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ROMEg Therapeutics Receives FDA Approval of GLOPERBA® (colchicine) for Prophylaxis of Adult Gout Flares

GLOPERBA® is the First FDA-approved Liquid Formulation for Prophylaxis of Gout Flares and Designed to Meet Dose Adjustment Needs That Are Unmet by Existing Therapies

WOBURN, Mass. (Feb. 26, 2019) – [ROMEg Therapeutics](#), an innovative drug development company focused on alternative formulations to better meet clinical and patient needs, today announced that the U.S. Food and Drug Administration (FDA) approved GLOPERBA® (colchicine) Oral Solution, 0.6 mg/5 mL for prophylaxis of gout flares in adults. GLOPERBA is the first liquid formulation of colchicine approved by the FDA for the prophylaxis of gout flares.

“GLOPERBA represents an important advancement for patients who are experiencing the recurring, painful effects of gout,” said Naomi Vishnupad, Ph.D., Chief Scientific Officer of ROMEg Therapeutics. “Existing therapies do not adequately address the physician’s need to adjust dosages of colchicine to manage the toxicity profile for patients with renal and liver impairments, side effects, common drug-to-drug interactions, and age-related health disorders. The approval of GLOPERBA addresses a significant unmet and underserved medical need.”

Gout is a form of arthritis affecting an estimated 8.7 million people in the United States. The current U.S. market for colchicine products is approximately \$800 million. The disease is caused by elevated levels of uric acid in the bloodstream, and symptoms from the buildup of uric acid crystals in the joints include sudden, severe attacks of pain, swelling and redness, frequently at the base of the big toe. Gout can become chronic if left untreated.

Physicians have used colchicine to treat gout for decades, but they are often required to adjust the dose or interrupt treatment to address drug interactions or health conditions such as when patients are undergoing kidney dialysis. Compared with currently available capsule and tablet formulations of colchicine, the GLOPERBA oral solution allows physicians to easily make dosage adjustments for their patients. GLOPERBA is also beneficial for patients who cannot swallow solid doses or pills. About 15 percent of elderly patients have difficulty swallowing and therefore require liquid formulations.

GLOPERBA will be available at chain, independent and specialty pharmacies, long-term care facilities, and hospitals across the U.S. in summer 2019.

About ROMEG Therapeutics, LLC

ROMEG Therapeutics, LLC, a privately held specialty pharmaceutical company based in Woburn, Mass., was founded by Indu Muni and Gita Muni in 2015. The company's mission is to develop new FDA-approved therapies by formulating novel dosage forms, improving the design and function of existing approved drugs, and expanding clinical indications for use of those drugs, thereby bringing greater value to earlier scientific discovery. The company is focused on developing a broad intellectual property portfolio to offer novel therapies to provide patients and physicians better treatment options. For more information, visit www.romegrx.com.

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