

Drug Pipeline **Monthly Update**

Critical updates in an ever changing environment

June 2018

New drug information

- **Consensi® (amlodipine/celecoxib):** The Food and Drug Administration (FDA) approved Kitov Pharma's Consensi for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Consensi is dosed once daily in 3 dosage forms. All of them contain the 200 mg dose of celecoxib for osteoarthritis pain and amlodipine in either 2.5, 5, or 10 mg for hypertension.
- **Imvexxy™ (estradiol vaginal inserts):** TherapeuticsMD's received FDA approval for Imvexxy, a bio-identical, applicator free, vaginal estrogen product for the treatment of moderate-to-severe vaginal pain associated with sexual activity, a symptom of vulvar and vaginal atrophy due to menopause.
- **Moxidectin:** Medicines Development for Global Health received FDA approval for moxidectin for the treatment of onchocerciasis due to *Onchocerca volvulus* (river blindness) in patients aged 12 years and older. Moxidectin is dosed as four 2 mg tablets as a single oral dose. River blindness is spread by repeated bites of infected black flies found by rivers in sub-Saharan Africa, Yemen, and South and Central America. Ivermectin is the current standard of care for river blindness.

Generic drug information

- **Suboxone® (buprenorphine/naloxone) sublingual film, 8–2 mg:** Both Dr. Reddy's and Mylan received FDA generic approval for Indivior's Suboxone for the treatment of opioid dependence. Dr. Reddy's launched their generic version 'at risk;' however, a U.S. court issued a temporary restraining order against making further sales. Dr. Reddy's and Indivior's court hearing will be held June 28, 2018. Due to Mylan and Indivior's confidential settlement, Mylan's launch date has not been released. According to IMS Health, Suboxone generated \$1.86 billion last year.

New molecular entity approvals in the past twelve months

Generic name	Brand name	Manufacturer	Indication(s)	Date approved*
moxidectin	Moxidectin	Medicines Development for Global Health	River blindness	June 2018
sodium zirconium cyclosilicate	Lokelma™	AstraZeneca	Hyperkalemia	May 2018
lofexidine	Lucemyra™	US WorldMeds	Mitigation of opioid withdrawal symptoms	May 2018
coagulation factor Xa (recombinant), inactivated-zhza)	Andexxa®	Portola	Factor Xa reversal agent	May 2018
benzhydrocodone/acetaminophen	Apadaz™	KemPharm	Pain	March 2018
bictegravir/emtricitabine/tenofovir alafenamide	Biktarvy™	Gilead	HIV	February 2018
ertugliflozin	Steglatro™	Merck/Pfizer	Diabetes	December 2017
ozenoxacin	Xepi™	Medimetriks	Impetigo	December 2017
netarsudil	Rhopressa®	Aerie Pharmaceuticals	Glaucoma or ocular hypertension	December 2017
semaglutide	Ozempic™	Novo Nordisk	Diabetes	December 2017
Letemovir	Prevymis™	Merck	Prophylaxis of CMV infection and disease	November 2017
secnidazole	Solosec™	Symbiomix	Bacterial vaginosis	October 2017
benznidazole	Benznidazole™ Tablets	Chemo Research/DNDi/Mundo Sano	Chagas disease	August 2017
betrixaban	Bevyxxa™	Portola	Prophylaxis of venous thromboembolism	July 2017

