

Top 20 Traditional Pipeline Report December 2018

Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
1. apomorphine sublingual film (Sunovion)	NDA Filed	1/29/2019	Apomorphine sublingual film to treat motor fluctuations (OFF episodes) experienced by people living with Parkinson's disease (PD); sublingual film.
2. bempedoic acid (ETC-1002 - Esperion)	Phase 3	2020	bempedoic acid is under development for treating 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 therapy
3. budesonide/ formoterol/ glycopyrronium (Pearl Triple - AstraZeneca)	Phase 3	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
4. bupivacaine/ meloxicam (Heron)	NDA Filed	4/30/2019 Priority Review	Combination of a long-acting extended-release formulation of bupivacaine and the anti-inflammatory drug meloxicam for postsurgical local analgesia; injectable. Breakthrough Therapy
5. buprenorphine / samidorphan (ALKS 5461 - Alkermes)	NDA Filed	1/31/2019 Priority Review	The 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 tablet.
6. buprenorphine depot injection (CAM2038- Braeburn)	NDA Filed	12/26/2018 Priority Review	Weekly and monthly buprenorphine subcutaneous injection products for the treatment of opioid addiction.
7. diazepam nasal spray (Valtoco - Neurelis)	NDA Filed	7/28/2019	Proprietary nasal formulation of diazepam for the treatment for epilepsy in patients six years and older who experience increased bouts of seizure activity; intranasal. Orphan Drug

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8. fexapotide trifluate (NX-1207 - Nymox)	NDA Filed	2/5/2019	An antineoplastic treatment for benign prostatic hyperplasia. The drug acts through neural thread proteins which kills cells treating malignant and benign tumors, including BPH; intraprostatic injection.
9. glucagon ready-to-use (MyGluca - Xeris)	NDA Filed	6/10/2019	Treatment of Hyperinsulinemic Hypoglycemia; ready-to-use IV formulation.
10. insulin glargine (Semglee - Mylan/Biocon)	Complete Response	2019	Follow-on insulin glargine product. It will be a brand competitor to Lantus (not a biosimilar); SQ therapy.
11. lasmiditan (Lilly)	NDA Filed	11/14/2019	Serotonin 1F receptor agonists, also known as "ditans", for the treatment of Migraine Headaches; oral therapy.
12. levodopa inhalation powder (Inbrija - Acorda)	NDA Filed	1/5/2019	Inbrija is a self-administered, orally inhaled levodopa (L-dopa) therapy indicated for symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen; inhalation therapy.
13. lumateperone (ITI-007 - Intra-Cellular Therapies)	NDA Filed	5/27/2019	The drug combines potent serotonin 5-HT _{2A} receptor antagonism, dopamine receptor phosphoprotein modulation, glutamatergic modulation, and serotonin reuptake inhibition for the treatment of schizophrenia; oral therapy
14. 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.
15. prucalopride (Motegrity - Shire)	NDA Filed	12/21/2018	A 5-HT ₄ receptor agonism is a gastrointestinal prokinetic agent that stimulates colonic peristalsis, for the once-daily treatment of chronic idiopathic constipation (CIC) in adults; oral therapy

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16. semaglutide, oral (Novo Nordisk)	Phase 3	2020	orally administered GLP-1 analog
17. solriamfetol (JZP-110 - Jazz Pharmaceuticals)	NDA Filed	12/20/2018	Dopamine and norepinephrine reuptake inhibitor (DNRI) for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA); oral
18. sotagliflozin (Zynquista - Lexicon / Sanofi)	NDA Filed	3/22/2019	A dual SGLT1 and SGLT2 inhibitor for use in combination with insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus; oral therapy.
19. ubrogepant (Allergan)	Phase 3	2020	An oral small molecule CGRP antagonists for the acute treatment of migraine headaches; oral therapy.
20. Viaskin peanut (DBV Technologies)	BLA Filed	6/22/2019 Priority Review	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.