# Intercept Pharmaceuticals Reports Full Year and Fourth Quarter 2017 Financial Results and Provides Business Update

February 14, 2018

- ***Worldwide Net Ocaliva® (obeticholic acid or OCA) full year 2017 net sales of $129.2 million, fourth quarter 2017 sales of $37.3 million***
- ***U.S. Prescribing Information for Ocaliva® updated to reinforce appropriate dosing in PBC patients with advanced cirrhosis***
- ***Continuing to advance industry leading NASH Phase 3 program: REGENERATE trial in NASH fibrosis on track to report data in 1H19; REVERSE trial in NASH cirrhosis enrolling***

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

NEW YORK, Feb. 14, 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 reported financial results for the three months and full year ended December 31, 2017 and provided other business updates.

"With an updated label that will help ensure correct dosing of Ocaliva in PBC patients with advanced cirrhosis, we are now pouring renewed energy into our efforts to bring our much-needed treatment to people living with this liver disease," said Mark Pruzanski, M.D., President and CEO of Intercept. "At the same time, we are focused on advancing our leading NASH Phase 3 program, supported by the most robust safety and efficacy data of any drug in development. With our flagship REGENERATE trial and recently announced REVERSE trial both underway, we are well on our way to cementing OCA's potential to treat NASH patients at the highest risk of progressing to liver failure."

"Our confidence in our ability to help people living with PBC has never been greater, and our collaborative approach during the recent months has further strengthened our relationships with our customers," said Richard Kim, Senior Vice President, U.S. Commercial at Intercept. "While we expect a transitional first quarter, we are actively re-engaging with physicians and patients and expect to reinvigorate growth in the PBC business throughout 2018, as we work diligently on physician education and broadening our reach among the large number of PBC patients who could benefit from Ocaliva."

**Ocaliva Commercial Highlights**

Intercept recorded $129.2 million of worldwide net Ocaliva sales for the full year 2017, and $37.3 million for the fourth quarter of 2017.

Net U.S. Ocaliva sales were $115.8 million for the full year 2017 and $32.0 million for the fourth quarter of 2017.

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. Earlier this month, the Prescribing Information in the United States was updated to reinforce appropriate dosing in PBC patients with Child-Pugh Class B or C or decompensated cirrhosis.

Net ex-U.S. international Ocaliva sales were $13.4 million for the full year 2017, and $5.3 million for the fourth quarter of 2017.

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. Intercept is working with the European Medicines Agency (EMA) to update the Ocaliva European Summary of Product Characteristics (SmPC) to reinforce appropriate dosing in patients with advanced cirrhosis. In the meantime, a Direct Healthcare Professional Communication is being issued to educate physicians on the need for appropriate dosing in patients with advanced cirrhosis.

Ocaliva was granted conditional approval by Health Canada in May 2017.

**Personnel Update**

Intercept announced today that Ryan Sullivan has been appointed as General Counsel and Secretary. Prior to joining Intercept, Mr. Sullivan worked at Anacor Pharmaceuticals, Inc., which was acquired by Pfizer Inc. At Anacor, Mr. Sullivan was most recently Executive Vice President, General Counsel and Secretary.

**Financial Results**

*Full Year 2017 Financial Results*

For the full year ended December 31, 2017, Intercept reported a net loss of $360.4 million. GAAP operating expense for the year ended December 31, 2017 was $466.6 million. Non-GAAP adjusted operating expense[1] for the full year ended December 31, 2017 was $405.0 million, which excludes non-cash stock-based compensation expense of $57.0 million and depreciation expense of $4.6 million.

[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."

***Revenues***

Intercept recognized $129.2 million and $18.2 million of net sales of Ocaliva for the year ended December 31, 2017 and 2016, respectively.

Intercept recognized $1.8 million and $6.8 million of license revenue related to the amortization of the up-front and milestone payments under the collaboration agreement with Sumitomo Dainippon for the year ended December 31, 2017 and 2016, respectively.

***Expenses***

Costs of goods sold (COGS) was negligible for 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 $273.7 million for the full year ended December 31, 2017, up from $273.6 million for the full year ended December 31, 2016. The increase is primarily due to personnel-related costs to support our commercial and international initiatives, expenses related to the 55 Hudson Yard lease termination, and Ocaliva commercialization activities. These increases were partially offset by the one-time net expense attributable to the settlement of a purported securities class action lawsuit in 2016 plus related legal expenses in 2016, along with a decrease in consultant spend.

Research and development expenses increased to $191.5 million for the full year ended December 31, 2017, up from $153.9 million for the full year ended December 31, 2016. The increase over the prior period was primarily driven by increases in OCA research and development activities and infrastructure to support such programs.

Interest expense for the full year ended December 31, 2017 and 2016 was $29.3 million and $14.2 million, respectively, due to the issuance of the 3.25% convertible senior notes due 2023 (convertible notes) in July 2016.

