FDA Grants Fast Track Designation for OrphoMed's ORP-101 for Treatment of IBS-D

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OrphoMed, Inc. →
Apr 25, 2018, 08:31 ET

SAN FRANCISCO, April 25, 2018 /PRNewswire/ -- OrphoMed, Inc., a clinical-stage biopharmaceutical company developing first-in-class dimer therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the Company's lead candidate ORP-101 for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

Fast Track designation is a process designed to facilitate the development and expedite the review of new therapies aimed at treating serious conditions and addressing unmet medical needs. This designation allows early and frequent communications between the FDA and the company sponsor throughout the drug development and review process. Additionally, Fast Track designated drugs are eligible for priority review, which can expedite the FDA's review of a New Drug Application (NDA).

"Over 28 million individuals are impacted by IBS-D, a chronic, debilitating condition with limited treatment options," said Gary Phillips, M.D., OrphoMed's President and Chief Executive Officer. "Fast Track designation recognizes the urgent need for new therapies to treat patients with IBS-D. Our goal is to continue to advance ORP-101 into Phase 2 by the end of 2018."

About ORP-101

ORP-101 is a metabolically stable, peripherally active partial agonist of the μ opioid receptor and antagonist of the κ opioid receptor that is designed to mitigate colonic hypersensitivity due to intestinal hyperalgesia and associated motility dysfunction in IBS-D. In multiple clinically relevant animal models ORP-101 has repeatedly been shown to suppress general and colon-specific hyperalgesic signals without CNS penetration and without constriction of the sphincter of Oddi, which could cause acute pancreatitis. ORP-101 is a proprietary molecule fully owned by OrphoMed without any downstream royalties or associated milestone payments.

About IBS-D

Irritable bowel syndrome with diarrhea (IBS-D), impacts more than 28 million individuals in the United States and Europe. This chronic, debilitating condition causes abdominal pain due to visceral hyperactivity and frequent diarrhea. Only 30% of patients consult a physician to treat this condition and of those who receive treatment, 60% do not respond to current therapies.

About OrphoMed, Inc.

OrphoMed is a clinical-stage biopharmaceutical company focused on the development of novel first-in-class dimer therapeutics. Leveraging its proprietary dimer platform technology engineered by Founder Nikhilesh Singh, Ph.D., OrphoMed is advancing ORP-101, a potential best-in-class buprenorphine dimer in clinical development for the treatment of IBS-D, and its pipeline of additional dimer conjugates. In May 2017, OrphoMed completed a $39 million Series A financing with New Enterprise Associates, Takeda Ventures, Pappas Capital and Relativity Healthcare. The capital will be used to advance the clinical development of ORP-101 through Phase 2. For more information please visit www.orphomed.com.

Disclaimer

This press release contains "forward-looking statements," which reflect our current views and expectations with respect to future outcomes or events. When used in this press release, the words "could," "believe," "anticipate," "intend," "estimate," "expect," "project" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. Because these statements are based on current estimates and assumptions, they are inherently subject to risks that could cause the

actual outcomes to differ materially from what we currently expect. These forward-looking statements are subject to numerous risks and uncertainties, including, among others, the facts that we are substantially dependent on our ability to successfully develop and commercialize our products; the commercial adoption of our products and any other product candidates we develop will depend on the degree of their market acceptance; we have only limited assets and will need to raise additional capital before we can expect to generate revenue or become profitable; and we have never generated any revenue and may never be profitable. Forward-looking statements in this presentation apply only as of the date made, and we undertake no obligation to update or revise any forward-looking statements to reflect subsequent events or circumstances.

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