

ISHA Therapeutics Receives U.S. FDA QIDP Designation for ISHA-004 for the Treatment of Oropharyngeal Candidiasis

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/EINPresswire.com/ -- ISHA

Therapeutics LLC, a company focused on advancing therapies through the 505(b)(2) regulatory pathway, today announced that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) designation to ISHA-004, its novel antifungal candidate for the treatment of oropharyngeal candidiasis.



Dr. Manoj Jadhav, PhD, FCP, Founder and CEO

The QIDP designation was granted by the Division of Infectious Diseases within the FDA's Center for Drug Evaluation and Research (CDER) and is intended to encourage development of therapies targeting serious or life-threatening infections, particularly those caused by drug-resistant pathogens.

ISHA-004 is a novel oral thin-film formulation of a potent antifungal agent, developed using ISHA's proprietary ionic-liquid platform technology (ILPT). The formulation is designed to adhere to oropharyngeal mucosal surfaces, enabling targeted delivery of the drug directly at the site of infection.

Following a pre-Investigational New Drug (pre-IND) meeting, ISHA Therapeutics received FDA guidance on its nonclinical, clinical, and chemistry, manufacturing, and controls (CMC) development strategy for ISHA-004. The company is advancing the program toward IND submission and clinical development.

"The FDA's decision to grant QIDP designation underscores the potential of ISHA-004 and supports our mission to develop innovative therapies that improve patient outcomes," said Dr. Manoj Jadhav, PhD, FCP, Founder and Chief Executive Officer of ISHA Therapeutics. "ISHA-004 addresses a significant unmet need for effective antifungal treatments, particularly for patients with drug-resistant Candida infections. We look forward to continued collaboration with the FDA



ISHA-004 novel oral film topical formulation that adheres to mucosal surfaces could be a real gamechanger, especially for those with refractory and/or antifungal resistant candida mucosal infections.”

*Dr. Peter Pappas, MD, Prof.
Infectious Diseases, Alabama,
Birmingham*

as we advance this program into clinical development later this year.”

Senior Clinical Advisor and world leader Dr. Peter Pappas, MD, Professor of Medicine- Infectious Diseases, University of Alabama, at Birmingham said “The development of ISHA-004 provides an enormous opportunity to treat oropharyngeal candidiasis with a new topical formulation, something that has eluded clinicians and patients for too long. The ability to provide ISHA-004 topically in a formulation that adheres to mucosal surfaces could be a real gamechanger, especially for those with refractory and/or antifungal resistant candida mucosal infections.”

Dr. David Perlin, Chief Scientific Officer at Hackensack Meridian Health Center for Discovery and Innovation, New Jersey, and senior scientific advisor to ISHA , further noted, “The safe and efficacious application of a mainstay antifungal agent in a novel delivery vehicle, designed to overcome difficult-to-treat infections, including those resistant to existing therapies, represents an important addition to the clinician’s therapeutic toolkit.”

Senior scientific advisor and a serial drug developer Dr. Krishna Devarakonda added, “ISHA-004 is a novel thin film delivery system, which stays in close contact with the oropharyngeal mucosa and delivers the drug directly at the site of candidal infection. Since the active is a known small molecule with potentially high degree of systemic toxicity, topical delivery minimizes the side effects while providing adequate therapeutic efficacy, with an anticipated good patient compliance”.

QIDP Designation and Development Benefits:

QIDP designation provides important incentives under the Generating Antibiotic Incentives Now (GAIN) Act, including Eligibility for Fast Track designation, Priority review, Rolling review of regulatory submissions, An additional five years of market exclusivity

ISHA Therapeutics plans to submit a request for Fast Track designation for ISHA-004 by the end of 2026.

About ISHA Therapeutics

ISHA Therapeutics LLC is a pharmaceutical company focused on repurposing and reformulating existing drugs to enhance safety, efficacy, and patient accessibility. The company is developing a pipeline of programs addressing unmet medical needs across anti-infectives, dermatology, lifestyle, and chronic disease indications.

For more information, visit www.ishatherapeutics.com

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations and are subject to risks and uncertainties that could cause actual results to differ materially.

Factors that may cause such differences include, but are not limited to, risks related to clinical development, regulatory approval, commercialization, competition, intellectual property protection, reimbursement, and the need for additional financing. ISHA Therapeutics undertakes no obligation to update any forward-looking statements.

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