



Intercept Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Business Update

November 5, 2019

Worldwide Ocaliva net sales of \$61.5 million in the third quarter of 2019 representing 32% growth versus the prior year quarter; increasing full year 2019 worldwide Ocaliva net sales guidance range to between \$245 million and \$250 million

U.S. NDA for NASH submitted; EU MAA submission for NASH planned for fourth quarter of 2019

New NASH and PBC clinical data to be presented at The Liver Meeting® 2019

Conference call scheduled for 8:30 a.m. ET today

NEW YORK, Nov. 05, 2019 (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 its financial results for the quarter ended September 30, 2019.

"During the third quarter, we submitted our NDA seeking accelerated approval of OCA for NASH in the U.S., a historic achievement for our company and a critically important milestone for the many patients currently without an approved treatment," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "With the submission behind us, we are actively preparing to launch the first therapy for advanced fibrosis due to NASH and our pre-launch disease state educational activities are accelerating with the continued expansion of our sales, medical and market access teams. In addition, we are looking forward to the presentation of important new data from the interim analysis of our ongoing Phase 3 REGENERATE study at the upcoming AASLD Liver Meeting. Based on our team's strong commercial execution in the third quarter, I am also pleased to announce that we are increasing our 2019 net sales guidance for Ocaliva to between \$245 million and \$250 million."

Ocaliva® (obeticholic acid) Commercial Highlights

We recognized \$61.5 million of worldwide Ocaliva net sales in the third quarter of 2019, as compared to \$46.6 million in the prior year quarter. Ocaliva net sales in the third quarter of 2019 were comprised of U.S. net sales of \$45.2 million and ex-U.S. net sales of \$16.3 million, as compared to U.S. net sales of \$36.7 million and ex-U.S. net sales of \$9.9 million in the prior year quarter.

Ocaliva was approved in the United States by the FDA in May 2016 and by the European Commission in December 2016 for the treatment of primary biliary cholangitis ("PBC") in combination with ursodeoxycholic acid ("UDCA") in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. Since December 2016, Ocaliva has also received regulatory approval in several of our target markets outside the United States and Europe, including Canada, Israel and Australia.

Selected Third Quarter 2019 Financial Results

Revenues

We recognized \$61.9 million in total revenue in the third quarter of 2019, as compared to \$47.0 million in total revenue in the prior year quarter. Total revenue in the third quarter of 2019 included \$61.5 million of Ocaliva net sales and approximately \$0.4 million of licensing revenue, as compared to \$46.6 million and approximately \$0.4 million, respectively, in the prior year quarter.

Operating Expenses

Our cost of sales was \$0.5 million in the third quarter of 2019, as compared to \$0.5 million in the prior year quarter. Our cost of sales for the quarters ended September 30, 2019 and 2018 consisted primarily of packaging, labeling, materials and related expenses.

Our selling, general and administrative expenses increased to \$76.8 million in the third quarter of 2019, up from \$56.8 million in the prior year quarter. The increase was primarily driven by increases in launch preparation activities related to our lead product candidate, obeticholic acid ("OCA"), for the potential treatment of liver fibrosis due to NASH.

Our research and development expenses increased to \$60.2 million in the third quarter of 2019, up from \$47.9 million in the prior year quarter. The increase was primarily driven by increases in development program expenses relating to OCA for NASH and costs associated with the NDA submission.

In the quarters ended September 30, 2019 and 2018, we recorded \$137.5 million and \$105.3 million, respectively, in total operating expenses and \$122.1 million and \$92.2 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of \$13.1 million and \$12.0 million, respectively, and depreciation and amortization expense of \$2.2 million and \$1.1 million, respectively.

References in this press release to "non-GAAP adjusted operating expenses" mean our total operating expenses, as calculated and presented in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"), adjusted for the effects of two non-cash items: stock-based compensation and depreciation and amortization. See "Non-GAAP Financial Measures" below. A reconciliation of non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included below under the heading "Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses."

Interest Expense

Interest expense in the quarters ended September 30, 2019 and 2018 was \$11.8 million and \$7.7 million, respectively. Our interest expense is related

to the \$460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the “2023 Convertible Notes”) that we issued in July 2016 and \$230 million aggregate principal amount of 2.00% Convertible Senior Notes due 2026 (the “2026 Convertible Notes”) that we issued in May 2019.

Net Loss

In the third quarter of 2019, we reported a net loss of \$84.8 million, up from a net loss of \$64.5 million in the prior year quarter.

Cash Position

As of September 30, 2019, we had cash, cash equivalents and investment debt securities available for sale of approximately \$712.4 million. As of December 31, 2018, we had cash, cash equivalents and investment debt securities available for sale of approximately \$436.2 million.

