

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

September 2020

NEW DRUG INFORMATION

- **Winlevi™ (clascoterone cream 1%):** The U.S. Food and Drug Administration (FDA) approved Cassiopea's Winlevi for the twice-daily topical treatment of acne vulgaris in male and female patients 12 years of age and older. Winlevi is a first-in-class topical androgen receptor inhibitor that limits the effects of hormones on increasing sebum production and inflammation. Approval of Winlevi was based on two Phase 3 clinical trials, STUDY 25 and STUDY 26, which achieved its primary endpoints of two-point reduction and Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) in both studies. In STUDY 25, IGA success was achieved in 18.8% of Winlevi patients compared to 8.9% of patients treated with vehicle. STUDY 26 demonstrated an IGA success rate of 20.8% in Winlevi patients versus 6.5% in vehicle treated patients.¹ Winlevi had long term favorable safety with low rates of treatment related adverse events. This medication is also in development as a 5% lotion formulation for the potential topical treatment of alopecia. Winlevi will launch in early 2021 and Cassiopea plans to announce the price in the fourth quarter.
- **Xaracoll™ (bupivacaine hydrochloride collagen-matrix implants):** Innocoll Holdings Limited's Xaracoll has been approved by the FDA as a non-opioid, drug-device treatment option for acute postsurgical pain relief for up to 24 hours following open inguinal hernia repair in adults. Xaracoll is a first-of-its-kind, fully bioresorbable collagen implant that delivers bupivacaine HCl directly to the surgical site providing long-lasting pain relief. Xaracoll was originally submitted to the FDA under the 505(b)2 pathway in 2016; however, they received a Refusal to File that required further studies. Approval was based on two Phase 3 clinical trials that demonstrated Xaracoll provided statistically significant pain relief compared to placebo. Additionally, the proportion of patients who did not receive opioid rescue analgesia through 72 hours in the Xaracoll and placebo treatment groups was 36% and 22% respectively, in Study 1, and 28% and 12% respectively, in Study 2² Launch and pricing are pending.
- **Qdolo™ (tramadol hydrochloride):** The FDA has approved Athena Biosciences' Qdolo for adult use when pain is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Qdolo is a 5mg/1mL oral solution and is scheduled by the DEA as a controlled substance IV.³ Tramadol is also available generically as a tablet, extended-release tablet and in combination with acetaminophen. Qdolo launch and pricing are pending.

GENERIC DRUG INFORMATION

- **Tecfidera® (dimethyl fumarate):** + Mylan has launched their generic version of Biogen's Tecfidera for the treatment of multiple sclerosis. Tecfidera generated \$3.99 billion in U.S. annual sales in 2019. Multiple manufacturers are set to launch third quarter of 2020.
- **Symfi Lo® (efavirenz/lamivudine/tenofovir disoproxil fumarate tab, 400-300-300 mg):** Laurus Labs Private Limited has launched their generic version of Mylan Specialty's Symfi Lo for the treatment of HIV. Symfi Lo generated <\$10 million in U.S. annual sales in 2019.
- **Symfi® (efavirenz/lamivudine/tenofovir disoproxil fumarate tab, 600-300-300 mg):** Laurus Labs Private Limited has launched their generic version of Mylan Specialty's Symfi for the treatment of HIV. Symfi generated <\$10 million in U.S. annual sales in 2019.
- **Adrenalin nasal soln® (epinephrine nasal soln, 0.1%):** BPI Labs launched their generic version of Par Sterile Products' Adrenalin nasal solution for treatment of nasal decongestion. U.S. annual sales for Adrenalin nasal solution is unknown.
- **Emtriva® (emtricitabine):** Cipla launched their generic version of Gilead's Emtriva for the treatment of HIV. Cipla was granted a 180-day exclusivity. Emtriva generated \$14 million in U.S. annual sales in 2019.
- **Moviprep® (peg-3350/Na sulfate/NaCl/KCl/Na ascorbate/ascorbic acid for oral soln):** Novel Laboratories/Teva launched their generic version of Bausch Health's Moviprep for use as a bowel cleanser. Teva was granted a 180-day exclusivity. Moviprep generated \$17 million in U.S. annual sales in 2019.
- **Kuvan® powder packets (sapropterin powder packets, 100 mg, 500 mg):** + Par Pharmaceuticals launched their generic version of Biomarin Pharmaceuticals' Kuvan powder packets for endocrine and nutritional diseases. Kuvan powder generated \$32 million in U.S. annual sales in 2019.
- **Kuvan® tablet (sapropterin):** + Par Pharmaceuticals launched their generic version of Biomarin Pharmaceuticals' Kuvan powder packets for endocrine and nutritional diseases. Kuvan powder generated \$32 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*
bupivacaine hydrochloride collagen-matrix implants	Xaracoll™	Innocoll Holdings Limited	Postsurgical pain	August 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
budesonide/glycopyrronium/formoterol fumarate	Breztri™ Aerosphere	AstraZeneca	COPD	July 2020
remimazolam	Byfavo™	Acacia Pharma	Procedure sedation	July 2020
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 & 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

