May 5, 2016

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

NEW YORK, May 05, 2016 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, today reported financial results for the quarter ended March 31, 2016 and provided other general business updates. Intercept will hold a conference call and audio webcast today at 5:00 p.m. Eastern Time to review this information with conference call details provided below.

Summary of Key Development Programs, Updates and Anticipated Milestones

- Primary Biliary Cirrhosis (recently renamed Primary Biliary Cholangitis [PBC]) Program
  - FDA Advisory Committee voted 17-0 in favor of accelerated approval on April 7, 2016
  - PDUFA date May 29, 2016 with planned US launch in June if Ocaliva™ (obeticholic acid or OCA) marketing approval granted
  - EU marketing approval decision anticipated in late 2016
- NASH Program
  - Complete enrollment of Phase 2 CONTROL trial expected by YE 2016
  - Complete enrollment of Phase 3 REGENERATE trial expected in 1H 2017
- Primary Sclerosing Cholangitis (PSC) Program
  - Complete enrollment of Phase 2 AESOP trial by YE 2016
- INT-767 Program
  - Completion of Phase 1 trial expected in 2H 2016

Financial Results

For the three months ended March 31, 2016 and 2015, Intercept reported a net loss of $126.7 million and $39.4 million, respectively. Adjusted operating expense[1] for the three months ended March 31, 2016 was $71.9 million, which excludes a one-time net expense of $45 million for the settlement of the purported securities class action lawsuit and stock compensation expense of $10.2 million. GAAP operating expense for the three months ended March 31, 2016 was $127.8 million.

Research and development (R&D) expenses increased to $37.4 million for the three months ended March 31, 2016 from $28.0 million for the three months ended March 31, 2015. The increase is primarily due to increased expenses of $5.4 million related to additional personnel on Intercept's development team to manage the increased activities around the OCA development program and increased expense of $2.5 million due to an increase in OCA manufacturing activities.

General and administrative (G&A) expenses increased to $90.4 million for the three months ended March 31, 2016 from $13.1 million for the three months ended March 31, 2015 primarily due to the one-time net expense of $45 million for the settlement of the purported securities class action lawsuit, increased expenses of $17.9 million related to additional personnel to support our increased corporate initiatives, increased expenses of $5.9 million related to pre-commercialization activities both in the U.S. and internationally; and increased operating and administrative costs, such as legal, facilities and technology-related expenses, of $3.7 million.

Cash Position & 2016 Operating Guidance

As of March 31, 2016, Intercept had cash, cash equivalents and investment securities available for sale of approximately $556.9 million, compared to $628.1 million as of December 31, 2015. The cash payment for the $45 million net expense for the settlement of the purported class action lawsuit is anticipated to be made in the second quarter of 2016.

Intercept continues to project adjusted operating expenses in the range of $360 million to $400 million for the fiscal year ending December 31, 2016, which excludes the one-time net expense of $45.0 million for the settlement of the purported securities class action lawsuit, stock-based compensation and other non-cash items. 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 pre-commercial and commercial activities in both the U.S. and internationally. We expect our expenses to be more heavily weighted towards the second half of the year.

Other than the net class action lawsuit 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.

Conference Call on May 5th at 5:00 p.m. ET

Intercept will hold its first quarter financial results conference call and webcast on Thursday, May 5th 5:00 p.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. The Company's lead product candidate, obeticholic acid (OCA), is an agonist of the farnesoid X receptor (FXR). OCA is being developed for a variety of chronic liver diseases, including primary biliary cirrhosis, recently renamed primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. The FDA has granted OCA breakthrough therapy designation for the treatment of NASH with liver fibrosis and granted OCA fast track designation for the treatment of patients with PBC. OCA has also received orphan drug designation in both the United States and Europe for the treatment of PBC and PSC. Intercept owns worldwide rights to OCA outside of Japan, China and Korea, where it has out-licensed the product candidate to Sumitomo Dainippon Pharma. The brand name Ocaliva has been provisionally approved by the FDA and European Medicines Agency, but Ocaliva is an investigational medicine that has not been granted marketing authorization or approval from any regulatory authority. Intercept's pipeline of product candidates includes other novel bile acid analogs such as INT-767, which is in clinical development. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

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 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 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 adjusted operating expense calculated in accordance with GAAP to non-GAAP 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.

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 our financial position, including expected adjusted operating expenses; the activities anticipated to be undertaken by us, including the potential regulatory approval and launch of OCA in PBC and the timelines related thereto; the initiation, enrollment, conduct and completion of clinical trials; the anticipated regulatory process and timetable with respect to our product candidates; our ongoing and anticipated buildout and hiring to support our growing business operations; the continued development of OCA and Intercept's other product candidates; 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 initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval of OCA and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; our ability to obtain and maintain intellectual property protection for its product candidates; our ability to successfully commercialize our product candidates; the size and growth of the markets for our product candidates and our ability to serve those markets; the rate and degree of market acceptance of any future products, which may be affected by the reimbursement that our products receive 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; our collaborators' election to pursue research, development and commercialization activities; our ability to attract collaborators with development, regulatory and commercialization expertise; our need for and ability to obtain additional financing; our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; our use of cash and short term investments; our ability to 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, 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 for the 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 March 31,	
	2016	**2015**
Licensing revenue	$ 445	$ 1,445
Costs and expenses:		
Research and development	37,413	27,966
General and administrative	90,432	13,138
Total costs and expenses	127,845	41,103
Other income (expense)		
Other income, net	726	272
	726	272
Net loss	$ (126,674)	$ (39,386)
Net loss per share: basic and diluted	$ (5.17)	$ (1.78)
Weighted average shares outstanding: basic and diluted	24,494,848	22,171,988

Condensed Consolidated Balance Sheet Information
(In thousands)

	Mar. 31 2016	**Dec. 31 2015**
Cash, cash equivalents and investment securities	$ 556,860	$ 628,055
Total assets	$ 593,375	$ 655,758
Deferred revenue, total	$ 7,572	$ 8,017
Total liabilities	$ 105,042	$ 53,609
Stockholders' equity	$ 488,333	$ 602,149

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

	Three Months Ended March 31,	
	2016	**2015**
Total Operating Expense	$ 127,845	$ 41,103
Adjustments:		
Share Based Compensation	10,244	9,738
Depreciation	684	250
Litigation Settlement	45,000	-
Adjusted Operating Expense	$ 71,917	$ 31,115

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