2019 Financial Guidance

Based on our third quarter results and our current outlook for the remainder of 2019, we are increasing our 2019 Ocaliva net sales guidance range to between \$245 million and \$250 million, from \$235 million to \$245 million. In addition, we are narrowing our 2019 non-GAAP adjusted operating expenses guidance range to between \$480 million and \$500 million, from \$470 million to \$500 million. See “Non-GAAP Financial Measures” below. 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.

Conference Call on November 5, 2019 at 8:30 a.m. ET

We are hosting our third quarter 2019 financial results conference call and webcast on Tuesday, November 5, 2019 at 8:30 a.m. ET. The conference call will be available on the investor page of our website at <http://ir.interceptpharma.com> or by calling (855) 232-3919 (toll-free domestic) or (315) 625-6894 (international) five minutes prior to the start time (no passcode is required). A replay of the call will be available on our website shortly following the completion of the call and will be available for 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). 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](#).

Non-GAAP Financial Measures

This press release presents non-GAAP adjusted operating expenses on a historical and projected basis. For the periods presented, 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 and amortization. Non-GAAP adjusted operating expenses is 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 table reconciling non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included below under the heading “Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses”. 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.

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 and, as early as 2020, the disease is projected to become the leading cause of liver transplants in the United States. There are currently no medications approved for the treatment of NASH.

About the REGENERATE Study

REGENERATE is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study assessing the safety and efficacy of obeticholic acid (OCA) on clinical outcomes in patients with liver fibrosis due to NASH. A pre-specified 18-month analysis was conducted to assess the effect of OCA on liver histology comparing month 18 biopsies with baseline. REGENERATE has completed target enrollment for the clinical outcomes cohort, with more than 2,400 adult NASH patients randomized across 339 qualified centers worldwide, and will continue through clinical outcomes for verification and description of clinical benefit. The end-of-study analysis will evaluate the effect of OCA on all-cause mortality and liver-related clinical outcomes, as well as its long-term safety.

About Ocaliva® (obeticholic acid)

Ocaliva is indicated in the United States for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

This indication is approved under the accelerated approval pathway based on a reduction in alkaline phosphatase (ALP) as a surrogate endpoint which is reasonably likely to predict clinical benefit, including an improvement in liver transplant free-survival. 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. We are conducting a Phase 4 clinical outcomes trial, which we refer to as our COBALT trial, of OCA in patients with PBC with the goal of confirming clinical benefit on a post-marketing basis.

In December 2016, Ocaliva received conditional marketing authorization in Europe for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA, conditioned upon us providing further data post-approval to confirm benefit. For detailed safety information for Ocaliva 5 mg and 10 mg tablets including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European Summary of Product Characteristics that can be found on www.ema.europa.eu.

U.S. IMPORTANT SAFETY INFORMATION FOR OCALIVA IN PBC

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS

- **In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with Primary Biliary Cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.**
- **The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.**

Contraindications

OCALIVA is contraindicated in PBC patients with complete biliary obstruction.

Warnings and Precautions

Hepatic Decompensation and Failure in Incorrectly-Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in PBC patients with decompensated cirrhosis or Child-Pugh B or C hepatic impairment when OCALIVA was dosed more frequently than the recommended starting dosage of 5 mg once weekly. Reported cases typically occurred within 2 to 5 weeks after starting OCALIVA and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (e.g., ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy).

Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption or discontinuation may be required. Close monitoring is recommended for patients at an increased risk of hepatic decompensation. Severe intercurrent illnesses that may worsen renal function or cause dehydration (e.g., gastroenteritis), may exacerbate the risk of hepatic decompensation. Interrupt treatment with OCALIVA in patients with laboratory or clinical evidence of worsening liver function indicating risk of decompensation, and monitor the patient's liver function. Consider discontinuing OCALIVA in patients who have experienced clinically significant liver-related adverse reactions. Discontinue OCALIVA in patients who develop complete biliary obstruction.

Liver-Related Adverse Reactions

Dose-related, liver-related adverse reactions including jaundice, worsening ascites and primary biliary cholangitis flare have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once daily up to 50 mg once daily (up to 5-times the highest recommended dosage). Monitor PBC patients during treatment with OCALIVA for elevations in liver biochemical tests and for the development of liver-related adverse reactions.

Severe Pruritus

Severe pruritus was reported in 23% of PBC patients in the OCALIVA 10 mg arm, 19% of PBC patients in the OCALIVA titration arm, and 7% of PBC patients in the placebo arm in a 12-month double-blind randomized controlled trial of 216 PBC 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 PBC patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid 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 PBC patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor PBC patients for changes in serum lipid levels during treatment. For PBC 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 from subjects taking OCALIVA for PBC were 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 coadministering OCALIVA and warfarin.

