Intercept Announces Restructuring to Strengthen Focus on Rare and Serious Liver Diseases and Significantly Reduce Operating Expenses

June 23, 2023

- *Measures reinforce Company's ability to drive growth in PBC business and continue developing innovative new medicines*
- *Company to discontinue all NASH-related investment and reduce workforce by approximately one third*
- *Company anticipates achieving profitability in 2024*
- *R&D investment prioritized on fixed-dose combination of OCA and bezafibrate with potential to establish best-in-class clinical benefits in the treatment of PBC*
- *Company lowers 2023 non-GAAP adjusted operating expense guidance to $350–$370 million, inclusive of restructuring costs; reiterates 2023 Ocaliva net sales guidance of $310–$340 million*
- *Company expects to achieve net reduction in annual non-GAAP adjusted operating expenses of approximately $140 million – relative to updated 2023 non-GAAP adjusted operating expense guidance*
- *Conference call scheduled for Friday, June 23, 2023, at 8:30 a.m. ET*

MORRISTOWN, N.J., June 23, 2023 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT) today announced a restructuring to strengthen the Company's focus on rare and serious liver diseases and significantly reduce operating expenses, including discontinuing all nonalcoholic steatohepatitis (NASH)-related investment.

"We are taking decisive actions that we believe will improve our ability to drive long-term growth and maintain leadership with our PBC business, continue to develop innovative new medicines, and achieve profitability beginning in 2024," said Jerry Durso, President and Chief Executive Officer of Intercept. "We will move quickly to make a strategic shift that puts Intercept in the best position to create value for shareholders while fully supporting our patient-driven mission."

Durso added, "We understand the implications of these changes on our employees and are committed to supporting them throughout this process."

Planned Actions and Financial Impacts

- The Company will promptly begin the process of closing out the REGENERATE study. The Company expects to substantially complete the trial shut-down process by the end of 2023.
- In addition to closing out REGENERATE, Intercept is quickly winding down all other NASH-related spending within the Company's R&D, commercial, medical affairs and administrative functions.
- Actions taken by Intercept to reduce its operating expenses are projected to result in a workforce reduction of approximately one third of the Company. Intercept expects to initiate workforce reductions in the third quarter of 2023, with the vast majority completed by the end of 2023. Intercept plans to maintain the scale of its current field sales organization to support the growth potential of Ocaliva® (obeticholic acid or OCA).
- Intercept is targeting a net reduction in annual non-GAAP adjusted operating expenses of approximately $140 million. These savings will be relative to updated 2023 non-GAAP adjusted operating expense guidance and will be effective upon completion of the restructuring and close out of the REGENERATE study.

Strengthened Focus on Rare and Serious Liver Diseases

- Intercept will continue its strong investment to support Ocaliva, the only U.S. Food and Drug Administration (FDA)-approved second-line treatment for people living with primary biliary cholangitis (PBC). The Company has generated meaningful new data with innovative studies that leverage real-world evidence and will continue to do so going forward.
- Intercept remains on track for a planned regulatory submission to the FDA in 2023 in support of fulfilling post-marketing requirements for Ocaliva in PBC. This submission will include data from the post-marketing study COBALT and supplementary real-world evidence from large datasets in the U.S. and Europe.
- Intercept will prioritize R&D investment on its fixed-dose combination of OCA and bezafibrate, a peroxisome proliferator-activated receptor agonist. The first Phase 2 interim analysis for the OCA-bezafibrate combination was presented today at the 2023 European Association for the Study of the Liver Congress (click here). The Company believes that OCA-bezafibrate offers the potential to establish best-in-class clinical benefits that can help further improve the treatment

of PBC. Two ongoing Phase 2 studies are exploring a range of therapeutic doses for the combination, with planned interim analyses from both studies expected to be completed in 2023. The planned interim analyses from Phase 2 studies, in addition to Phase 1 and preclinical data, will serve as the basis for an end-of-phase 2 meeting with FDA.

