolisant	Wakix™	Harmony	Narcolepsy	August 2019
imipenem, cilastatin and relebactam	Recarbrio™	Merck	Complicated UTI and infections	July 2019

\*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**

<b>GENERIC NAME</b>	<b>BRAND NAME</b>	<b>MANUFACTURER</b>	<b>INDICATION(S)</b>	<b>DATE APPROVED*</b>
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
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
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	Dificid™	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
levamlodipine tablets	Conjupri™	Conjupro Biotherapeutics, Inc	Hypertension	December 2019
cefiderocol	Fetroja™	Shionogi	Complicated urinary tract infections (cUTI)	November 2019
rifabutin, amoxicillin and omeprazole	Talicia™	RedHill	Helicobacter pylori	November 2019
minocycline foam 4%	Amzeeq™	Foamix Pharmaceuticals	Acne vulgaris	October 2019
cetirizine, injectable	Quzyttir™	JDP Therapeutics	Acute urticaria	October 2019
trifarotene cream	Aklief™	Galderma Laboratories	Acne	October 2019
dexamethasone	Hemady™	Dexcel	Multiple myeloma	October 2019

continued

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

<b>GENERIC NAME</b>	<b>BRAND NAME</b>	<b>MANUFACTURER</b>	<b>INDICATION(S)</b>	<b>DATE APPROVED*</b>
baclofen	Ozobax™	Metacel Pharmaceuticals	Muscle relaxant	September 2019
fosaprepitant	Fosaprepitant™	Teva	Chemotherapy-induced nausea and vomiting	September 2019
glucagon injection	Gvoke™	Xeris Pharmaceuticals	Severe hypoglycemia in diabetes	September 2019
metformin HCl for extended-release oral suspension	Riomet ER®	Sun Pharma	Type 2 diabetes	September 2019
semaglutide	Rybelsus®	Novo Nordisk	Type 2 diabetes	September 2019
ferric maltol	Accrufer™	Shield Therapeutics	Iron deficiency	July 2019
nasal glucagon	Bagsimi™	Lilly	Hypoglycemia	July 2019
duloxetine DR	Drizalma Sprinkle™	Sun	Depression, anxiety, and neuropathic pain	July 2019
amlodipine benzoate suspension	Katerzia™	Silergate Pharms	Hypertension	July 2019
tiopronin DR	Thiola EC™	Mission Pharmacal/ Retrophin	Cystinuria	July 2019
budesonide	Ortikos™	Sun Pharma	Crohn's disease	June 2019
drospirenone	Slynd™	Exeltis	Pregnancy prevention	June 2019

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**PIPELINE WATCH**

<b>GENERIC NAME</b>	<b>BRAND NAME</b>	<b>MANUFACTURER</b>	<b>INDICATION(S)</b>	<b>DATE APPROVED*</b>
E-58425 (tramadol 44mg and celecoxib 56mg tablet)	N/A	Esteve Pharmaceuticals	Pain	2020
naloxone nasal spray	N/A	Insys	Opioid overdose	May 2020
fenfluramine, ZX008	Fintepla™	Zogenix	Seizures associated with Dravet syndrome	June 2020
metoclopramide nasal spray	Gimoti™	Evoke Pharma	Diabetic gastroparesis	June 2020
fosfomycin for injection	Contepo™	Nabriva Therapeutics PLC	cUTI	June 2020
RVL-1201 (oxymetazoline ophthalmic solution 0.1%)	N/A	Vertical Pharmaceuticals (Osmotica)	Acquired blepharoptosis (droopy eyelid)	July 2020
calcipotriene 0.005% and betamethasone 0.064% cream	Wynzora™	MC2 Therapeutics	Plaque psoriasis	July 2020
cantharidin 0.7% topical solution	Ycanth™	Verrica Pharmaceuticals	Molluscum contagiosum	July 2020
donepezil, transdermal	Adlarity™	Corium	Alzheimer's dementia	July 2020
oliceridine	Olinvo™	Trevena	Pain	August 2020
fostemsavir	N/A	Viiv Healthcare	HIV	August 2020
loteprednol etabonate (KPI-121) 0.25%	N/A	Kala Pharmaceuticals	Dry eyes	August 2020
veverimer	N/A	Tricida	Metabolic acidosis in patients with chronic kidney disease (CKD)	August 2020
clascoterone	Winlevi™	Cassiopea SPA	Acne	August 2020
testosterone undecanoate	Tlando™	Lipocine	Hormonal therapy replacement	August 2020
diazepam buccal film	Libervant™	Aquestive Therapeutics	Seizures	September 2020
ALKS 3831 (olanzapine and samidorphan)	N/A	Alkermes	Schizophrenia	November 2020
AR19	N/A	Arbor Pharmaceuticals	ADHD	November 2020
naloxone pre-filled syringe	Zimhi™	Adamis	Opioid overdose	November 2020
daxibotulinumtoxinA	N/A	Revance Therapeutics	Frown lines	November 2020
tirbanibulin (ALM14789)	N/A	Athenex and Almirall	Actinic keratosis	December 2020
KP415	N/A	KemPharm	ADHD	March 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*
tolvaptan+	Samsca®	Otsuka America	Hypervolemic hyponatremia	May 2020
albuterol sulfate	Proventil® HFA/ ProAir® HFA	Merck/Teva	Asthma/COPD	March 2020
travoprost ophth soln.	Travatan Z®	Alcon Novartis	Glaucoma or ocular hypertension	December 2019
everolimus+	Afinitor®	Novartis	Certain forms of cancer	December 2019
etonogestrel/ethinyl estradiol	NuvaRing®	Organon	Pregnancy prevention	December 2019
deferasirox+	Jadenu®	Novartis	Iron overload	November 2019
fosaprepitant dimeglumine	Emend®	Merck Sharp & Dohme	Chemotherapy-induced nausea and vomiting	September 2019
posaconazole	Noxafil®	Merck Sharp & Dohme	Fungal infections	September 2019
pregabalin	Lyrica®	Pfizer	Neuropathic pain, and seizures	July 2019