*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*
celecoxib/amlodipine	Consensi™	Kitov Pharma	Osteoarthritis pain/hypertension	May 2018
vaginal estradiol	Imvexxy™	TherapeuticsMD	Menopause symptoms	May 2018
polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution	Plenvu®	Norgine	Osmotic laxative	May 2018
efavirenz, lamivudine, tenofovir disoproxil fumarate	Symfi™	Mylan	HIV	April 2018
efavirenz, lamivudine, tenofovir disoproxil fumarate	Symfi Lo™	Mylan	HIV	March 2018
lamivudine, tenofovir disoproxil fumarate	Cimduo™	Mylan	HIV	March 2018
lidocaine topical system 1.8%	ZTlido™	Sorrento Therapeutics	Pain associated with post-herpetic neuralgia (PHN)	March 2018
amantadine extended release	Osmolex ER™	Osmotica Pharmaceutical	Parkinson's disease and drug-induced extrapyramidal symptoms	February 2018
ertugliflozin/metformin	Segluromet™	Merck/Pfizer	Diabetes	December 2017
ertugliflozin/sitagliptin	Steglujan™	Merck/Pfizer	Diabetes	December 2017
mometasone furoate	Sinuva™	Intersect ENT, Inc	Recurrent nasal polyps	December 2017
glycopyrrolate	Lonhala™ Magnair™	Sunovion Pharmaceuticals	COPD	December 2017
dolutegravir/rilpivirine	Juluca™	Viiiv Healthcare	HIV-1 infection	December 2017
sodium hyaluronate	TriVisc™	OrthogenRx, Inc	Osteoarthritis	November 2017
aprepitant	Cinvanti™	Heron Therapeutics	Chemotherapy-induced nausea and vomiting	November 2017
aripiprazole with sensor	Abilify® MyCite™	Otsuka	Drug-device combo for schizophrenia, bipolar disorder and major depression	November 2017
latanoprostene bunod	Vyzulta®	Valeant Pharmaceuticals	Glaucoma or ocular hypertension	November 2017
pregabalin extended release	Lyrica® CR	Pfizer	Neuropathic pain	October 2017
rolapitant	Varubi™	Tesara/Opko Health	Chemotherapy-induced nausea and vomiting	October 2017
exenatide extended-release	Bydureon® BCise™	AstraZeneca	Diabetes	October 2017
insulin aspart	FIAsp™	Novo Nordisk	Diabetes	October 2017
fluticasone propionate nasal spray	Xhance™	Optinose US, Inc.	Nasal polyps	October 2017
fluticasone furoate, umeclidinium, vilanterol	Trelegy™ Ellipta®	GSK/Innoviva	COPD	September 2017
amphetamine extended release suspension	Adzenys™ ER	Neos Therapeutics	ADHD	September 2017
spironolactone suspension	CaroSpir™	CMP Pharma	Cardiovascular	August 2017

Other new product approvals in the past 12 months (continued)

Generic name	Brand name	Manufacturer	Indication(s)	Date approved*
insulin lispro	Admelog®	Sanofi	Diabetes	September 2017 (full approval December 2017)
lesinurad/allopurinol	Duzallo™	Ironwood Pharmaceuticals	Uncontrolled gout	August 2017
pitavastatin sodium	Nikita™	Lupin	High cholesterol	August 2017
beclomethasone dipropionate	Qvar® RediHaler™	Teva	Asthma	August 2017
insulin glargine	Lusduna® Nexvue™	Merck	Diabetes	August 2017
methylphenidate extended-release orally disintegrating tablets	Cotempla™ XR-ODT	Neos Therapeutics	ADHD	July 2017
mixed salts of a single-entity amphetamine products	Mydayis™	Shire	ADHD	July 2017
pitavastatin	Zypitamag™	Zydus	High cholesterol	July 2017

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

Pipeline watch

Generic Name	Brand Name	Manufacturer	Indication(s)	Anticipated FDA Decision Date
plazomicin	N/A	Achaogen	Bacterial infection	June 2018
tafenoquine	N/A	60 Degrees Pharmaceuticals and USMMDA	Prevention of malaria	June 2018
glycopyrronium tosylate	N/A	Dermira	Excessive sweating	June 2018
aripiprazole lauroxil NanoCrystal Dispersion (ALNCD)	N/A	Alkermes	Schizophrenia, bipolar disorder and major depression	June 2018
risperidone SC	N/A	Indivior	Schizophrenia	July 2018
buprenorphine SL spray	Buvaya™	Insys Therapeutics	Acute pain	July 2018
tafenoquine	N/A	GSK/Medicines for Malaria Venture	Radical cure of Plasmodium vivax malaria	July 2018
elagolix	N/A	Abbvie Inc./ Neurocrine Biosciences	Pain associated with endometriosis	August 2018
cyclosporine A ophthalmic solution	N/A	Sun Pharma	Dry eye disease	August 2018
oxycodone, controlled-release	Remoxy ER™	Pain Therapeutics and Durect	Pain, abuse deterrent	August 2018
tecovirimat	Tpoxx™	Siga Technologies	Smallpox	August 2018
ulipristal acetate	Esmya™	Allergan	Abnormal bleeding with uterine fibroids	August 2018
loteprednol etabonate	Inveltys™	Kala Pharmaceuticals	Inflammation/pain with ocular surgery	August 2018

Pipeline watch (continued)

