NEW DRUG INFORMATION

- **Baqsimi® (nasal glucagon):** Lilly has been granted approval for Baqsimi from the U.S. Food and Drug Administration (FDA) as the first nasally administered glucagon to treat severe hypoglycemia in adults and children with diabetes. Prior to the Baqsimi approval, glucagon was only available as an injectable kit that needs to be reconstituted. The wholesale acquisition cost (WAC) for Baqsimi one-pack is $280.80 and for a two-pack is $561.60.1

- **Wakix® (pitolisant):** Harmony Biosciences received FDA approval for the non-stimulant treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. There are multiple medications already approved for narcolepsy including Jazz's Xyrem® (sodium oxybate) and Teva's Provigil® (modafinil). Wakix is the first treatment approved for the treatment of narcolepsy that is not scheduled. Launch is anticipated in the fourth quarter of 2019.2

- **Xenleta™ (lefamulin):** Nabriva Therapeutics received FDA approval of Xenleta, in both an oral and intravenous formulation, for the treatment of adults with community-acquired bacterial pneumonia. Xenleta is the first in a new class of antibiotics which target a different protein synthesis binding site than other antibiotics that are currently available. Xenleta is anticipated to launch in September.3

- **Accrufer® (ferric maltol):** The FDA approved Shield Therapeutics' Accrufer for the treatment of iron deficiency in adults. The FDA approval allows use for as long as necessary to restore iron levels. In a clinical trial, Accrufer was found to be non-inferior in treatment effect to an IV iron therapy.4 Accrufer launch date and pricing are pending.
**GENERIC DRUG INFORMATION**

- **Lyrica® oral solution (pregabalin oral solution):** Multiple manufacturers have launched their generic versions of Pfizer’s Lyrica oral solution for neurological pain associated with diabetic peripheral neuropathy or spinal cord injury, postherpetic neuralgia, partial-onset seizures, and fibromyalgia. Lyrica oral solution generated <$10 million in U.S. annual sales in 2018.

- **Rozerem® (ramelteon):** Multiple manufacturers have launched their generic versions of Takeda’s Rozerem for insomnia. Rozerem generated $93 million in U.S. annual sales in 2018.

- **Firazyr® (icatibant acetate):** Teva launched the first generic version of Shire/Takeda’s Firazyr for the treatment of acute attacks of hereditary angioedema. Takeda launched an authorized generic version of Firazyr in August 2019. There are no patents or regulatory exclusivities remaining. Firazyr generated $329 million in U.S. annual sales in 2018.

- **Halog® (halcinonide cream, 0.1%):** Mylan launched the first generic version of Ranbaxy’s Halog cream, 0.1% for the treatment of inflamed and itchy skin.

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**REFERENCES**

4. [https://www.healio.com/nephrology/chronic-kidney-disease/news/online/%7B7b74e9721b-62ee-4dec-b2c3-5087a2d07f5%7D/fda-approves-new-oral-iron-drug-for-ckd](https://www.healio.com/nephrology/chronic-kidney-disease/news/online/%7B7b74e9721b-62ee-4dec-b2c3-5087a2d07f5%7D/fda-approves-new-oral-iron-drug-for-ckd)

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