Intercept Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Business Update

October 31, 2018

- *Worldwide Ocaliva net sales of $46.6 million in the third quarter of 2018*
- *Leading Phase 3 NASH program continues to advance: REGENERATE trial in NASH patients with advanced liver fibrosis expected to report data in the first half of 2019*

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

NEW YORK, Oct. 31, 2018 (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, 2018.

“2018 has been an important year for Intercept as we have continued to make progress executing against our key strategic priorities in our Phase 3 NASH program and our PBC commercial efforts,” said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. “We remain on track to report top line data from the Phase 3 REGENERATE trial in the first half of 2019. We have also continued to advance our efforts to bring Ocaliva to eligible PBC patients in need and believe that we are well positioned to drive growth and capitalize on this sizeable market opportunity.”

Ocaliva® (obeticholic acid or OCA) Commercial Highlights

We recorded $46.6 million of Ocaliva net sales in the third quarter of 2018, as compared to $40.9 million in the prior year quarter. Ocaliva net sales in the third quarter of 2018 were comprised of U.S. net sales of $36.7 million and ex-U.S. net sales of $9.9 million, as compared to U.S. net sales of $36.2 million and ex-U.S. net sales of $4.7 million in the prior year quarter.

Ocaliva was approved in the United States by the U.S. Food and Drug Administration (“FDA”) in May 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. We commenced sales and marketing of Ocaliva in the United States shortly after receiving marketing approval, and Ocaliva is now available to patients primarily through a network of specialty pharmacy distributors.

Ocaliva was granted conditional approval by the European Commission in December 2016 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, and we commenced our European commercial launch in January 2017. Since January 2017, 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 2018 Financial Results

Revenues

We recognized $47.0 million in total revenue in the quarter ended September 30, 2018, up from $41.3 million in total revenue in the quarter ended September 30, 2017. Total revenue in the third quarter of 2018 included $46.6 million of Ocaliva net sales and approximately $0.4 million of licensing revenue related to the amortization of upfront payments under our license agreement with Sumitomo Dainippon Pharma Co., Ltd., as compared to $40.9 million and approximately $0.4 million, respectively, in the prior year quarter. Included in total revenue in the third quarter of 2017 is $4.1 million of previously deferred revenue recognized in connection with our adoption of a sell-in basis revenue recognition policy in such quarter.

Operating Expenses

Our cost of sales was $0.5 million in the third quarter of 2018, as compared to $0.2 million in the prior year quarter. Prior to the FDA's approval of Ocaliva, we expensed costs related to the manufacturing and buildup of our Ocaliva commercial launch supplies. As a result, our cost of sales in the quarters ended September 30, 2018 and 2017 consisted primarily of packaging and labeling expenses.

Our selling, general and administrative expenses decreased to $56.8 million in the quarter ended September 30, 2018, down from $61.4 million in the prior year quarter. The decrease was primarily driven by a decrease in consultant spend and personnel-related costs.

Research and development expenses increased to $47.9 million in the quarter ended September 30, 2018, up from $46.0 million in the prior year quarter. The increase was primarily driven by an increase in OCA research and development activities and other costs.

In the quarters ended September 30, 2018 and 2017, we recorded $105.3 million and $107.5 million, respectively, in total operating expenses and $92.2 million and $92.9 million, respectively, in non-GAAP adjusted operating expenses, which excludes non-cash stock-based compensation expense of $12.0 million and $13.2 million, respectively, and depreciation expense of $1.1 million and $1.4 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. 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

Our interest expense in the quarters ended September 30, 2018 and 2017 was $7.7 million and $7.4 million, respectively. Our interest expense is

related to the $460.0 million aggregate principal amount of 3.25% Convertible Senior Notes due 2023 (the “Convertible Notes”) that we issued in July 2016.

Net Loss

During the third quarter of 2018, we reported a net loss of $64.5 million, down from a net loss of $72.6 million in the prior year quarter.

Cash Position

As of September 30, 2018, we had cash, cash equivalents and investment securities available for sale of approximately $489.1 million. As of December 31, 2017, we had cash, cash equivalents and investment securities available for sale of approximately $414.9 million.