*Three Months Ended December 31, 2017*

Intercept recognized $37.3 million and $13.4 million of net sales of Ocaliva for the three months ended December 31, 2017 and 2016, respectively.

Intercept reported a net loss of $111.3 million for the three months ended December 31, 2017, compared to a net loss of $120.0 million for the three months ended December 31, 2016. The net loss included $15.4 million and $19.2 million of non-cash stock-based compensation expenses for the three months ended December 31, 2017 and 2016, respectively.

**Cash Position**

As of December 31, 2017, Intercept had cash, cash equivalents and investment securities available for sale of approximately $414.9 million, compared to $689.4 million as of December 31, 2016.

**Financial guidance**

Intercept projects non-GAAP adjusted operating expenses of $390 million to $410 million for the fiscal year ending December 31, 2018. 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, continued clinical development for OCA in PBC, NASH, PSC and other earlier stage pipeline programs.

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.

**Strategic Collaborations and Research Arrangement Update**

In February, Intercept amended its exclusive license agreement with Sumitomo Dainippon to regain the rights to develop and commercialize OCA in Japan and Korea. Under the new terms of the license agreement, Intercept will forego any further milestone or royalty payments for the development and commercialization of OCA in these countries. Sumitomo Dainippon will retain the rights to develop and commercialize OCA in China, and the two companies have agreed on milestone and royalty payments for the development and commercialization of OCA in this market. Sumitomo Dainippon has also waived its option rights to develop OCA in any country outside of the originally licensed territories.

**Conference Call on February 14th at 8:30 a.m. ET**

Intercept will hold its full year and fourth quarter 2017 financial results conference call and webcast on Wednesday, February 14th at 8:30 a.m. ET. The live event will be available on the investor page of the Intercept website at http://ir.interceptpharma.comor 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 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 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 year ended December 31, 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 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.***

**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 on the safety, benefits and efficacy of Ocaliva, the commercial potential of Ocaliva, any future events that may be experienced by patients who use Ocaliva and the association of such events with its use, the results of Intercept's educational efforts with healthcare providers and other planned and ongoing initiatives, the dosing of Ocaliva, and our 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 effect of label changes on prescriptions and sales of Ocaliva, 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; 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 its products and 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 received from payors; the success of competing drugs that are or become available; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; 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; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; 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.*

**Contact**

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| Revenue: | | | | |
| Product revenue, net | $ 37,242 | $ 13,362 | $ 129,175 | $ 18,169 |
| Licensing revenue | 445 | 446 | 1,781 | 6,782 |
| Total revenue | 37,687 | 13,808 | 130,956 | 24,951 |
| Operating expenses: | | | | |
| Cost of sales | 823 | - | 1,371 | - |
| Selling, general and administrative | 84,335 | 73,995 | 273,698 | 273,596 |
| Research and development | 57,498 | 53,821 | 191,499 | 153,893 |
| Total operating expenses | 142,656 | 127,816 | 466,568 | 427,489 |
| Operating loss | (104,969) | (114,008) | (335,612) | (402,538) |
| Other income (expense): | | | | |
| Interest expense | (7,431) | (7,131) | (29,271) | (14,196) |
| Other income, net | 1,128 | 1,097 | 4,516 | 3,904 |
| Total other income (expense) | (6,303) | (6,034) | (24,755) | (10,292) |
| Net loss | $ (111,272) | $ (120,042) | $ (360,367) | $ (412,830) |
| Net loss per common and potential common share: | | | | |
| Basic and diluted | $ (4.43) | $ (4.84) | $ (14.38) | $ (16.74) |
| Weighted average common and potential common shares outstanding: | | | | |
| Basic and diluted | 25,146 | 24,812 | 25,054 | 24,663 |

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

| | **December 31, 2017** | **December 31, 2016** |
|---|---|---|
| Cash, cash equivalents and investment securities | $ 414,917 | $ 689,385 |
| Total assets | $ 484,347 | $ 739,253 |
| Deferred revenue, total | $ 4,454 | $ 10,147 |
| Total liabilities | $ 467,961 | $ 424,321 |
| Stockholders' equity | $ 16,386 | $ 314,932 |

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |

| | | | | |
|---|---|---|---|---|
| Total operating expense | $ 142,656 | $ 127,816 | $ 466,568 | $ 427,489 |
| Adjustments: | | | | |
| Stock based compensation | 15,384 | 19,164 | 56,968 | 46,205 |
| Depreciation | 1,345 | 1,644 | 4,601 | 3,831 |
| Litigation settlement | - | - | - | 45,000 |
| Adjusted operating expense | $ 125,927 | $ 107,008 | $ 404,999 | $ 332,453 |


Primary Logo

Source: Intercept Pharmaceuticals, Inc.