

FDA approves Voquezna for erosive esophagitis, GERD

November 8 2023, by Lori Solomon



The U.S. Food and Drug Administration has approved Phathom Pharmaceuticals' Voquezna (vonoprazan), a novel potassium-competitive acid blocker, as a new treatment for adults for with all grades of erosive esophagitis or erosive gastroesophageal reflux disease (GERD).

The approval is based on the results of the PHALCON-EE Phase III

trial, in which Voquezna 20 mg met the primary end point of noninferiority for complete healing by week eight in patients with all grades of erosive GERD.

The healing rate was 93% for Voquezna 20 mg versus 85% for lansoprazole 30 mg, with superior rates of healing demonstrated in a secondary end point in patients with moderate-to-severe disease at week two versus lansoprazole (70% for Voquezna 20 mg versus 53% for lansoprazole 30 mg).

Compared with lansoprazole 30 mg, Voquezna 20 mg also demonstrated noninferiority for the mean percentage of 24-hour heartburn-free days during the healing period. Voquezna 10 mg was superior to lansoprazole 15 mg in maintaining healing at six months in all randomly assigned patients (79% for Voquezna 10 mg versus 72% for lansoprazole 15 mg).

Adverse event rates were similar for Voquezna and lansoprazole, with the most common adverse events in the healing phase ($\geq 2\%$ in the Voquezna treatment arm) being gastritis (3.0% for Voquezna 20 mg and 2.0% for lansoprazole 30 mg), diarrhea (2.0 versus 3.0%), [abdominal distension](#) (2.0 versus 1.0%), [abdominal pain](#) (2.0 versus 1.0%), and nausea (2.0 versus 1.0%).

In the maintenance phase, the most common adverse events ($\geq 3\%$ in the Voquezna treatment arm) were gastritis (6.0% for Voquezna 10 mg versus 3.0% for lansoprazole 15 mg), abdominal pain (4.0 versus 2.0%), dyspepsia (4.0 versus 3.0%), hypertension (3.0 versus 2.0%), and [urinary tract infection](#) (3.0 versus 2.0%).

"This approval demonstrates Phathom's commitment to changing the gastrointestinal treatment landscape for [patients](#) and [health care providers](#), bringing the first major innovation to the U.S. erosive GERD market in over 30 years," Terrie Curran, president and CEO of Phathom,

said in a statement.

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