November 1, 2017

Intercept Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Business Update

- ***Worldwide net Ocaliva® (obeticholic acid or OCA) 3Q 2017 sales of $40.9 million (including one-time increase of $4.1M in deferred net revenue)***
- ***Continuing to advance NASH Phase 3 program: REGENERATE trial in NASH fibrosis on track and NASH cirrhosis trial to initiate by year end 2017***

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

NEW YORK, Nov. 01, 2017 (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 reported financial results for the three months ended September 30, 2017, and provided other general business updates.

"We are pleased with our solid commercial performance, with continued quarter over quarter growth underscoring Ocaliva's importance as a new treatment option in PBC," said Mark Pruzanski, M.D., President and CEO of Intercept.

"We have continued to build on our leadership position in NASH and are planning to initiate our Phase 3 cirrhosis trial by the end of this year," added Dr. Pruzanski. "The interim analysis in our flagship Phase 3 REGENERATE trial is on track to report in the first half of 2019, and is intended to support the filing of a supplemental New Drug Application for accelerated approval of OCA in NASH patients with fibrosis. We also recently presented positive results of our Phase 2 AESOP trial in primary sclerosing cholangitis (PSC) at The Liver Meeting hosted by AASLD, establishing proof-of-concept in another progressive, cholestatic liver disease with high unmet need."

Ocaliva Third Quarter Commercial Highlights

Intercept recorded $40.9 million of worldwide net Ocaliva sales, including a change in estimate related to deferred revenue with a net effect of a one-time increase of $4.1 million in net revenue for the quarter. Net U.S. Ocaliva sales were $36.2 million, which included $3.7 million for the change in estimate related to deferred revenue.

Ocaliva was approved 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. Intercept commercially launched Ocaliva in the United States in June 2016 and in conjunction launched Interconnect®, a comprehensive, personalized program that connects patients with dedicated care coordinators who help them understand their disease and provides treatment support and, for eligible patients, financial assistance options.

Net ex-U.S. international Ocaliva sales were $4.7 million for the third quarter of 2017, which included $0.4 million for the change in estimate related to deferred revenue.

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. We commenced our European commercial launch in January 2017. Ocaliva was granted conditional approval by Health Canada in May 2017.

Upcoming Milestones

- PBC Program
  - Continue growth in ongoing Ocaliva launch in U.S., Europe and Canada
  - Updated U.S. label for Ocaliva anticipated by early 2018
  - Continue enrolling COBALT (Phase 4 confirmatory trial in PBC)
- NASH Program
  - Continue enrolling clinical outcomes cohort in REGENERATE (Phase 3 trial in NASH patients with fibrosis)
  - Initiate Phase 3 trial in NASH patients with cirrhosis by YE 2017
- Pipeline

- Define path forward for OCA in PSC in 2018

Third Quarter 2017 Financial Results
During the quarter, Intercept reported a net loss of $72.6 million. GAAP operating expense was $107.5 million, and non-GAAP adjusted operating expense[1] was $92.9 million, excluding non-cash stock-based compensation expense of $13.2 million and depreciation expense of $1.4 million.

Revenues
Intercept recognized $40.9 million of net sales of Ocaliva, which included a one-time increase of $4.1 million in deferred net revenue.

Prior to July 2017, Intercept recognized revenue using the sell-through method (i.e., recognition occurred when its specialty pharmacies dispensed Ocaliva to patients, not when products were sold to the specialty pharmacies). During the third quarter of 2017, Intercept revenue recognition transitioned from the sell-through method to the sell-in method as a sufficient period of commercial experience had occurred to enable the Company to reasonably estimate product returns.

[1] Adjusted operating expense, as presented above and elsewhere in this press release, is a non-GAAP financial measure. Adjusted operating expense excludes stock-based compensation and other non-cash items from GAAP operating expenses. A table reconciling historical adjusted operating expense to GAAP operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense."

