

Top 20 Traditional Pipeline Report July 2018

Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
1. bempedoic acid (ETC-1002 - Esperion)	Phase 3	2019	ETC-1003 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
2. bremelanotide (Rekynda - Palatin Technologies)	NDA Filed	3/23/2019	Melanocortin 4 receptor agonist for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women; subcutaneous injection with a pre-filled autoinjector pen.
3. buprenorphine SL spray (Insys)	NDA Filed	7/28/2018	Novel formulation of buprenorphine (sublingual spray) for the management of moderate-to-severe acute pain; sublingual spray.
4. cyclosporine A ophthalmic soln (OTX- 101 - Sun)	NDA Filed	8/27/2018	A novel nanomicellar formulation of cyclosporine A 0.09% ophthalmic solution for treating dry eyes syndrome; ophthalmic therapy.
5. dasotraline (Sunovion)	NDA Filed	8/31/2018	Dual dopamine and norepinephrine reuptake inhibitor (DNRI) for treating attention deficit hyperactivity disorder (ADHD); oral therapy.
6. elagolix (ABT-620 - AbbVie/Neurocrine)	NDA Filed	8/6/2018 Priority Review	Oral, non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist for treating endometriosis-associated pain; oral therapy
7. fexapotide (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.

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8. fremanezumab (Teva)	BLA Filed	9/16/2018 Priority Review	Anti-CGRP mAb for the prevention of chronic and high frequency episodic migraines; subcutaneous therapy.
9. galcanezumab (Lilly)	BLA Filed	10/11/2018	A once-monthly, subcutaneously administered monoclonal antibody that neutralizes calcitonin gene-related peptide (CGRP) for the prophylaxis of migraine headaches; subcutaneous injection.
10. glycopyrronium tosylate (DRM04 - Dermira)	NDA Filed	6/30/2018	Topical anticholinergic product for treatment of severe hyperhidrosis; topical therapy
11. insulin glargine (Lusduna Nexvue - Merck / Samsung Bioepis)	Tentative Approval	Mid 2019	Follow-on insulin glargine product. It will be a brand competitor to Lantus (not a biosimilar); SQ therapy.
12. insulin glargine (Semglee - Mylan/Biocon)	Complete Response	2019	biosimilar to Lantus; SQ therapy
13. lasmiditan (Lilly)	Phase 3	2019	Serotonin 1F receptor agonists, also known as "ditans", for the treatment of Migraine Headaches; oral therapy.
14. oxycodone, extended-release (Remoxy - Pain Therapeutics)	NDA Filed	8/7/2018 Priority Review	Abuse-resistant long-acting (twice daily) oral formulation of oxycodone for round-the-clock treatment of persistent pain. When crushed, the Remoxy gel-cap yields a viscous gel presumably too thick to snort or inject; oral therapy.
15. prucalopride (Resolor - Shire)	NDA Filed	12/21/2018	A 5-HT4 receptor agonist. 5-HT4 receptors are mainly found in the gut wall and are involved in the stimulation of high-amplitude contractions and coordination of bowel motility; oral therapy.

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16. sarecycline (Seysara - Allergan / Paratek)	NDA Filed	10/20/2018	Narrow spectrum tetracycline-derived antibiotic with anti-inflammatory properties for use as an oral treatment of moderate to severe acne vulgaris in patients 9 years of age and older; oral therapy.
17. solriamfetol (JZP-110 - Jazz Pharmaceuti cals)	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 2	2019	An oral small molecule CGRP antagonists for the acute treatment of migraine headaches; oral therapy.
20. ulipristal acetate (Esmya - Allergan)	NDA Filed	August 2018	Progesterone agonist/antagonist for the treatment of abnormal uterine bleeding in women with uterine fibroids; Oral therapy.