Avior

PRESS RELEASE

Avior Bio Receives Authorization to Initiate First-in-Human Phase 1 Pharmacokinetics, Safety and Tolerability Study with AV104 Buccal Films

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Holly Springs, N.C., July 23, 2020 - Avior Bio Inc. is pleased to announce that it received authorization from the Centre for Product & Cosmetic Evaluation at the Malaysian Ministry of Health to initiate a Phase I clinical trial in Malaysia with AV104 buccal film for the treatment of moderate to severe pruritus. The clinical program will initiate its first dose on Friday, July 24, 2020, with expected results by the end of September 2020.

The first-in-human clinical trial is designed to assess the safety, tolerability, and pharmacokinetics of AV104 buccal film in comparison to an oral comparator. AV104 is based on Avior's powerful, patent-pending delivery technology called Speedit™ transmucosal film, where nano- and microparticles of drug reside on the surface of an oral transmucosal thin film. AV104 buccal films are targeted for the treatment of moderate to severe pruritus in liver diseases such as primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), alcoholic liver disease (ALD), fatty liver disease (FLD), hepatitis (B/C), and liver cirrhosis. There are currently no FDA approved therapies available for this ailment.

"We are excited about the initiation of the AV104-101 clinical study. The successful dosing of the first patient is a major event for this promising product candidate," said Dr. Niraj Vasisht, President and CEO of Avior Bio. "We look forward to completing the healthy volunteer study and advancing AV104 into patients."

Dr. Vivian Doelling, VP - Investment, Emerging Company Development at North Carolina Biotechnology Center (NCBC) commented, "Avior's management team has shown incredible resolve in getting AV104 into the clinic in less than two years. This is particularly impressive in light of the COVID-19 pandemic. We are pleased to support the development of the Speedit™ film technology."

Dr. Yousry Sayed, President of Quality Chemical Laboratories, and an angel investor supporting Avior said, "Initiating the first-in-human trial is a major milestone for Avior. If the data looks as good as the preclinical studies, the product will have tremendous positive implications in the 2.5 millions suffering from pruritus-associated liver disease."

About Pruritus

Intermittent moderate-to-severe -pruritus (itch) is a common comorbid symptom of chronic liver diseases such as primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), alcoholic liver disease (ALD), fatty liver disease (FLD), hepatitis (B/C), and liver cirrhosis. It is estimated that over 2.5 million patients suffer from intractable, persistent pruritus in liver disease patients with no FDA approved therapies currently available. Pruritus in liver disease is a refractory symptom and it reduces the patients' quality of life (QOL) causing insomnia, anxiety, depression, nocturnal scratching, excoriation, and bleeding.

The disease state is also common in atopic dermatitis (*eczema*) where 91% of the 15.6 million patients experience pruritus. However, despite new therapies to treat atopic dermatitis, approximately 31% do not find relief for their pruritus.

About Avior Bio

Avior Bio Incorporated, located in the RTP region of North Carolina, is a clinical-stage, pharmaceutical company developing drugs for distressed neurological conditions. Our lead product – AV104 buccal film- focuses on the treatment for moderate to severe pruritus in patients suffering from liver disease. AV104 is based on a high affinity, partial KOR and MOR antagonist, and is designed to avoid the first-pass metabolism of the impaired liver. Avior's management team has experienced executives with a history of success in bringing products to market and building teams. Avior is seeking approval of AV104 through an NDA submission in 2Q2023.

For further information about Avior Bio Incorporated, visit their website at www.AviorBio.com