2018 Financial Guidance

Based on our third quarter results and our current outlook for the remainder of 2018, we are confirming our previously announced 2018 Ocaliva net sales guidance range of between $170 million and $185 million. In addition, we are confirming our previously announced 2018 non-GAAP adjusted operating expenses guidance range of between $390 million and $410 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 October 31, 2018 at 8:30 a.m. ET

We are hosting our third quarter 2018 financial results conference call and webcast on Wednesday, October 31, 2018 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), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. Founded in 2002 in New York, Intercept has operations in the United States, Europe and Canada.

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. 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 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 accelerated approval 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

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 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 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 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 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 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 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 from subjects taking OCALIVA 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"), the potential approval of OCA for indications other than primary biliary cholangitis ("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 or completing and timely reporting the results of our NASH or PBC clinical trials; our ability to timely and cost-effectively obtain regulatory approval of our product candidates, including OCA for NASH; 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 maintain our relationships with, and the performance of, third-party vendors upon whom we are substantially dependent, including contract research organizations for our clinical trials and our third-party suppliers and manufacturers; our ability to identify, develop and commercialize our products and product candidates; our ability to obtain and maintain intellectual property protection for our products and product candidates; our ability to successfully commercialize our product candidates, if approved; 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, which may be affected by the ability of patients and healthcare providers to obtain coverage or reimbursement from payors for our products and the extent to which such coverage or reimbursement is provided; our ability to establish and maintain an effective sales and marketing infrastructure 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 attract and maintain collaborators with development, regulatory and commercialization expertise; our need for and ability to obtain additional financing; our estimates regarding 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; 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, 2017.

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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,	
	2018	2017	2018	2017
Revenue:				
Product revenue, net	$ 46,581	$ 40,889	$ 124,908	$ 91,933
Licensing revenue	405	445	1,616	1,336
Total revenue	46,986	41,334	126,524	93,269
Operating expenses:				
Cost of sales	519	172	1,512	548
Selling, general and administrative	56,812	61,356	184,503	189,363
Research and development	47,941	45,977	144,028	134,001

Total operating expenses	105,272	107,505	330,043	323,912
Operating loss	(58,286)	(66,171)	(203,519)	(230,643)
Other income (expense):				
Interest expense	(7,671)	(7,354)	(22,769)	(21,840)
Other income, net	1,503	924	5,051	3,388
	(6,168)	(6,430)	(17,718)	(18,452)
Net loss	$ (64,454)	$ (72,601)	$ (221,237)	$ (249,095)
Net loss per common and potential common share:				
Basic and diluted	$ (2.18)	$ (2.89)	$ (7.89)	$ (9.96)
Weighted average common and potential common shares outstanding:				
Basic and diluted	29,615	25,104	28,057	25,021

Condensed Consolidated Balance Sheet Information
(In thousands)

	September 30, 2018 (Unaudited)	December 31, 2017(1)
Cash, cash equivalents and investment securities	$ 489,093	$ 414,917
Total assets	$ 556,953	$ 484,347
Deferred revenue, total	$ 2,838	$ 4,454
Total liabilities (2)	$ 461,144	$ 467,961
Stockholders' equity	$ 95,809	$ 16,386

(1) Derived from the audited financial statements included in Intercept's Annual Report on Form 10-K for the year ended December 31, 2017.

(2) Includes $367.2 million and $355.7 million related to the Convertible Notes as of September 30, 2018 and December 31, 2017, respectively. Intercept separately accounts for the debt and equity components of the Convertible Notes. The aggregate outstanding principal amount of the Convertible Notes was $460.0 million as of September 30, 2018 and December 31, 2017.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Total operating expenses	$ 105,272	$ 107,505	$ 330,043	$ 323,912
Adjustments:				
Stock-based compensation	11,994	13,237	38,415	41,584
Depreciation	1,123	1,382	3,551	3,256
Non-GAAP adjusted operating expenses	$ 92,155	$ 92,886	$ 288,077	$ 279,072

Source: Intercept Pharmaceuticals, Inc.