- The Company continues to advance the Phase 2a FRESH study for INT-787, a next-generation farnesoid X receptor (FXR) agonist, to establish a proof-of-concept in severe alcohol-associated hepatitis.

2023 Financial Targets

- The Company has lowered 2023 non-GAAP adjusted operating expense guidance to $350 million to $370 million. This guidance includes expenses to wind down the REGENERATE study and stop all other NASH-related activity, as well as estimated charges of approximately $16 million relating to the planned workforce reduction in 2023. The Company expects the majority of restructuring costs to be incurred during the third quarter of 2023.
- Intercept reiterated its full-year 2023 Ocaliva net sales guidance of $310 million to $340 million, as compared to 2022 Ocaliva U.S. net sales of $285.7 million.
- As of March 31, 2023, Intercept had cash, cash equivalents, restricted cash, and investment debt securities available for sale of $435.2 million. As previously disclosed, the Company will use available cash to settle $110 million of convertible notes on or around July 1, 2023.

Conference Call on Friday, June 23, 2023, at 8:30 a.m. ET
As previously announced, the Company will host a conference call on Friday, June 23, 2023, at 8:30 a.m. ET to address the restructuring and provide updated financial guidance. The conference call will be available via a listen-only webcast on the investor page of the Company's website at http://ir.interceptpharma.com. Participants who wish to ask a question may register here to receive dial-in numbers and a unique pin to join the call. A replay of the call will be available on the Intercept website shortly following the completion of the call and will be available for one year.

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

About the Investigational OCA-bezafibrate Fixed-Dose Combination
Intercept is investigating a fixed-dose combination of OCA and bezafibrate for the potential treatment of individuals with PBC. OCA, a farnesoid X receptor (FXR) agonist, is marketed by Intercept as Ocaliva in the United States for the treatment of PBC (see below for full indication and Important Safety Information). Bezafibrate, a pan-peroxisome proliferator-activated receptor (pan-PPAR) agonist, is not approved in the United States for any indication.

FXR and PPAR are distinct pathways that each play a role in PBC. Simultaneously targeting both pathways may offer the greatest potential to impact bile acid synthesis, metabolism, and clearance that underly cholestatic liver diseases. Published studies establish a clinical proof-of-concept that suggests that the combination of OCA and bezafibrate may provide additive clinical efficacy and tolerability benefits in the treatment of PBC. OCA-bezafibrate combination therapy is investigational; safety and efficacy have not been established.

About Primary Biliary Cholangitis
Primary biliary cholangitis (PBC) is a rare, progressive, and chronic autoimmune disease that affects the bile ducts in the liver and is most prevalent (approximately 1 in 10,000) in women over the age of 40. PBC causes bile acid to build up in the liver, resulting in inflammation and scarring (fibrosis), which, if left untreated, can lead to cirrhosis, a liver transplant, or death.

About Ocaliva® (obeticholic acid)
Ocaliva, a farnesoid X receptor (FXR) agonist, is indicated for the treatment of adult patients with primary biliary cholangitis (PBC)

- without cirrhosis or
- with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- **Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with Ocaliva treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis.**
- **Ocaliva is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.**
- **Permanently discontinue Ocaliva in patients who develop laboratory or clinical evidence of hepatic**

decompensation; have compensated cirrhosis and develop evidence of portal hypertension; or experience clinically significant hepatic adverse reactions while on treatment.

Contraindications

OCALIVA is contraindicated in patients with:

- decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event
- compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
- complete biliary obstruction

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis
Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in PBC patients with cirrhosis, either compensated or decompensated. Among post-marketing cases reporting it, median time to hepatic decompensation (e.g., new onset ascites) was 4 months for patients with compensated cirrhosis; median time to a new decompensation event (e.g., hepatic encephalopathy) was 2.5 months for patients with decompensated cirrhosis.

Some of these cases occurred in patients with decompensated cirrhosis when they were treated with higher than the recommended dosage for that patient population; however, cases of hepatic decompensation and failure have continued to be reported in patients with decompensated cirrhosis even when they received the recommended dosage.