Intercept recognized $0.4 million and $0.4 million of license revenue related to the amortization of the up-front and milestone payments under the collaboration agreement with Sumitomo Dainippon for the third quarters ended September 30, 2017 and 2016, respectively.

Expenses

Cost of goods sold (COGS) was negligible for the third quarter of 2017. Prior to the FDA approval of Ocaliva, Intercept had expensed costs related to the manufacturing and buildup of commercial launch supplies of OCA. Therefore, COGS was only reflective of packaging and labeling costs incurred during the period. Intercept expects COGS to remain negligible until previously expensed supplies of OCA are sold.

Selling, general and administrative expenses increased to $61.4 million for the quarter, up from $52.8 million for the same period last year. The increase from the prior period was primarily driven by personnel-related costs to support commercial and international initiatives and an increase in indirect expenses.

Research and development expenses increased to $46.0 million for the quarter, up from $35.4 million for the same period last year. The increase over the prior period was primarily driven by increases in clinical development programs for OCA and infrastructure to support such programs.

Interest expense for the quarter was $7.4 million. The interest expense is related to the 3.25% convertible senior notes due 2023 issued in July 2016.

Nine Months Ended September 30, 2017

Intercept reported a net loss of $249.1 million for the nine months ended September 30, 2017, compared to a net loss of $292.8 million for the nine months ended September 30, 2016. The net loss included $41.6 million and $27.0 million of non-cash stock-based compensation expenses for the nine months ended September 30, 2017 and 2016, respectively, as well as a one-time net expense of $45.0 million for the settlement of the purported securities class action lawsuit in the nine months ended September 30, 2016.

Cash Position
As of September 30, 2017, Intercept had cash, cash equivalents and investment securities available for sale of approximately $492.7 million, compared to $689.4 million as of December 31, 2016.

Financial guidance

Intercept projects non-GAAP adjusted operating expenses for the fiscal year ending December 31, 2017 will fall in the middle of the previously guided range of $380 million to $420 million. This guidance excludes non-cash items such as stock-based compensation and depreciation. These expenses are planned to support the continued commercialization of Ocaliva in PBC in the United States and other markets and the continued development for OCA in PBC, NASH, PSC and biliary atresia. In order to streamline operating expenses, Intercept has decided to deprioritize its INT-767 development program

for the foreseeable future.

Intercept anticipates that stock-based compensation expense will represent the most significant non- cash item that will be excluded in adjusted operating expenses as compared to operating expenses under GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. A reconciliation of projected operating expense calculated in accordance with GAAP to non- GAAP adjusted operating expense is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense.

Management Update

Intercept announced today that Rachel McMinn, Ph.D. will be leaving Intercept at the end of the year to pursue an entrepreneurial opportunity in a different therapeutic area. Effective as of November 1, 2017, Dr. McMinn is stepping down from her position as Chief Business and Strategy Officer and will act in an advisory capacity through December 31, 2017.

"We greatly appreciate Rachel's significant contributions to the company, which helped to accelerate our transition from a small company of approximately 50 people to a global commercial biopharmaceutical company," said Mark Pruzanski, M.D., Chief Executive Officer. "We are fortunate to have had her leadership during a critical time in the company's life cycle, and wish her success in the next chapter of her career."

"I am grateful for the opportunity to have worked at Intercept during this formative growth period. Nonetheless, I have been considering for some time and am excited to begin an entrepreneurial venture in an area I am deeply passionate about," said Dr. McMinn. "As the leader in the field of progressive non-viral liver diseases, Intercept continues to make important progress for patients, and I look forward to following the company's future progress."

Conference Call on November 1st at 8:30 a.m. ET

Intercept will hold its third quarter 2017 financial results conference call and webcast on Wednesday, November 1st at 8:30 a.m. ET. The live event will be available on the investor page of the Intercept 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 the Intercept website approximately two hours after the completion of the call and will be archived for two weeks.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, including primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. Founded in 2002 in New York, Intercept now has operations in the United States, Europe and Canada.