Generic Name	Brand Name	Manufacturer	Indication(s)	Anticipated FDA Decision Date
tretinoin lotion	Altreno™	Ortho Dermatologics (Valeant)	Acne	August 2018
eravacycline	N/A	Tetraphase Pharma	Infection	August 2018
dasotraline	N/A	Sunovion	ADHD	August 2018
clobazam OSF	N/A	Aquestive Therapeutics	Lennox-Gastaut syndrome	September 2018
amikacin liposome inhalation suspension	ALIS	Insmed Inc	NTM lung disease caused by MAC	September 2018
testosterone enanthate auto-injector	Xyosted QuickShot™	Antares Pharmaceuticals	Testosterone replacement therapy	September 2018
omadacycline	N/A	Paratek	Pneumonia and skin infections	October 2018
sarecycline	Seysara™	Allergan/Paratek	Acne	October 2018
levodopa inhalation powder	Inbrija™	Acorda Therapeutics	Off symptoms of Parkinson's disease	August 2018
halobetasol lotion	Jemdel™	Ortho Dermatologics	Plaque psoriasis	October 2018
doravirine, lamivudine, tenofovir disoproxil fumarate	N/A	Merck	HIV	October 2018
doravirine	N/A	Merck	HIV	October 2018
estradiol and progesterone	N/A	TherapeuticsMD	Menopause	October 2018
segestrone/ethinyl estradiol	Nesterone	Population Council	Pregnancy prevention	November 2018
rifamycin SV MMX	Aemcolo™	Cosmo Pharmaceuticals	Travelers' diarrhea	November 2018
revefenacin	N/A	Mylan/Theravance Biopharma	COPD	November 2018
brexanolone	N/A	Sage Therapeutics	Postpartum depression	December 2018
solriamfetol	N/A	Jazz Pharmaceuticals	Excessive sleepiness with narcolepsy or obstructive sleep apnea	December 2018
prucalopride	N/A	Shire	Chronic idiopathic constipation	December 2018

First generic approvals of top selling brand name drugs in the past twelve months

Generic name	Brand name	Manufacturer	Indication(s)	Date approved*
buprenorphine/naloxone sublingual film, 8 mg – 2 mg	Suboxone®	Indivior	Opioid dependence	June 2018
colesevelam hydrochloride	Welchol®	Sankyo	High cholesterol and type 2 DM	May 2018
memantine ER	Namenda® XR	Allergan	Alzheimer's disease	March 2018
estradiol vaginal cream	Estrace®	Allergan	Menopause symptoms	January 2017
tenofovir disoproxil fumarate, 300 mg	Viread® 300 mg	Teva	HIV	December 2017
sildenafil citrate	Viagra®	Pfizer	Erectile dysfunction	December 2017
glatiramer acetate	Copaxone®	Teva Neuroscience	Multiple sclerosis	October 2017
prasugrel	Effient®	Eli Lilly/ Daiichi Sankyo	Reduction of CV events	August 2017
eletriptan	Relpax®	Pfizer	Migraine	August 2017
mesalamine delayed release	Lialda®	Zydus	Ulcerative colitis	August 2017
moxifloxacin ophthalmic solution	Vigamox®	Apotex	Eye infection	July 2017
testosterone topical transdermal solution	Axiron®	Lilly	Testosterone replacement	July 2017

*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.

Other first generic launches in the past twelve months

Generic name	Brand name	Manufacturer	Indication(s)	Date approved*
doxycycline hyclate	Targadox®	Journey Medical	Bacterial infection	May 2018
praziquantel	Biltricide®	Bayer Healthcare	Infection	May 2018
miglustat	Zavesca®	Actelion	Gaucher disease	May 2018
clozapine orally disintegrating tablet	Fazaclo® ODT	Teva	Schizophrenia	April 2018
cyclophosphamide	Cyclophosphamide®	Amerigen	Malignant diseases	April 2018
drosiprone/ethinyl estradiol/levomefolate	Safyral®	West-Ward	HIV	April 2018
ritonavir tablets	Norvir®	AbbVie	HIV	April 2018
tiagabine 12 mg, 16 mg	Gabitril®	Cephalon	Seizures	March 2018
methylphenidate, 10 mg capsule	Ritalin LA®	Novartis	ADHD	March 2018
minocycline ER	Solodyn®	Valeant	Acne	March 2018
sumatriptan/naproxen 85 mg – 500 mg	Treximet®	Aurobindo Pharma	Migraine	February 2018
hydrocortisone butyrate	Locoid® Lotion	Valeant	Atopic dermatitis	February 2018

continued

Other first generic launches in the past twelve months (*continued*)