Hepatotoxicity was observed in the OCALIVA clinical trials. A dose-response relationship was observed for the occurrence of hepatic adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare with dosages of OCALIVA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCALIVA in two 3-month, placebo-controlled clinical trials in patients with primarily early stage PBC.

Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments to determine whether drug discontinuation is needed. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (e.g., autoimmune hepatitis, alcoholic liver disease), and/or with severe intercurrent illness for new evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed. Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction. If severe intercurrent illness occurs, interrupt treatment with OCALIVA and monitor the patient's liver function. After resolution of the intercurrent illness, consider the potential risks and benefits of restarting OCALIVA treatment.

Severe Pruritus
Severe pruritus was reported in 23% of patients in the OCALIVA 10 mg arm, 19% of patients in the OCALIVA titration arm, and 7% of patients in the placebo arm in a 12-month double-blind randomized controlled clinical trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. Consider clinical evaluation of patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid binding resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing.

Reduction in HDL-C
Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high-density lipoprotein-cholesterol (HDL-C). Dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in OCALIVA-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to OCALIVA after 1 year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions
The most common adverse reactions (≥5%) are: pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

Drug Interactions

- Bile Acid Binding Resins
  Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of OCALIVA. If taking a bile acid binding resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid binding resin, or at as great an interval as possible.
- Warfarin
  The International Normalized Ratio (INR) decreased following coadministration of warfarin and OCALIVA. Monitor INR and adjust the dose of warfarin, as needed, to maintain the target INR range when co-administering OCALIVA and warfarin.
- CYP1A2 Substrates with Narrow Therapeutic Index
  Obeticholic acid may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g., theophylline and tizanidine) is recommended when

co-administered with OCALIVA.

- Inhibitors of Bile Salt Efflux Pump
  Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin.

Please click here for Full Prescribing Information, including Boxed WARNING.
To report SUSPECTED ADVERSE REACTIONS, contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Non-GAAP Financial Measures

This news release presents non-GAAP adjusted operating expenses on a projected basis. Non-GAAP adjusted operating expenses exclude from total operating expenses, as calculated and presented in accordance with GAAP, the effects of two non-cash items: stock-based compensation and depreciation. Non-GAAP adjusted operating expenses are a financial measure that has not been prepared in accordance with GAAP. Accordingly, investors should consider non-GAAP adjusted operating expenses in addition to, but not as a substitute for, total operating expenses that we calculate and present in accordance with GAAP. Among other things, our management uses non-GAAP adjusted operating expenses to establish budgets and operational goals and to manage our business. Other companies may define or use this measure in different ways. We believe that the presentation of non-GAAP adjusted operating expenses provides investors and management with helpful supplemental information relating to operating performance and trends. A quantitative reconciliation of projected non-GAAP adjusted operating expenses to total operating expenses is not available without unreasonable effort primarily due to our inability to predict with reasonable certainty the amount of future stock-based compensation expense.

Forward-Looking Statements
This news release contains forward-looking statements (“FLS”), including regarding a planned corporate restructuring, restructuring timing and implementation, corporate strategy and priorities, corporate financial performance and profitability, timing of profitability, Ocaliva net sales, expense levels and expense reductions, restructuring costs, workforce size, investments in new drug development, payment of debt, results and timing of clinical trial activity, regulatory submission activity, meetings with regulators, contents and timing of a submission to the FDA in support of post-marketing requirements for Ocaliva for PBC, success with existing and pipeline products, and drug efficacy, safety, and tolerability. Important factors could cause actual results to differ materially from the FLS. For example, we may be less effective than expected in implementing strategic changes, restructuring and clinical trial wind-down may be slower and have greater costs than expected, Ocaliva sales may be lower than expected, our clinical trials could be unsuccessful, and regulators could object to our plans on the basis of drug efficacy, safety, or tolerability, or on the basis of clinical trial and real-world evidence methodology.

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