Non-GAAP Financial Measures

This press release presents adjusted operating expense, which is a non-GAAP measure, both on a historical and projected basis. Adjusted operating expense should be considered in addition to, but not as a substitute for, operating expense that Intercept prepares and announces in accordance with GAAP. Intercept excludes certain items from adjusted operating expense, such as stock-based compensation and depreciation, that management does not believe affect Intercept's basic operations and that do not meet the GAAP definition of unusual or nonrecurring items. For the nine months ended September 30, 2016, adjusted operating expense also excludes the one-time $45 million net expense for the settlement of the purported class action lawsuit.

A table reconciling historical GAAP operating expense to non-GAAP adjusted operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense." A reconciliation of projected operating expense calculated in accordance with GAAP to non-GAAP adjusted operating expense is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage Intercept's business. Other companies may define this measure in different ways. Intercept believes this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

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. Intercept is currently enrolling COBALT, a Phase 4 clinical outcomes trial of Ocaliva 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, conditional to the company providing further data post-approval to confirm benefit. For detailed safety information for Ocaliva (obeticholic acid) 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
Contraindications
Ocaliva is contraindicated in patients with complete biliary obstruction.

Warnings and Precautions

Liver-Related Adverse Reactions

In two 3-month, placebo-controlled clinical trials a dose-response relationship was observed for the occurrence of liver-related adverse reactions including jaundice, 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 a pooled analysis of three placebo-controlled trials in patients with PBC, the exposure-adjusted incidence rates for all serious and otherwise clinically significant liver-related adverse reactions, and isolated elevations in liver biochemical tests, per 100 patient exposure years (PEY) were: 5.2 in the Ocaliva 10 mg group (highest recommended dosage), 19.8 in the Ocaliva 25 mg group (2.5 times the highest recommended dosage) and 54.5 in the Ocaliva 50 mg group (5 times the highest recommended dosage) compared to 2.4 in the placebo group.

Monitor patients during treatment with Ocaliva for elevations in liver biochemical tests and for the development of liver-related adverse reactions. Weigh the potential risks against the benefits of continuing treatment with Ocaliva in patients who have experienced clinically significant liver-related adverse reactions. The maximum recommended dosage of Ocaliva is 10 mg once daily. Adjust the dosage for patients with moderate or severe hepatic impairment.

Discontinue Ocaliva in patients who develop complete biliary obstruction.

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 the POISE trial, 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. In the subgroup of patients in the Ocaliva titration arm who increased their dosage from 5 mg once daily to 10 mg once daily after 6 months of treatment (n=33), the incidence of severe pruritus was 0% from months 0 to 6 and 15% from months 6 to 12. The median time to onset of severe pruritus was 11, 158 and 75 days for patients in the Ocaliva 10 mg, Ocaliva titration and placebo arms, respectively.

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 (HDLC). In the POISE trial, 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. At month 12, the reduction from baseline in mean HDL-C level was 19% in the Ocaliva 10 mg arm, 12% in the Ocaliva titration arm and 2% in the placebo arm. Nine patients in the Ocaliva 10 mg arm and six patients in the Ocaliva titration arm, versus three patients in the placebo arm had reductions in HDL-C to less than 40 mg/dL.

Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to Ocaliva after one 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 (≥5%) were pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality and eczema.

Drug Interaction

Bile Acid Binding Resins
Bile acid binding resins such as cholestyramine, colestipol or colesevelam absorb and reduce bile acid absorption and may reduce the absorption, systemic exposure and efficacy of Ocaliva. If taking bile acid binding resins, take Ocaliva at least 4 hours before or 4 hours after (or at as great an interval as possible) taking a bile acid binding resin.

Please see the U.S. Full Prescribing Information for Ocaliva (obeticholic acid) 5 mg and 10 mg tablets.

