August 4, 2016

Intercept Pharmaceuticals Reports Second Quarter 2016 Financial Results and Provides Business Update

- ***Ocaliva® (obeticholic acid or OCA) approved by the FDA under the accelerated approval pathway on May 27, 2016***
- ***Net Ocaliva 2Q sales of $75,000 shipped to patients, $2.7 million recorded as deferred revenue***
- ***REGENERATE NASH trial targeted to complete enrollment for interim analysis in 1H17***

Conference call scheduled for 8:30 am ET today

NEW YORK, Aug. 04, 2016 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, today reported financial results for the three and six months ended June 30, 2016 and provided other general business updates.

"The approval of Ocaliva in the United States for the treatment of PBC was a momentous event not just for the company, but also for patients with PBC, who have been without a new therapeutic option for nearly 20 years," said Mark Pruzanski, M.D., President and CEO of Intercept. "While it is still very early days, I am pleased with the progress of the launch to date. Our organization was well prepared and within a few days of approval we had Ocaliva shipped to specialty pharmacies and our Territory Business Managers had begun reaching out to key physicians."

"We look forward to continuing our efforts to bring Ocaliva to PBC patients worldwide," added Dr. Pruzanski.

Ocaliva Commercial Update
Following a 17 to 0 FDA Advisory Committee vote in favor of accelerated approval, Ocaliva was approved by the FDA on May 27 for the treatment of 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 launched Ocaliva 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.

Anticipated Upcoming Development Milestones

- Primary Biliary Cholangitis [PBC] Program
  - Planned submission of updated COBALT Phase 4 clinical trial protocol to regulatory authorities by YE16
  - EU marketing approval decision anticipated by YE 2016
- NASH Program
  - Phase 2 CONTROL trial enrollment completion expected by YE 2016
  - Phase 3 REGENERATE trial enrollment completion for interim analysis expected in 1H 2017
- Primary Sclerosing Cholangitis (PSC) Program
  - Phase 2 AESOP trial enrollment completion expected by YE 2016
- INT-767 Program
  - Phase 1 trial completion expected by YE 2016

Financial Results
Three Months Ended June 30, 2016

For the three months ended June 30, 2016, Intercept reported a net loss of $77.3 million. GAAP operating expense for the three months ended June 30, 2016 was $83.6 million. Non-GAAP adjusted operating expense[1] for the three months ended June 30, 2016 was $78.5 million, which excludes non-cash stock-based compensation expense of $4.3 million and depreciation expense of $0.9 million.

Revenues

The Company recognized $75,000 of net sales of Ocaliva for the second quarter of 2016, pursuant to the product launch in June. The Company also recorded $2.7 million in deferred revenue on its balance sheet, which represents product shipped to distributors, but not sold through as of June 30, 2016. The Company currently recognizes revenue using the sell-through method, when its specialty pharmacies dispense Ocaliva to patients and not when the Company ships product to the specialty pharmacies. Revenue recognition will transition from the sell-through method to the sell-in method once a sufficient period of commercial experience has occurred to enable the Company to estimate product returns.

The Company recognized $5.4 million and $0.4 million of license revenue for the three months ended June 30, 2016 and 2015, respectively. For both the three months ended June 30, 2016 and June 30, 2015, $0.4 million was related to the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and for the three months ended June 30, 2016 an additional $5.0 million was recognized for a milestone achieved during the period under the collaboration.

Expenses

Costs of goods sold (COGS) was de minimis for the second quarter of 2016. Prior to the FDA approval of Ocaliva, the Company had expensed costs related to the manufacturing and build up of commercial launch supplies of OCA. Therefore, COGS was only reflective of packaging and labeling costs incurred in the quarter. The Company expects COGS to remain negligible until previously expensed supplies of OCA are sold.

Research and development expenses increased to $41.3 million for the three months ended June 30, 2016, up from $28.3 million for the three months ended June 30, 2015. The increase over the prior period was primarily driven by increased staff and respective expenses as well as increased activities around the Company's OCA research and development program.

General and administrative expenses increased to $42.3 million for the three months ended June 30, 2016, up from $21.0 million for the three months ended June 30, 2015. The increase over the prior period was driven by infrastructure expansion to support the Company's corporate and pre-commercial activities as well as increased market research supporting pre-launch activities in preparation for commercialization and to support future growth.