*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*
tramadol oral solution	Qdolo™	Athena Biosciences	Pain	September 2020
calcipotriene 0.005% and betamethasone 0.064% cream	Wynzora™	MC2 Therapeutics	Plaque psoriasis	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	Elyxib™	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

continued

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

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
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

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PIPELINE WATCH

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
donepezil, transdermal	Adlarity™	Corium	Alzheimer's dementia	July 2020
testosterone undecanoate	Tlando™	Lipocine	Hormonal therapy replacement	August 2020
hydrocortisone granules	Alkindi™	Diurnal Group	Adrenal insufficiency	September 2020
diazepam buccal film	Libervant™	Aquestive Therapeutics	Seizures	September 2020
loteprednol etabonate (KPI-121) 0.25%	Eysuvis™	Kala Pharmaceuticals	Dry eyes	October 2020
SPN-812 (viloxazine hydrochloride extended release formulation)	N/A	Supernus	ADHD	November 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
vibegron	N/A	Sumitomo Pharmaceuticals Co.	Overactive bladder	December 2020
tirbanibulin (ALM14789)	N/A	Athenex and Almirall	Actinic keratosis	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
KP415	N/A	KemPharm	ADHD	March 2021
dasiglucagon HypoPal Rescue Pen	N/A	Zealand Pharma	Hypoglycemia	March 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
relugolix, estradiol and norethindrone	N/A	Myovant (Sumitomo Dainippon)	Heavy menstrual bleeding	June 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*
dimethyl fumarate+	Tecfidera®	Biogen	Multiple sclerosis	August 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
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

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+ Specialty medication

OTHER FIRST GENERIC LAUNCHES IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
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
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

continued

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

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
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 ophth 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

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+Specialty medication

GENERICS OF TOP SELLING BRAND DRUGS POTENTIALLY AVAILABLE SOON

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
emtricitabine; tenofovir disoproxil fumarate	Truvada®	Gilead	HIV	2020
efavirenz; emtricitabine; tenofovir disoproxil fumarate	Atripla®	Gilead	HIV	2020
everolimus+	Afinitor®	Novartis	Kidney cancer	2020
topiramate	Qudexy XR®	Upsher-Smith	Epilepsy	2020
hydralazine hydrochloride; isosorbide dinitrate	Bidil®	Arbor Pharmaceuticals	Heart failure	2020
levothyroxine sodium	Tirosint®	IBSA institut	Hypothyroidism	2020
risperidone	Risperdal Consta®	Janssen	Schizophrenia	2020
varenicline Tartrate	Chantix®	Pfizer	Smoking cessation	2020
acetaminophen	Ofirmev®	Mallinckrodt	Pain	2020
asenapine maleate	Saphris®	Forest	Bipolar	2020
isotretinoin	Absorica®	Ranbaxy	Acne	2020
exenatide	Byetta®	AstraZeneca	Diabetes	2020
difluprednate	Durezol®	Alcon/Novartis	Eye inflammation	2020
cyclosporine	Restasis®	Allergan	Dry eye	2020
icosapent ethyl	Vascepa®	Amarin	Dyslipidemia	2020
teriparatide+	Forteo®	Lilly	Osteoporosis	2020
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
neбиволol	Bystolic®	Allergan	Hypertension	2021
cabazitaxel+	Jevtana Kit®	Sanofi	Prostate cancer	2021
arformoterol tartrate	Brovana®	Sunovion	COPD	2021

GENERICS OF TOP SELLING BRAND DRUGS POTENTIALLY AVAILABLE SOON *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
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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- <https://www.biospace.com/article/releases/fda-approves-xaracoll-bupivacaine-hcl-implant-a-non-opioid-drug-device-treatment-option-for-acute-postsurgical-pain-relief-for-up-to-24-hours-following-open-inguinal-hernia-repair-in-adults/?s=74>
- <https://www.biospace.com/article/releases/u-s-fda-approves-athena-bioscience-s-new-drug-application-nda-for-qdolo-tramadol-hydrochloride-oral-solution/>

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