

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

September 2021

NEW DRUG INFORMATION

- **Korsuva™ (difelikefalin):** The U.S. Food and Drug Administration (FDA) has approved Cara Therapeutics and Vifor Pharma's Korsuva for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. Korsuva is a first-in-class kappa opioid receptor (KOR) agonist that targets the body's peripheral nervous system. Korsuva is administered as an injection into the venous line of a dialysis circuit at the end of each hemodialysis treatment. Korsuva's approval was based on two Phase 3 clinical trials, KALM-1 and KALM-2. KALM-1 demonstrated a statistically significant three-point or greater improvement from baseline in the weekly mean of the daily 24-hour Worst Itching Intensity Numeric Rating Scale (WI-NRS) score at week 12 compared to placebo (51% vs. 28%). KALM-2 achieved a three-point or greater improvement from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 12 (54% vs. 42%) for patients on placebo.¹ Korsuva will launch first quarter of 2022 with a wholesale acquisition cost (WAC) of \$17,000 annually.
- **Invega Hafyera™ (paliperidone palmitate):** The FDA has approved Janssen's long-acting atypical antipsychotic Invega Hafyera, a twice-yearly injectable for the treatment of schizophrenia in adults. Before transitioning to Invega Hafyera, patients must be adequately treated with Invega Sustenna, a one-month paliperidone palmitate injection, for at least four months, or Invega Trinza, a three-month paliperidone palmitate, for at least one three-month injection cycle. The FDA approval of Invega Hafyera is based on the non-inferiority Phase 3 global trial that demonstrated non-inferiority of Invega Hafyera compared to Invega Trinza on the primary endpoint of time to first relapse at the end of the 12-month period. Results found that 92.5% of patients treated with Invega Hafyera and 95% treated with Invega Trinza were relapse-free at 12 months.² Invega Hafyera has launched with an average wholesale price (AWP) of either \$14,112 or \$21,168 per syringe depending on dose.

GENERIC DRUG INFORMATION

- **Sutent®⁺ (sunitinib malate):** Sun launched their generic version of CPPI CV's Sutent for gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate, advanced renal cell carcinoma and progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease. Sutent generated \$254 million in U.S. annual sales in 2020.
- **Epaned® (enalapril oral soln, 1 mg/mL):** Bionpharma launched their generic version of Azurity Pharmaceuticals' Epaned for the treatment of treatment of hypertension in adults and children older than one month, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Also, the treatment of symptomatic heart failure and of asymptomatic left ventricular dysfunction, to decrease the rate of development of overt heart failure and reduce hospitalization for heart failure. Multiple manufacturers are expected to launch their generic versions in 2022. Epaned generated \$43 million in U.S. annual sales in 2020.
- **Bystolic® (nebivolol hydrochloride):** Multiple manufactures have launched their generic version of Allergan's Bystolic for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Bystolic generated \$1.154 billion in U.S. annual sales in 2020.
- **Durezol® (difluprednate ophth emulsion, 0.05%):** Cipla launched their generic version of Novartis' Durezol for the treatment of inflammation and pain associated with ocular surgery. Durezol generated \$111 million in U.S. annual sales in 2020.
- **Chantix® (varenicline tablet 0.5mg, 1mg):** Par has launched their generic version of Pfizer's Chantix for use as an aid to smoking cessation treatment. Multiple manufacturers are set to launch later this year. Chantix generated \$1.189 billion 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*
difelikefalin	Korsuva®	Cara Therapeutics	Chronic kidney disease-associated pruritis (CKD-aP) in hemodialysis patients	August 2021
fexinidazole	N/A	Sanofi	Trypanosoma brucei gambiense form of sleeping sickness	July 2021
finerenone	Kerendia®	Bayer	Chronic kidney disease (CKD) and type 2 diabetes	July 2021
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 dexmethylphenidate	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

*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*
paliperidone palmitate extended-release injectable suspension	Invega Hafyera®	Janssen Pharmaceuticals, Inc.	Schizophrenia	September 2021
dihydroergotamine mesylate, DHE	Trudhesa®	Impel Neuropharma	Migraine	September 2021
benzoyl peroxide and tretinoin	Twynéo®	Sol-Gel Technologies	Acne vulgaris	July 2021
torsemide	Soaanz®	Sarfez Pharmaceuticals	Edema caused by heart failure	June 2021
cyclosporine ophthalmic emulsion	Verkazia™	Santen	Vernal keratoconjunctivitis	June 2021
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

