

PIPELINE REPORT

Brand Drugs

February 2019



PIPELINE DRUG	CURRENT STATUS	ANTICIPATED APPROVAL	WHAT IS THIS DRUG BEING DEVELOPED FOR?
apomorphine (Sunovion)	NDA Filed	1/29/2019	A dopamine agonist indicated for the on-demand management of OFF episodes associated with Parkinson's disease (PD); this novel formulation is being developed as a fast-acting sublingual film (SL) dosed up to five times throughout the day.
bempedoic acid (ETC-1002- Esperion)	Phase 3	2020	This dual acting ATP citrate lyase inhibitor and 5'-adenosine monophosphate-activated protein kinase activator is in development for the treatment of hyperlipidemia in patients who cannot tolerate statins. Dosing is once daily; oral
budesonide/formoterol/ glycopyrronium (Pearl Triple - AstraZeneca)	Phase 3	2019	Triple combination inhalation therapy for the treatment of chronic obstructive pulmonary disease (COPD); contains glycopyrronium; a long-acting muscarinic antagonist (LAMA), budesonide (corticosteroid) and formoterol; a long-acting beta agonist (LABA);
bupivacaine/meloxicam (Heron)	NDA Filed	4/30/2019 Priority Review	Combination of a long-acting extended-release formulation of bupivacaine and meloxicam; a nonsteroidal, anti-inflammatory drug (NSAID) being developed for postsurgical local anesthesia; injectable Breakthrough Therapy
buprenorphine/ samidorphan (ALKS 5461- Alkermes)	NDA Filed	1/31/2019 Priority Review	A combination of a non-addictive opioid modulator and buprenorphine for treating major depressive disorder in patients who have had an inadequate response to standard therapies: sublingual (SL) tablet
buprenorphine depot injection (CAM 2038- Braeburn)	NDA Filed	12/26/2018 Priority Review	Weekly and monthly buprenorphine subcutaneous injections for the treatment of opioid addiction; using proprietary FluidCrystal® injection depot technology SC injections
diazepam nasal spray (Valtoco - Neurelis)	NDA Filed	7/28/2019	Proprietary nasal formulation of diazepam for the treatment of epilepsy in patients six years and older who experience increased bouts of seizure activity; intranasal Orphan Drug
fexapotide trifluate (NX-1207 - Nymox)	NDA Filed	2/5/2019	An antineoplastic treatment for benign prostatic hyperplasia (BPH). This drug acts through neural thread proteins which kills cells treating malignant and benign tumors, including BPH; intraprostatic injection
glucagon ready-to-use (MyGluca-Xeris)	NDA Filed	6/10/2019	A ready to use injectable formulation of glucagon for the treatment of hyperinsulinemic hypoglycemia; eliminating the need for reconstitution, long-term room-temperature stability; autoinjector
insulin glargine (Semglee - Mylan/ Biocon)	Complete Response	2019	Follow-on insulin glargine product that will be a brand competitor to Lantus (NOT a biosimilar); SC therapy

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lasmiditan (Lilly)	NDA Filed	11/14/2019	A serotonin 1F receptor agonist for the treatment of migraine headaches; also known as 'ditans' and will be an oral formulation
levodopa inhalation powder (Inbrija - Acorda)	NDA Filed	1/5/2019	A self-administered, orally inhaled levodopa (L-dopa) therapy in development for treatment of symptoms of OFF periods in people with Parkinson's disease currently taking a carbidopa/levodopa regimen
lumateperone (ITI-007- Intracellular Therapies)	NDA Filed	5/27/2019	A combination of serotonin 5-HT2A receptor antagonist, dopamine receptor phosphoprotein modulator (DPPM), glutamatergic modulator and serotonin reuptake inhibitor for the treatment of schizophrenia; oral therapy
metoclopramide intranasal (Gimoti - Evoke Pharma)	NDA Filed	4/1/2019	Intranasal formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women with diabetes mellitus; intranasal therapy
prucalopride (Motegrity - Shire)	NDA Filed	12/17/2018 APPROVED	A 5-HT4 receptor antagonist, prokinetic agent that stimulates colonic peristalsis for the treatment of chronic idiopathic constipation (CIC) in adults; once daily oral therapy
semaglutide (Novo Nordisk)	Phase 3	2020	A GLP-analog in development for treatment of diabetes mellitus type II in adult patients; oral therapy (would be the first oral GLP-1 therapy approved for type II DM)
solriamfetol (JZP-110 - Jazz Pharmaceuticals)	NDA Filed	12/20/2018	A dopamine and norepinephrine reuptake inhibitor (DNRI) for the treatment of excessive sleepiness in adults patients with narcolepsy or obstructive sleep apnea (OSA); oral therapy
sotagliflozin (Zynquista - Lexicon/Sanofi)	NDA Filed	3/22/2019	Dual sodium-glucose linked-transporter (SGLT-1 and SGLT-2) inhibitor for use in combination with insulin therapy to improve glycemic control in adults with type I diabetes mellitus (DM); this would be the first oral therapy for the treatment of type I DM
ubrogepant (Allergan)	Phase 3	2020	A small molecule calcitonin gene-related peptide (CGRP) antagonist for the acute treatment of migraine headaches; oral therapy
Viaskin peanut (DBV Technologies)	BLA Filed	6/22/2019 Priority Review	Epicutaneous immunotherapy (EPIT) that delivers small amounts of peanut protein to help desensitize patients to this protein and to help avoid potentially life-threatening allergic reactions in children ages 4 to 11 years old; transdermal patch