Generic name	Brand name	Manufacturer	Indication(s)	Date approved*
trientine	Syprine®	Valeant	Wilson's disease	February 2018
efavirenz 600 mg	Sustiva®	BMS	HIV	February 2018
atazanavir	Reyataz®	BMS	HIV	January 2018
carbinoxamine maleate	Palgic®	Alfasigma USA	Allergies and cold	January 2018
efavirenz, 50 mg and 200 mg	Sustiva®	BMS	HIV	January 2018
timolol maleate ophth solution	Istalol®	Valeant	Glaucoma	December 2017
pramoxine/hydrocortisone	Novacort® gel 1–2%	Novum Pharma	Skin irritation	December 2017
fluoxetine tab, 60 mg	Fluoxetine®	Almatica	Major depressive disorder, obsessive compulsive disorder, bulimia nervosa, panic disorder	November 2017
dapsone gel, 5%	Aczone®	Allergan	Acne	November 2017
oseltamivir suspension	Tamiflu®	Genentech	Influenza	November 2017
carvedilol ER	Coreg® CR	GSK	Cardiovascular	November 2017
testosterone gel	Testim® 1%	Endo Pharmaceuticals	Testosterone replacement	October 2017
abacavir solution	Ziagen®	Viiv Healthcare	HIV	October 2017
sodium phenylbutyrate	Buphenyl®	Horizon Pharma	Urea cycle disorders	October 2017
paroxetine mesylate	Brisdelle®	Sebela Pharmaceuticals	VMS with menopause	October 2017
fosamprenavir	Lexiva®	Viiv Healthcare	HIV	October 2017
adapalene/benzoyl peroxide	Epiduo®	Galderma	Acne	August 2017
scopolamine	Transderm-Scop®	Sandoz, Baxter Healthcare, Glaxo Consumer Healthcare	Motion sickness	August 2017
sevelamer carbonate	Renvela®	Genzyme	Control serum phosphorus	August 2017
melphalan	Alkeran®	Apo Pharma	Multiple myeloma/epithelial carcinoma of the ovary	July 2017

*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.

Generics of top selling brand drugs potentially available soon

Generic name	Brand name	Manufacturer	Indication(s)	To market date*
cinacalcet	Sensipar®	Amgen	Hyperparathyroidism	2Q2018
cyclosporine	Restasis®	Allergan	Dry eye	2Q2018
tenofovir disoproxil fumarate 150 mg, 200 mg, 250 mg	Viread®	Gilead	HIV/HBV	1H2018
hydroxyprogesterone caproate	Makena® (vial)	AMAG Pharmaceuticals	Reduce the risk of preterm birth	1H2018
tadalafil	Adcirca®	Eli Lilly	Pulmonary arterial hypertension (PAH)	June 2018
treprostinil	Remodulin®	United Therapeutics	PAH	June 2018
ambrisentan	Letairis	Gilead	Pulmonary arterial hypertension	July 2018
dalfampridine	Ampyra	Acorda	Multiple sclerosis	July 2018
ascorbic acid; PEG; potassium chloride; sodium ascorbate; sodium chloride; sodium sulfate	Moviprep®	Salix Valeant	Osmotic laxative	September 2018
tadalafil	Cialis®	Eli Lilly	Erectile dysfunction	September 2018
vardenafil	Levitra®	Bayer	Erectile dysfunction	October 2018
clobazam	Onfi	H. Lundbeck A/S	Seizures	October 2018
abiraterone	Zytiga	Janssen	Prostate cancer	October 2018
epinephrine	Auvi-Q	Kaleo Pharma	Anaphylaxis	November 2018
silodosin	Rapaflo	Allergan	Benign prostatic hyperplasia	December 2018
mesalamine	Canasa	Forest/Allergan	Ulcerative colitis	December 2018
pimecrolimus	Elidel	Valeant	Atopic dermatitis	December 2018
ethinyl estradiol/etonogestrel	NuvaRing®	Organon/Merck & Co	Pregnancy prevention	2018
exenatide	Byetta®	AstraZeneca	Diabetes	2018
testosterone	AndroGel® (1.62%)	AbbVie	Testosterone replacement	2018
loteprednol	Lotemax®	Bausch + Lomb/ Valeant	Eye inflammation	2018
difluprednate	Durezol®	Alcon/Novartis	Eye inflammation	2018
ganirelix acetate	Ganirelix®	Organon/Merck & Co	Infertility	2018
epinephrine	EpiPen®	Merck	Anaphylaxis	2018
albuterol sulfate	Proventil® HFA/ ProAir® HFA	Merck/Teva	Asthma/COPD	2018 – 2019
fluticasone/salmeterol	Advair® Diskus	GSK	Asthma/COPD	2018 – 2019

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

References

1. <https://www.fiercepharma.com/dr-reddy-s-forced-to-stop-suboxone-generic-rollout-amid-indivior-patent-dispute>

All brand names are property of their respective owners.