Intercept Announces Efficacy and Safety Data from Phase 3 REGENERATE Study in Liver Fibrosis due to NASH to be Presented at NASH-TAG Conference 2023

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MORRISTOWN, N.J., Jan. 04, 2023 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced two abstracts on obeticholic acid (OCA) will be presented at the NASH-TAG Conference 2023. The conference will be held from January 5 – 7, 2023, in Park City, Utah.

"We are looking forward to joining clinicians, researchers and industry peers in-person this year at NASH-TAG 2023 to share additional data from the second interim analysis of our pivotal Phase 3 REGENERATE study," said M. Michelle Berrey, M.D., MPH, President of R&D and Chief Medical Officer of Intercept. "These data demonstrate the robust antifibrotic effect of OCA, as well as its favorable long-term safety profile, and ultimately reaffirm our belief that OCA can be an important treatment for people living with fibrosis due to NASH."

Presentations at the NASH-TAG Conference 2023 include:

"Topline Results from a New Analysis of the REGENERATE Trial of Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis" Abstract # 26
January 7, 2023; 4:00 – 4:10 p.m. MST
Arun J. Sanyal, Rohit Loomba, Quentin M. Anstee, Vlad Ratziu, Kris V. Kowdley, Mary E. Rinella, Muhammad Y. Sheikh, James F. Trotter, Whitfield L. Knapple, Eric J. Lawitz, Manal F. Abdalmalek, Philip N. Newsome, Jerome Boursier, Philippe Mathurin, Jean-Francois Dufour, M. Michelle Berrey, Steven J. Shiff, Sangeeta Sawhney, Thomas Capozza, Rina Leyva, Stephen A. Harrison and Zobair M. Younossi

"Focused Monitoring and Management Guidance Reduces the Incidence of Hepatic Safety Events: Results from the Phase 3 REGENERATE Trial of Obeticholic Acid for Nonalcoholic Steatohepatitis" Abstract # 33
January 6, 2023; 7:30 a.m. – 7:10 p.m. MST
Vlad Ratziu, Stephen A. Harrison, Arun J. Sanyal, Mary E. Rinella, Quentin M. Anstee, Kris V. Kowdley, Sangeeta Sawhney, Steven J. Shiff, M. Michelle Berrey, Karisse-Roman Torres, Thomas Capozza, Zobair M. Younossi and Rohit Loomba

The use of OCA for fibrosis due to NASH is investigational and has not been approved by the U.S. Food and Drug Administration, the European Commission or any other health authority.

A full list of sessions at the NASH-TAG Conference 2023 is available at nash-tag.org.

About the REGENERATE Study
REGENERATE (Randomized Global Phase 3 Study to Evaluate the Impact on NASH with Fibrosis of Obeticholic Acid Treatment) is an ongoing Phase 3, randomized, double-blind, placebo-controlled, multicenter, international study assessing the safety and efficacy of obeticholic acid (OCA) on clinical outcomes in patients with liver fibrosis due to NASH. A pre-specified interim analysis was conducted in 931 subjects who had a liver biopsy at Month 18 to assess the effect of OCA on liver histology as compared to baseline biopsies. REGENERATE is fully enrolled with 2,480 randomized participants and is expected to continue while collecting data on the incidence of clinical outcomes for verification and description of clinical benefit. The end-of-study primary endpoint will compare the impact of treatment group (placebo, OCA 10 mg or OCA 25 mg daily) on all-cause mortality and liver-related clinical outcomes, as well as on long-term safety.

About Liver Fibrosis due to NASH
Nonalcoholic steatohepatitis (NASH) is a serious progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. Advanced fibrosis is associated with a substantially higher risk of liver-related morbidity and mortality in patients with NASH. There are currently no medications approved for the treatment of NASH.

About Intercept
Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH) and severe alcohol-associated hepatitis (sAH). For more information, please visit www.interceptpharma.com or connect with the Company on Twitter and LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements (FLS), including regarding the results of our clinical studies, and the safety and efficacy of OCA. Important factors could cause actual results to differ materially from the FLS, including further developments regarding understanding of patient outcomes, side effects, or study methodology.

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