Oral Liquid Approved to Treat *Clostridium Difficile*–Associated Diarrhea

CutisPharma announced that the U.S. Food and Drug Administration (FDA) approved Firvanq™ (vandocymycin hydrochloride) for oral solution for the treatment of *Clostridium difficile*–associated diarrhea (CDAD) and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains. Firvanq is the only FDA-approved vancomycin oral liquid treatment option for CDAD.

Firvanq is expected to be available for use beginning in April 2018, and will replace CutisPharma’s FIRST® Vancomycin Unit-of-Use Compounding Kit, which has been available to pharmacists to compound vancomycin oral liquid therapy. Firvanq will be commercially available in 25 mg/mL and 50 mg/mL strengths in 150 mL and 300 mL sizes, and is expected to improve patient access and reduce pharmacist burden by eliminating the need to compound liquid formulations.


FDA Approves New Treatment for Pain Associated With Migraine in Adult Patients

electroCore, LLC, a commercial-stage bioelectronic medicine company, announced that it received clearance from the U.S. Food and Drug Administration (FDA) for an expanded label for gammaCore® (nVNS) as an acute treatment of pain associated with migraine in adult patients. gammaCore is the first non-invasive, hand-held medical therapy applied at the neck that acutely treats pain associated with episodic cluster headache and migraine in adult patients using a mild electrical stimulation to the vagus nerve that passes through the skin. gammaCore can be self-administered by patients as needed.

The FDA clearance of gammaCore for acute treatment of pain associated with migraine was principally supported by the results of the multicenter, randomized, double-blind, sham-controlled trial, PRESTO. Results demonstrated that treatment with gammaCore for acute treatment of pain associated with migraine was superior to sham, and enabled patients to reach pain freedom more frequently by 30, 60, and 120 minutes compared with sham treatment. In addition, a significantly higher proportion of gammaCore-treated patients achieved pain relief within 2 hours compared with the control treatment.