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PIPELINE WATCH

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED
daxibotulinumtoxinA	N/A	Revance Therapeutics	Frown lines	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
AXS-05 (dextromethorphan and bupropion)	N/A	Axsome Therapeutics	Major depressive disorder	Delayed
cantharidin 0.7% topical solution	Ycanth®	Verrica Pharmaceuticals	Molluscum contagiosum	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
ET-101 (topiramate oral solution)	N/A	Azurity Pharmaceuticals	Seizures	November 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
buprenorphine depot, formerly CAM2038	Brixadi™	Braeburn Pharmaceutical	Opioid use disorder	December 2021
diazepam buccal film	Libervant™	Aquestive Therapeutics	Seizures	December 2021
DARE-BV1 (clindamycin 2% hydrogel)	N/A	Daré Bioscience	Bacterial vaginosis	December 2021
BXCL501 (dexmedetomidine orally dissolving film)	N/A	BioXcel Therapeutics	Schizophrenia and bipolar disorders	January 2022
daridorexant	N/A	Idorsia	Insomnia	January 2022
oteseconazole (VT-1161)	N/A	Mycovia Pharmaceuticals	Vulvovaginal candidiasis	January 2022
letibotulinumtoxinA	N/A	Hugel America	Frown lines	March 2022
gefapixant	N/A	Merck	Chronic cough	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*
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
tolvaptan ⁺	Samsca®	Otsuka America	Hypervolemic hyponatremia	May 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*
enalapril oral soln, 1 mg/mL	Epaned®	Azurity Pharmaceuticals	Heart failure, hypertension	August 2021
atropine prefilled syringe inj, 0.25 mg/5 mL (0.05 mg/mL)	N/A	Hospira	Temporary blockade of severe or life-threatening muscarinic effects	August 2021
argatroban	Argatroban®	Hikma	Heparin-induced thrombocytopenia (HIT)	July 2021
etravirine	Intelence®	Janssen	HIV	June 2021
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
emtricitabine; tenofovir disoproxil fumarate	Truvada® (100mg /150mg, 133mg /200mg, 167mg /250mg)	Gilead	HIV	January 2021
levorphanol tab, 3mg	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, 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
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

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GENERICS OF TOP SELLING BRAND DRUGS POTENTIALLY AVAILABLE SOON

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	DATE APPROVED*
propranolol hydrochloride	InnoPran® XL	ANI Pharmaceuticals Akrimax Pharmaceuticals	Hypertension	10/04/2021
adapalene; benzoyl peroxide	Epiduo Forte®	Galderma	Acne vulgaris	2H 2021
cabazitaxel ⁺	Jevtana Kit®	Sanofi	Prostate cancer	2H 2021
exenatide synthetic	Byetta®	AstraZeneca	Diabetes mellitus	2021
glycopyrrolate	Cuvposa®	Merz	Cerebral palsy	2021
roflumilast	Daliresp®	AstraZeneca	Chronic obstructive pulmonary disease (COPD)	2021
aprepitant	Emend® (for oral suspension)	Merck & Co	Nausea/vomiting	2021
teriparatide recombinant human ⁺	Forteo®	Eli Lilly	Osteoporosis	2021
ritonavir	Norvir® (capsules)	AbbVie	HIV	2021
posaconazole	Noxafil® (oral suspension)	Merck & Co	Fungal infection	2021
unoprostone isopropyl	Rescula®	Sucampo R-Tech Ueno	Glaucoma or ocular hypertension	2021
octreotide acetate ⁺	Sandostatin® LAR	Novartis	Endocrine gland disease	2021
fesoterodine fumarate	Toviaz®	Pfizer	Overactive bladder	2021
benzyl alcohol	Ulesfia®	Concordia Shionogi	Infectious and parasitic diseases	2021
everolimus ⁺	Afinitor® (10mg)	Novartis	Kidney cancer	2021 – 2022
everolimus ⁺	Afinitor® Disperz	Novartis	Certain forms of cancer	2021 – 2022
ethinyl estradiol; levonorgestrel	Balcoltra®	Avion Pharmaceuticals Albion International	Pregnancy prevention	2021 – 2022
enalapril maleate	Epaned® KIT	Silergate	Hypertension	2021 – 2022
fluticasone furoate	Flonase® Sensimist Allergy Relief	GSK	Allergic rhinitis	2021 – 2022
naloxone hydrochloride	Narcan® (nasal spray)	Adapt Pharma Emergent BioSolutions Opiant	Opioid overdose	2021 – 2022
rotigotine	Neupro®	UCB	Parkinson's disease	2021 – 2022

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

⁺ Specialty medication

REFERENCES

- <https://www.globenewswire.com/news-release/2021/08/23/2285085/0/en/Cara-Therapeutics-and-Vifor-Pharma-announce-U-S-FDA-approval-of-KORSUVA-difelikefalin-injection-for-the-treatment-of-moderate-to-severe-pruritus-in-hemodialysis-patients.html>.
- <https://www.jnj.com/janssen-announces-u-s-fda-approval-of-invega-hafyera-6-month-paliperidone-palmitate-first-and-only-twice-yearly-treatment-for-adults-with-schizophrenia>.

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