CYP1A2 Substrates with Narrow Therapeutic Index

Obeticholic acid, the active ingredient in OCALIVA, 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 coadministered 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 see [Full Prescribing Information, including Boxed WARNING](#) and [Medication Guide](#) for OCALIVA.

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 contains forward-looking statements, including, but not limited to, statements regarding 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 development candidates, including OCA for NASH, the timing and acceptance of our potential regulatory filings and potential approval of OCA for NASH or any other indications in addition to PBC, the timing and potential commercial success of OCA and any other product candidates we may develop and our strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans, objectives of management and expected market growth.

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. The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by our forward-looking statements: our ability to successfully commercialize Ocaliva for PBC; our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization; the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, retaining patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials; our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates, including OCA for NASH, in the United States, Europe and our other target markets; conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations and/or warnings contained in the label of any of our products or product candidates; any potential side effects associated with Ocaliva for PBC, OCA for NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions, or otherwise limit the sale of such product or product candidate; our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for NASH, and our clinical trial activities; our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to timely and successfully launch OCA for NASH, if approved; our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights; the size and growth of the markets for our products and product candidates and our ability to serve those markets; the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for NASH or our other product candidates among physicians, patients and healthcare payors; the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for NASH, and our ability to obtain adequate pricing for such products; our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties; competition from existing drugs or new drugs that become available; our ability to prevent system failures, data breaches or violations of data protection laws; costs and outcomes relating to any disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation; our collaborators’ election to pursue research, development and commercialization activities; our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise; our need for and ability to generate or obtain additional financing; our estimates regarding future expenses, revenues and capital requirements and the accuracy thereof; our use of cash and short-term investments; our ability to acquire, license and invest in businesses, technologies, product candidates and products; our ability to attract and retain key personnel to manage our business effectively; our ability to manage the growth of our operations, infrastructure, personnel, systems and controls; our ability to obtain and maintain adequate insurance coverage; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and the other risks and uncertainties identified in our periodic filings filed with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2018.

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Intercept Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue, net	\$ 61,545	\$ 46,581	\$ 179,286	\$ 124,908
Licensing revenue	405	405	1,216	1,616
Total revenue	61,950	46,986	180,502	126,524
Operating expenses:				
Cost of sales	487	519	1,738	1,512
Selling, general and administrative	76,828	56,812	223,738	184,503
Research and development	60,168	47,941	178,163	144,028
Total operating expenses	137,483	105,272	403,639	330,043
Operating loss	(75,533)	(58,286)	(223,137)	(203,519)
Other income (expense):				
Interest expense	(11,795)	(7,671)	(29,518)	(22,769)
Other income, net	2,495	1,503	6,132	5,051
Net loss	\$ (84,833)	\$ (64,454)	\$ (246,523)	\$ (221,237)
Net loss per common and potential common share:				
Basic and diluted	\$ (2.59)	\$ (2.18)	\$ (7.88)	\$ (7.89)
Weighted average common and potential common shares outstanding:				
Basic and diluted	32,717	29,615	31,275	28,057

Condensed Consolidated Balance Sheet Information
(In thousands)

	September 30, 2019 (Unaudited)	December 31, 2018 (1)
Cash, cash equivalents and investment debt securities	\$ 712,371	\$ 436,160
Total assets	\$ 802,094	\$ 509,167
Deferred revenue, total	\$ 1,216	\$ 2,432
Total liabilities (2)	\$ 671,359	\$ 490,037
Stockholders' equity	\$ 130,735	\$ 19,130

- (1) Derived from the audited financial statements included in Intercept's Annual Report on Form 10-K for the year ended December 31, 2018. Includes \$525.3 million related to the 2023 Convertible Notes and the 2026 Convertible Notes (together, the "Convertible Notes") as of September 30, 2019. Includes \$371.2 million related to the 2023 Convertible Notes as of December 31, 2018. Intercept separately accounts for the debt and equity components of the Convertible Notes. The aggregate outstanding principal amount of the Convertible Notes was \$690.0 million as of September 30, 2019, and the aggregate outstanding principal amount of the 2023 Convertible Notes was \$460.0 million as of December 31, 2018.

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total operating expenses	\$ 137,483	\$ 105,272	\$ 403,639	\$ 330,043
Adjustments:				
Stock-based compensation	13,130	11,994	42,809	38,415
Depreciation and amortization	2,203	1,123	6,813	3,551
Non-GAAP adjusted operating expenses	\$ 122,150	\$ 92,155	\$ 354,017	\$ 288,077



Source: Intercept Pharmaceuticals, Inc.