NEW DRUG INFORMATION

- **Hemady™ (dexamethasone):** The U.S. Food and Drug Administration (FDA) has approved Dexcel’s Hemady, an oral 20 mg tablet to be used in combination with other anti-myeloma products for the treatment of adults with multiple myeloma. Dexamethasone is available generically as injectable solution and tablets of different strengths. Launch plans and pricing are pending.¹

- **Aklief™ (trifarotene cream):** The FDA approved Galderma Laboratories’ Aklief for the treatment of acne vulgaris in patients 9 years of age and older. Aklief is the first new retinoid molecule to receive FDA approval for treatment of acne in more than 20 years. It is the only topical retinoid that selectively targets retinoic acid receptor (RAR) gamma, the most common RAR found in the skin.² Aklief is indicated for both facial and truncal acne. It will be available as a 30-gram, 45-gram and 75-gram pump device. Aklief cream is expected to be available in the United States in November 2019. Pricing is pending.³

- **Quzyttir™ (cetirizine, injectable):** JDP Therapeutics received FDA approval of Quzyttir for the treatment of acute urticaria in adults and children 6 months of age and older. Quzyttir is the first FDA approved intravenous (IV) formulation of cetirizine. Oral formulations of cetirizine are available generically by prescription or over the counter. A Phase III study found Quzyttir non-inferior to IV diphenhydramine with lower side effect panel. Quzyttir will be available as 10 mg/mL single use vials. Launch plans and pricing are pending.⁴

- **Reyvow™ (lasmiditan):** The FDA approved Lilly’s Reyvow for the oral treatment of acute migraine, with or without aura, in adults. Reyvow is the first migraine medication in a new class of serotonin (5-HT)1F receptor agonists. The Drug Enforcement Administration is currently reviewing Reyvow for controlled substance classification. This is typically a 90-day process, after which the treatment will be available in retail pharmacies.⁵ Pricing has not been announced.⁶

- **Secuado™ (asenapine):** Noven Pharmaceuticals’ Secuado has been granted FDA approval for the treatment of adults with schizophrenia. Secuado is the first transdermal patch formulation for the treatment of schizophrenia. Allergan’s Saphris® (asenapine) is available as a sublingual (SL) tablet. Noven Pharmaceuticals suggests once-daily transdermal drug delivery systems provide sustained concentrations during 24-hour wear time, which may help mitigate some challenges patients face with the management of their schizophrenia.⁷ Noven Pharmaceuticals, has not announced a definite launch date or pricing, but it intends to introduce Secuado as soon as possible in the United States.⁸

While the information in this newsletter is from sources we believe to be reliable, we do not warrant that the information in this document is free from error. Use it only as a guide. Statements regarding drugs or manufacturers are not intended as promotion; those statements should not be used to make assumptions about formulary status. Each trademarked drug name is the property of its respective owner.
● **Amzeeq™ (minocycline foam 4%)**: The FDA has granted approval of Foamix Pharmaceuticals Amzeeq for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older. Minocycline is a broad-spectrum antibiotic used for acne, but its use is limited in some patients due to systemic side effects when taken orally. According to Foamix Pharmaceuticals, minocycline has not been available as a topical treatment due to its instability in traditional topical formulations. Amzeeq has leveraged its proprietary Molecule Stabilizing Technology (MST™) platform to effectively deliver minocycline in a foam-based vehicle. Foamix Pharmaceuticals plans to launch Amzeeq in January 2020, price pending.

**GENERIC DRUG INFORMATION**

● **Trisenox® (arsenic trioxide)**: Multiple manufacturers have launched their generic versions of Cephalon’s Trisenox for the treatment of leukemia. Trisenox generated $97 million in U.S. annual sales in 2018.

● **Orfadin® (nitisinone)**: Novitium/Endo launched its generic version of Swedish Orphan Biovitrum’s Orfadin for hereditary tyrosinemia type 1. Orfadin generated $85 million global annual sales in 2018.

● **Soolantra® (ivermectin cream 1%)**: Multiple manufacturers have launched their generic versions of Galderma’s Soolantra for rosacea. Soolantra generated $175 million in U.S. annual sales in 2018.

**REFERENCES**


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