Intercept Announces Advanz Pharma to Acquire Ocaliva in PBC in Markets Outside the U.S. for up to $450MM, including $405MM Upfront and an Additional $45MM in Contingent Payments

May 5, 2022

Agreement includes rights for Advanz to commercialize orphan drug Ocaliva® for PBC outside the U.S., as well as the transition to Advanz of the international commercial and medical infrastructure of Intercept

Additionally, Intercept will receive royalties on any future ex-U.S. net sales of obeticholic acid in NASH

Intercept to discuss further details during Q1 2022 earnings call on Friday, May 6th at 8:30 a.m. ET

MORRISTOWN, N.J., May 05, 2022 (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 it has entered into an agreement to sell to Advanz Pharma, a pharmaceutical company with a strategic focus on specialty and hospital pharmaceuticals in Europe, certain foreign subsidiaries and rights regarding Intercept's international operations, including a license to commercialize Ocaliva® (obeticholic acid) outside of the U.S.

"This agreement marks an important step forward for Intercept as the value it brings to our company allows us to significantly strengthen our balance sheet while providing us with greater strategic optionality during this transformational year and beyond," said Jerry Durso, President and Chief Executive Officer of Intercept. "We are committed to investing in our core focus areas in the U.S., including our PBC business, potential future activities in NASH, and our advancing and expanding pipeline. At the same time, we are confident that the strong international team will continue to build on our successful PBC business as they transition to Advanz Pharma."

Upon closing of the transaction:

- Intercept will receive consideration in the amount of $405 million upfront, subject to customary working capital and other adjustments. The company will receive an additional $45 million from Advanz Pharma contingent upon receipt of an extension of pediatric orphan exclusivity in Europe.
- Intercept will receive royalties on any future net sales of obeticholic acid in NASH outside of the U.S., should Advanz Pharma pursue marketing authorization for this indication in ex-U.S. regions.
- Intercept will continue to be responsible for the manufacturing and supply of obeticholic acid globally and Advanz Pharma will be responsible for packaging, distribution and commercialization of the therapy in all markets outside of the U.S.
- The majority of Intercept employees outside of the U.S. will transfer to Advanz Pharma. The remaining international employees will continue to work for Intercept.
- Intercept will maintain an office in the UK to manage its global supply chain, support its quality organization, and support its global clinical trials.

Intercept and Advanz Pharma will work closely together to help ensure a seamless transition of Intercept's ex- U.S. business to Advanz Pharma. The transaction is subject to customary legal and regulatory closing conditions and is expected to be completed in two to three months.

Ocaliva was granted conditional approval by the European Commission in December 2016 for the treatment of PBC in combination with ursodeoxycholic acid in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA and is currently approved in more than 40 countries worldwide.

Piper Sandler acted as exclusive financial advisor, and DLA Piper acted as legal counsel to Intercept.

The conference call on Friday, May 6, will be available on the investor page of Intercept's website at http://ir.interceptpharma.com or by calling (855) 232-3919 (toll-free) with passcode 7738727. Archived webcasts will be available on Intercept's website for approximately two weeks.

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) and nonalcoholic steatohepatitis (NASH). For more information, please visit www.interceptpharma.com or connect with the company on Twitter and LinkedIn. Founded in 2002 in New York, Intercept has operations in the United States, Europe and Canada. For more information, please visit www.interceptpharma.com or connect with the company on Twitter and LinkedIn.

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.

