Albireo Announces Royalty Monetization Agreement with HealthCare Royalty Partners for Elobixibat in Japan

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—Albireo subsidiary eligible to receive up to $60 million under agreement —

—Decision on Japanese New Drug Application for elobixibat expected in first half of 2018 —

BOSTON, Jan. 03, 2018 (GLOBE NEWSWIRE) -- Albireo Pharma, Inc. (NASDAQ:ALBO), a clinical-stage orphan pediatric liver disease company developing novel bile acid modulators, today announced that subsidiary Elobix AB has entered into an agreement with HealthCare Royalty Partners (HCR) to monetize its royalty rights under its license agreement with EA Pharma Co., Ltd. for elobixibat in the treatment of chronic constipation in Japan. EA Pharma is a subsidiary of Eisai Co, Ltd.

"We believe the commitment shown through this agreement by HealthCare Royalty Partners, a leading healthcare investment firm, provides additional validation for the therapeutic promise of ileal bile acid transporter (IBAT) inhibition. The transaction is designed to provide significant nondilutive capital for Albireo if elobixibat is approved in Japan, allowing us to further strengthen our cash position as we focus on the development of our lead product candidate A4250," said Ron Cooper, President and Chief Executive Officer of Albireo. "We expect to initiate a Phase 3 trial of A4250, an IBAT inhibitor, in patients with the orphan pediatric cholestatic liver disease progressive familial intrahepatic cholestasis (PFIC) by the spring of this year."

Under the terms of the agreement with HCR, Albireo subsidiary Elobix will receive $45 million if elobixibat is approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) and is eligible to receive an additional $15 million upon achievement of a specified sales milestone. In return, HCR obtains the right to receive royalties and sales milestones for elobixibat in Japan that may become payable by EA Pharma, up to a specified threshold. If the specified threshold is reached, Elobix will again become eligible to receive royalties and sales milestones for elobixibat under the terms of its license agreement with EA Pharma. Elobix has retained its right to receive a milestone payment from EA Pharma if elobixibat is approved by the MHLW.

As previously announced, EA Pharma submitted a new drug application for elobixibat to treat chronic constipation in Japan in February 2017, following highly statistically significant results from a Phase 3 clinical trial in Japan. If approved by the MHLW, elobixibat would become the first IBAT inhibitor approved anywhere in the world.

"HCR is pleased to invest in elobixibat, as it presents an exciting opportunity to bring a novel, dual-activity therapy to chronic constipation patients in Japan," said John Urquhart, Principal of HCR.

About Elobixibat
Elobixibat is a first-in-class product candidate to treat chronic idiopathic constipation (or, in Japan, chronic constipation). Elobixibat is an inhibitor of the ileal bile acid transporter (IBAT, and also sometimes referred to as the apical sodium-dependent bile acid transporter) in the terminal ileum to increase secretion and motility in the large bowel without negatively affecting important functions in the small intestine. Elobixibat has been evaluated to date in more than 1,000 healthy volunteers and chronic constipation patients worldwide. A new drug application has been submitted to the Japanese Ministry of Health, Labour and Welfare for elobixibat for the treatment of chronic constipation in Japan.

About HealthCare Royalty Partners
HCR is a private investment firm that purchases royalties and uses debt-like structures to invest in commercial or near-commercial stage life science assets. HCR has $3.5 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.healthcareroyalty.com.

About Albireo
Albireo Pharma is a clinical-stage biopharmaceutical company focused through its operating subsidiary on the development of novel bile acid modulators to treat orphan pediatric liver diseases and other liver and gastrointestinal diseases and disorders. Albireo's clinical pipeline includes a Phase 3 product candidate, a Phase 2 product candidate and a product candidate for which an application for regulatory approval has been submitted in Japan. Albireo was spun out from AstraZeneca in 2008.

Albireo Pharma is located in Boston, Massachusetts, and its key operating subsidiary is located in Gothenburg, Sweden. For more information on Albireo, please visit www.albireopharma.com.

Forward-Looking Statements
This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements, other than statements of historical fact, regarding: the timing for the decision whether to approve the new drug application for elobixibat in Japan; any payments that HealthCare Royalty Partners (HCR) or EA Pharma may make to Albireo or its subsidiaries and the effect of any such payments on Albireo's cash position; the commercial prospects for elobixibat in Japan; plans for A4250, including the timing for initiation of the planned Phase 3 clinical trial in patients with PFIC; or Albireo's plans, expectations or future operations, financial position, revenues, costs or expenses. Albireo often uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "planned," "continue," "guidance," and similar expressions to identify forward-looking statements. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks and uncertainties, including, but not limited to, risks and uncertainties relating to: whether the new drug application submitted by EA Pharma in Japan for elobixibat for the treatment of chronic constipation in Japan will be approved and, if so, when; if approved, the extent of market acceptance and

commercial success of elobixibat in Japan; the occurrence of any event, change or other circumstances that could give rise to the termination of the royalty monetization agreement with HCR without payment to Albireo or its subsidiaries; whether the sales milestone specified in the royalty monetization agreement with HCR for elobixibat in Japan will be achieved; whether the threshold of royalties and sales milestones for elobixibat in Japan specified in the royalty monetization agreement with HCR after which Elobix would again become eligible to receive royalties and sales milestones for elobixibat under the terms of its license agreement with EA Pharma will be achieved; the significant control that EA Pharma has over the commercialization of elobixibat in Japan; the timing for initiation of the planned Phase 3 trial of A4250 in patients with PFIC; and whether changes made in the process of finalizing the protocol for the planned Phase 3 trial of A4250 in patients with PFIC result in a delay in its initiation. These and other risks and uncertainties that Albireo faces are described in greater detail under the heading “Risk Factors” in Albireo’s most recent Annual Report on Form 10-K and in other filings that it makes with the Securities and Exchange Commission. As a result of risks and uncertainties that Albireo faces, the results or events indicated by any forward-looking statement may not occur. Albireo cautions you not to place undue reliance on any forward-looking statement. In addition, any forward-looking statement in this press release represents Albireo’s views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Albireo disclaims any obligation to update any forward-looking statement, except as required by applicable law.

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