Avior

PRESS RELEASE

Avior Bio Announces Results from its Formulation Comparison AV104-102 Study

Cary, North Carolina, February 23, 2022 – Avior Bio, a company focused on developing AV104 transmucosal film for treatment of pruritus associated with primary biliary cholangitis (PBC), today announced pharmacokinetic (PK) data from its AV104-102 clinical study.

The study compared the pharmacokinetics of AV104 buccal and sublingual formulations with an oral solution of the drug. The key PK data points from the study demonstrated:

- Equivalent single doses of AV104 buccal nalmefene film produced *significantly higher* plasma nalmefene concentrations (Cmax) and overall exposure (AUC) compared to oral nalmefene solution.
- An equivalent single dose of AV104 sublingual nalmefene film produced *significantly higher* plasma nalmefene concentrations (Cmax) and overall exposure (AUC) compared to oral nalmefene solution.
- The duration of nalmefene exposure from both *buccal and sublingual films suggest that once daily dosing* may be suitable for the target liver disease population.

"The results of this study in normal volunteers, provide us confidence that an appropriate dose of AV104 can be administered that will have both antipruritic and anti-inflammatory effects when administered once-daily in our Phase II program," said Andrew Finn, PharmD, Chief Medical Officer of Avior Bio.

The AV104-102 was an open-label, 3-period crossover, single-sequence study designed to compare the pharmacokinetic parameters based on a 4-hour post-dose period. There was a minimum 4-day washout period between doses.

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

Avior brings two innovative solutions to the treatment of this disease. First, our drug - AV104 - blocks the neuropeptide that transmits the itch response, and it inhibits the inflammatory cytokines that otherwise cause skin inflammation. Second, Avior uses its transmucosal delivery technology - to bypass the liver. Avior's platform technology facilitates rapid absorption which has additional applications in drug delivery.

Avior recently completed non-clinical studies that will enable our Phase 2 clinical program. We are exploring Series A funding for up to $24M to complete our NDA submissions with multiple, milestones-dependent inflection points. For further information about Avior Bio Incorporated, visit their website at www.AviorBio.com