Cautionary Note Regarding Forward-Looking Statements

This press release (or, in each case that this press release is mentioned below, the Current Report on Form 8-K, including the Question and Answer document, that this press release is incorporated into by reference) contains forward-looking statements, including, but not limited to, statements regarding the planned divestiture of our ex-US business to Advanz Pharma and the related transactions. In addition, this press release contains statements related to the progress, timing and results of our clinical trials, including our clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH"), the safety and efficacy of our approved product, Ocaliva (obeticholic acid or "OCA") for primary biliary cholangitis ("PBC"), and our product candidates, including OCA for liver fibrosis due to NASH, the timing and acceptance of our regulatory filings and the potential approval of OCA for liver fibrosis due to NASH, the review of our New Drug Application for OCA for the treatment of liver fibrosis due to NASH by the U.S. Food and Drug Administration (FDA), our intent to work with the FDA to address the issues raised in the complete response letter (CRL), the potential commercial success of OCA in the US and internationally, as well as our strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans and objectives.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "possible," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by our management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. These forward-looking statements include, but are not limited to statements regarding estimates and forecasts of financial and performance metrics, including the benefits of the transaction with Advanz Pharma, including the upfront cash consideration, contingent cash payment and potential royalties, the anticipated timing of the consummation of the transaction, projections of market opportunity, business strategies, various addressable markets, industry environment, developments in markets in which we operate, the initiation, timing, progress, scope and results of our ongoing pre-clinical studies, planned clinical trials and research and development programs, the timing, availability and presentation of pre-clinical and regulatory developments, our ability to timely file and obtain approval of investigational new drug applications for its planned clinical trials, the potential benefits of our platforms, programs and product candidates, the development of our product candidates, if approved, and the drivers, timing, impact and results thereof, the potential and future results of current and planned collaborations, our ability to obtain and maintain regulatory approval of any of our product candidates, our ability to expand its and our operational capabilities, and to supply Advanz Pharma and ourselves with sufficient supplies of our product(s) or product candidates, our ability to meet certain milestones, and the effects of regulations or our projected future results. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of our management team and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions this press release relies on. Many actual events and circumstances are beyond our control.

These forward-looking statements are subject to a number of risks and uncertainties, including (i) changes in domestic and foreign business, market, financial, political, economic and legal conditions; (ii) the risk that the transaction may not be completed in a timely manner or at all, which may adversely affect the price of our securities; (iii) the failure to satisfy the conditions to the transaction agreements, consummate the transaction with Advanz Pharma in the anticipated manner on the anticipated timeline, including the receipt of certain governmental and regulatory approvals; (iv) the outcome of any legal proceedings that may be instituted against us related to the transaction with Advanz Pharma, transaction agreements or the manufacture, supply and sublicensing arrangements we enter into in connection with the transactions; (v) the risks that the announcement and consummation of the transaction with Advanz Pharma disrupts our current plans, operations, business relationships, performance, and business

generally; (vi) our ability to implement business plans, forecasts, and other expectations after the completion of the transaction with Advanz Pharma, and identify and realize additional opportunities; (vii) the risk that the announcement or consummation of the transaction with Advanz Pharma has an adverse impact on the price of our securities, including volatility resulting from the announcement thereof; (viii) the risks relating to the uncertainty of projected information, including our product candidates; (ix) our ability to protect our intellectual property rights; (x) difficulties arising from our licenses, or supply-chain or manufacturing challenges; (xi) trends in the industry, changes in the competitive landscape, and delays or disruptions due to the COVID-19 pandemic, including the risk that the ongoing COVID-19 pandemic and the associated containment efforts may disrupt our business and/or the global healthcare system (including its supply chain) more severely than it has to date or more severely than anticipated; (xii) the risks relating to the development of clinical stage pharmaceutical treatments and our approach to discover and develop novel therapeutics, including unexpected safety or efficacy data observed during pre-clinical or clinical studies and adverse reactions exhibited by participants in our trials; (xiii) the risk that delays or difficulties in the commencement, enrollment or completion of clinical trials, or unsatisfactory results from such trials, could increase product development costs and delay commercialization of our products; (xiv) the risk that our products will not receive full approval in jurisdictions where such products have previously received full or conditional approval; (xv) changes in the legal and regulatory framework for the global healthcare industry or unexpected litigation or disputes and future expenditures; (xvi) any changes to accounting methods; and (xvii) those factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2021 under the headings “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors,” and other documents which we have filed, or will file, with the Securities and Exchange Commission (the “SEC”). If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements.

There may be additional risks that we do not presently know, or that we currently believe are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect our expectations, plans, or forecasts of future events and views as of the date of this press release. We anticipate that subsequent events and developments will cause our assessments to change. However, we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our assessments as of any date subsequent to the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

CONTACT

For more information about Intercept, please contact:

Investor inquiries: investors@interceptpharma.com

Media inquiries: media@interceptpharma.com

Source: Intercept Pharmaceuticals, Inc.