

PIPELINE REPORT

Brand Drugs

July 2019



Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
bempedoic acid (ETC-1002-Esperion)	NDA Filed	February 2020	Treatment for hyperlipidemia in patients that cannot tolerate statins. This drug targets inhibition of ATP citrate lyase (ACL), a key enzyme in the cholesterol biosynthetic pathway, and activates a complementary enzyme, 5'-adenosine monophosphate-activated protein kinase (AMPK); oral
budesonide/ formoterol / glycopyrronium (Pearl Triple-AstraZeneca)	NDA Filed	3Q 2019	Combination of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), formoterol fumarate, a long-acting beta-2 agonist (LABA), and an inhaled corticosteroid (ICS) delivered via a single metered-dose hydrofluoroalkane (HFA) inhaler.
diazepam nasal spray (Valtoco-Neurelis)	NDA Filed	July 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.
glucagon intranasal (Lilly)	NDA Filed	October 2019	Intranasal powder formulation of glucagon for the treatment for severe hypoglycemia in people with diabetes treated with insulin; intranasal.
glucagon, ready-to-use (GvokeHypoPen-Xeris)	NDA Filed	September 2019	Treatment of hyperinsulinemic hypoglycemia; ready-to-use injectable formulation.
insulin glargine (Semglee-Mylan/Biocon)	Complete Response	2019	Follow-on insulin glargine product. It will be a brand competitor to Lantus (not a biosimilar); subcutaneous
lasmiditan (Lilly)	NDA Filed	November 2019	Serotonin 1F receptor agonists, also known as "ditans", for the treatment of migraine headaches; oral
lefamulin (Nabriva Therapeutics)	NDA Filed	August 2019	Pleuromutilin antibiotic for the treatment of community acquired bacterial pneumonia; oral.
lemborexant (Eisai)	NDA Filed	December 2019	Lemborexant is a dual orexin receptor antagonist (orexin receptor 1 and 2) for treatment of patients with insomnia. The orexin system is thought to regulate sleep and wakefulness; oral
loxicodegol (Nektar Therapeutics)	NDA Filed	August 2019	Long-acting, selective full mu-opioid agonist for the treatment of chronic low back pain in adult patients new to opioid therapy; oral.

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lumateperone (Intra-Cellular Therapies)	NDA Filed	September 2019	The drug combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation, glutamatergic modulation, and serotonin reuptake inhibition for the treatment of schizophrenia; oral
mometasone/ olopatadine (Ryaltris- Glenmark)	NDA Filed	June 2019	Fixed-dose combination of mometasone furoate(25mcg) and olopatadine (665mcg) for the treatment of seasonal and perennial allergic rhinitis in patients 12 years of age and older; intranasal spray.
naloxone injection (Adamis)	NDA Filed	October 2019	Higher dose of naloxone, an opioid antagonist, formulated in a prefilled syringe for injection to treat an opioid overdose; intramuscular injection.
peanut allergen oral immunotherapy (ARI01-Aimmune Therapeutics)	NDA Filed	January 2020	Oral immunotherapy (OIT) for the management of children and adolescents (ages 4-17 years) with severe peanut allergies; oral
pitolisant (Harmony)	NDA Filed	August 2019	Selective histamine H3-receptor antagonist/inverse agonist for the treatment of adult patients with narcolepsy with or without cataplexy; oral.
riluzole sublingual (Exservan- Aquestive)	NDA Filed	November 2019	Oral soluble film formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS); oral
semaglutide,oral (Novo Nordisk)	NDA Filed	September 2019	Oral formulation of Ozempic (semaglutide), a GLP-1 analog for the treatment of patients with type 2 diabetes; oral
tenapanor (Ardelyx)	NDA Filed	September 2019	NHE3 inhibitor for the treatment of patients with irritable bowel syndrome with constipation (IBS-C); oral
ubrogepant (Allergan)	NDA Filed	4Q 2019	An oral small molecule CGRP antagonists for the acute treatment of migraine headaches; oral
viaskin peanut (DBV Technologies)	Phase 3	2020	Transdermal system (patch) that delivers small amounts of peanut protein to help desensitize patients to this protein to help avoid potentially life-threatening allergic reactions in children 4-11 years old; transdermal patch.