\*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*
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

*continued*



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

<b>GENERIC NAME</b>	<b>BRAND NAME</b>	<b>MANUFACTURER</b>	<b>INDICATION(S)</b>	<b>DATE APPROVED*</b>
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
amphetamine ER susp	Adzenys ER suspension®	Neos Therapeutics	Attention deficit hyperactivity disorder	December 2019
hydrocodone bitartrate 12 hr abuse-deterrent	Zohydro ER caps®	Pernix Therapeutics	Pain	December 2019
doxepin hcl	Silenor®	Somaxon Pharmaceuticals	Insomnia	December 2019
sulconazole nitrate cream, 1%	Exelderm cream®	Ranbaxy Pharmaceuticals	Tinea corporis, tinea pedis	December 2019
sulconazole nitrate solution, 1%	Exelderm soln®	Ranbaxy Pharmaceuticals	Tinea corporis, tinea pedis	December 2019
dapsone gel, 7.5%	Aczone 7.5%®	Allergan	Acne	December 2019
sucralfate suspension	Carafate®	Forest/Allergan	Ulcers	December 2019
pentamidine	Nebupent®	Seton Pharmaceuticals	Serious lung infections	December 2019
mesalamine ER	Apriso®	Bausch Health	Ulcerative colitis	December 2019
ciprofloxacin/fluocinolone otic	Otovel®	Arbor Pharmaceuticals	Ear infections	November 2019
ivermectin cream, 1%	Soolantra®	Galderma	Rosacea	October 2019
aminocaproic acid oral syrup	Amicar®	Clover Pharmaceuticals	Hemostasis	September 2019
triamterene	Dyrenium®	Concordia	Edema	September 2019
halcinonide	Halog®	Ranbaxy	Itchy skin	August 2019
ramelteon	Rozerem®	Takeda	Insomnia	August 2019
icatibant injection+	Firazyr®	Shire/Takeda	HAE	July 2019
daptomycin injection	Daptomycin®	Sagent/Xelia	Complicated bacterial infections	July 2019
carboprost injection	Hemabate®	Pfizer	Termination of pregnancy	July 2019
febuxostat	Uloric®	Takeda	Hyperuricemia in patients with gout	July 2019

\*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**

<b>GENERIC NAME</b>	<b>BRAND NAME</b>	<b>MANUFACTURER</b>	<b>INDICATION(S)</b>	<b>DATE APPROVED*</b>
ascorbic acid; PEG; potassium chloride; sodium ascorbate; sodium chloride; sodium sulfate	Moviprep®	Salix Valeant	Osmotic laxative	2020
difluprednate	Durezol®	Alcon/Novartis	Eye inflammation	2020
exenatide	Byetta®	AstraZeneca	Diabetes	2020
teriparatide+	Forteo®	Lilly	Osteoporosis	2020
topiramate	Qudexy XR®	Upsher-Smith	Seizures	2020
asenapine maleate	Saphris®	Forest	Bipolar	2020
everolimus+	Afinitor®	Novartis	Kidney cancer	2020
pomalidomide+	Pomalyst®	Celgene	Multiple myeloma	2020
emtricitabine; tenofovir disoproxil fumarate	Truvada®	Gilead	HIV	2020
efavirenz; emtricitabine; tenofovir disoproxil fumarate	Atripla®	Gilead	HIV	2020
dimethyl fumarate+	Tecfidera®	Biogen	MS	2020
varenicline Tartrate	Chantix®	Pfizer	Smoking cessation	2020
mometasone/formoterol fumarate	Dulera®	Merck & Co	Asthma	2020
vilazodone hydrochloride	Viibryd®	Forest	Depression	2021
fluticasone propionate	Flovent®	GSK	Respiratory	2021
nebivolol	Bystolic®	Allergan	Hypertension	2021
dabigatran	Pradaxa®	Boehringer Ingelheim Pharmaceuticals	Anticoagulant	2021

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

+ Specialty medication

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