Safe Harbor Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Intercept's financial position, including expected adjusted operating expenses; the planned revisions to the label for Ocaliva and the timing and impact related thereto; the activities anticipated to be undertaken by Intercept, including the anticipated progression of the U.S. and ex-U.S. launches of Ocaliva® in PBC; the potential approval of OCA in PBC by regulatory bodies outside of jurisdictions in which Ocaliva is approved for use and the timelines related thereto; the timelines for access to OCA for the treatment of PBC in Europe and other jurisdictions outside the United States and timelines related thereto; the initiation, enrollment, conduct and completion of clinical trials and the timelines related thereto, including the initiation of the Phase 3 trial of OCA in NASH patients with cirrhosis; the anticipated regulatory process and timetable with respect to Intercept's product candidates; the continued development of OCA and Intercept's other product candidates; and Intercept's strategic directives under the caption "About Intercept." These "forward- looking statements" are based on management's current expectations of future events and are subject to a number of important risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the potential benefit and commercial potential of Ocaliva in PBC, and Intercept's ability to maintain its regulatory approval in jurisdictions in which Ocaliva is approved for use in PBC; the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials, including Intercept's development program in NASH; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA in PBC in countries outside the ones in which it is approved and in indications other than PBC and any other product candidates it may develop such as INT-767; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its 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 in the label of any approved products and product candidates; Intercept's plans to research, develop and commercialize its product candidates; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates; Intercept's ability to successfully commercialize OCA in indications other than PBC and its other product candidates; the size and growth of the markets for Intercept's products and product candidates and its ability to serve those markets; the rate and degree of market acceptance of any of Intercept's products, which may be affected by the reimbursement that it may receive for its products from payors; the success of competing drugs that are or become available; the election by Intercept's collaborators to pursue research, development and commercialization activities; Intercept's ability to attract collaborators with development, regulatory and commercialization expertise; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; Intercept's use of cash, short-term investments and the proceeds from the offering; Intercept's ability to attract and retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2016 filed on March 1, 2017 as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Intercept undertakes no duty to update this information unless required by law.

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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,	
	2017	2016	2017	2016
Revenue:				
Product revenue, net	$ 40,889	$ 4,732	$ 91,933	$ 4,807
Licensing revenue	445	445	1,336	6,336
Total revenue	41,334	5,177	93,269	11,143
Operating expenses:				
Cost of sales	172	-	548	-
Selling, general and administrative	61,356	52,802	189,363	197,382
Research and development	45,977	35,411	134,001	102,292
Total operating expenses	107,505	88,213	323,912	299,674
Operating loss	(66,171)	(83,036)	(230,643)	(288,531)
Other income (expense):				
Interest expense	(7,354)	(7,065)	(21,840)	(7,065)
Other income, net	924	1,286	3,388	2,807
	(6,430)	(5,779)	(18,452)	(4,258)
Net loss	$ (72,601)	$ (88,815)	$ (249,095)	$ (292,789)
Net loss per common and potential common share:				
Basic and diluted	$ (2.89)	$ (3.59)	$ (9.96)	$ (11.90)
Weighted average common and potential common shares outstanding:				
Basic and diluted	25,101	24,738	25,021	24,614

Condensed Consolidated Balance Sheet Information
(Unaudited)
(In thousands)

	September 30, 2017	December 31, 2016
Cash, cash equivalents and investment securities	$ 492,750	$ 689,385
Total assets	$ 560,426	$ 739,253
Deferred revenue, total	$ 4,900	$ 10,147
Total liabilities	$ 448,759	$ 424,321
Stockholders' equity	$ 111,667	$ 314,932

Reconciliation of GAAP to Non-GAAP Operating Expense
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Total operating expense	$ 107,505	$ 88,213	$ 323,912	$ 299,674
Adjustments:				
Stock based compensation	13,237	12,544	41,584	27,041
Depreciation	1,382	643	3,256	2,187
Litigation settlement	-	-	-	45,000
Adjusted operating expense	$ 92,886	$ 75,026	$ 279,072	$ 225,446