Six Months Ended June 30, 2016

Intercept reported a net loss of $204.0 million for the six months ended June 30, 2016, compared to a net loss of $87.3 million for the six months ended June 30, 2015. The net loss included $14.5 million and $16.4 million of non-cash stock-based compensation expenses for the six months ended June 30, 2016 and 2015, respectively, as well as a one-time net expense of $45.0 million for the proposed settlement of the purported securities class action lawsuit in the six months ended June 30, 2016.

Cash Position

As of June 30, 2016, Intercept had cash, cash equivalents and investment securities available for sale of approximately $439.5 million, compared to $628.1 million as of December 31, 2015. In July 2016, Intercept completed an underwritten public offering of 3.25% convertible senior notes due 2023 (convertible notes). After deducting the underwriting discount and offering expenses, Intercept estimates that net proceeds from the convertible notes offering were approximately $447.7 million. Approximately $38.4 million of the net proceeds from the offering were used to fund the payment of the cost of capped call transactions entered into in connection with the issuance of the convertible notes.

Financial guidance

Intercept projects non-GAAP adjusted operating expenses towards the lower end of the previously provided range of $360 million to $400 million for the fiscal year ending December 31, 2016. This guidance excludes the one-time net expense of $45.0 million for the settlement of the purported securities class action lawsuit, as well as non-cash items such as stock-based compensation. These expenses are planned to support the continued clinical development programs for OCA in PBC, NASH and PSC, increased OCA manufacturing activities, the continued development of INT-767 and other preclinical programs, as well as commercial activities in the United States and pre-commercial activities internationally.

Other than the class action lawsuit net settlement amount, which is a one-time expense, Intercept anticipates that stock-based compensation expense will represent the most significant non-cash item that is 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.

Conference Call on August 4th at 8:30 a.m. ET

Intercept will hold its second quarter financial results conference call and webcast on Thursday, August 4th 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 the one-time net expense of $45.0 million for the proposed settlement of the purported securities class action lawsuit, 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.

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.

A marketing authorization application for Ocaliva for the treatment of PBC was accepted by the European Medicines Authority (EMA) in June 2015 and is currently under review. The brand name Ocaliva has been provisionally approved by the EMA.

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 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 activities anticipated to be undertaken by Intercept, including the anticipated progression of the U.S. launch of Ocaliva® in PBC, the potential regulatory approval and launch of OCA in PBC outside the United States and the timelines related thereto; the initiation, enrollment, conduct and completion of clinical trials; the anticipated regulatory process and timetable with respect to Intercept's product candidates; Intercept's ongoing and anticipated buildout and hiring to support our growing business operations; 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: Intercept's ability to successfully commercialize Ocaliva in PBC, and Intercept's ability to maintain its regulatory approval of Ocaliva in the United States for Ocaliva in PBC; the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA in PBC in countries outside the United States 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 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 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 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 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, 2015 filed on February 29, 2016 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.

[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, in addition to the one-time net expense of $45 million for the proposed settlement of the purported class action lawsuit. A table reconciling adjusted operating expense to GAAP operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense."

Intercept Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenue:				
Product revenue, net	$ 75	$ -	$ 75	$ -
Licensing revenue	5,445	445	5,891	1,891
Total revenue	5,520	445	5,966	1,891
Costs and expenses:				
Research and development	41,340	28,295	78,753	56,260
General and administrative	42,275	20,974	132,707	34,112
Total costs and expenses	83,615	49,269	211,460	90,372
Other income (expense):				

Other income (expense), net	796	930	1,521	1,201
	796	930	1,521	1,201
Net loss attributable to common stockholders	$ (77,299)	$ (47,894)	$ (203,973)	$ (87,280)
Net loss per common share:				
Basic and diluted	$ (3.14)	$ (1.99)	$ (8.31)	$ (3.78)
Weighted average number of shares of common stock outstanding:				
Basic and diluted	24,611,631	24,014,092	24,553,239	23,100,222

Condensed Consolidated Balance Sheet Information
(In thousands)

	June 30, 2016	December 31, 2015
Cash, cash equivalents and investment securities	$ 439,487	$ 628,055
Total assets	$ 524,174	$ 655,758
Deferred revenue, total	$ 9,807	$ 8,018
Total liabilities	$ 107,500	$ 53,609
Stockholders' equity	$ 416,674	$ 602,149

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Total operating expense	$ 83,615	$ 49,269	$ 211,460	$ 90,372
Adjustments:				
Stock based compensation	4,253	6,631	14,497	16,369
Depreciation	860	396	1,544	646
Litigation settlement	-	-	45,000	-
Adjusted operating expense	$ 78,502	$ 42,242	$ 150,419	$ 73,357

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