



## PRESS RELEASE

# Avior Bio Receives Authorization to Initiate Evaluation of the Pharmacokinetics and Tolerability of AV104 Transmucosal Films in Cholestatic Liver Disease Subjects

Cary, N.C., February 28, 2022 - Avior Bio Inc. is pleased to announce that it received notification of approval from the Drug Controller General of India and the Central Drugs Standard Control Organization, Government of India to initiate a multi-centered, pharmacokinetics and tolerability study of AV104 transmucosal films in cholestatic liver disease subjects (AV104-106).

AV104 is based on Avior's powerful, patent-pending delivery technology, where nano- and microparticles of drug reside on the surface of an oral transmucosal thin film. Using this technology, the drug in AV104 film avoids first-pass liver metabolism. There are currently no approved therapies available specifically for the treatment of pruritus in liver cholestasis.

"We are thrilled to receive authorization to initiate the AV104-106 clinical study. This will be our first study in patients with chronic liver disease and a major milestone for this promising product candidate," said Dr. Niraj Vasisht, President and CEO of Avior Bio. "The study will provide the necessary safety information to enable patients in our planned AV104 Phase 2 program to reach an antipruritic dose quickly," added Dr. Andrew Finn, Chief Medical Officer of Avior Bio. Avior expects to complete this safety and pharmacokinetic study by end of the 2Q2022.

### ***Avior Bio***

Avior Bio is a clinical-stage, pharmaceutical company advancing therapies for the treatment of pruritus (itch) and inflammatory skin disease in rare diseases. Our lead product – AV104 buccal film – is the first-in-kind, dual-action, product for the treatment of pruritus in primary biliary cholangitis (PBC), a rare disease.

Avior brings two innovative solutions to the treatment of this disease. First, AV104 blocks the neuropeptide associated with itch, and it inhibits the production of inflammatory cytokines associated with inflammation. Second, Avior uses its transmucosal delivery technology - to enable the active drug to bypass the liver. Avior's platform technology also offers rapid onset of absorption which has many more applications in drug delivery.

Avior recently completed non-clinical studies and two Phase I studies that will support our Phase 2 clinical program. We are exploring Series A funding for up to \$24M to complete development of AV104 and NDA submission with multiple, milestones-dependent inflection points. For further information about Avior Bio Incorporated, visit their website at [www.AviorBio.com](http://www.AviorBio.com)