Albireo Recognizes PFIC Awareness Day 2020

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Albireo stands together with the PFIC community to highlight critical need for education and advances in research for rare cholestatic liver diseases

BOSTON, Oct. 05, 2020 (GLOBE NEWSWIRE) -- Albireo Pharma, Inc. (Nasdaq: ALBO), a clinical-stage orphan pediatric liver disease company developing novel bile acid modulators, joins the PFIC Advocacy and Resource Network (PFIC Network) in recognition of PFIC Awareness Day 2020, a global effort to support patients and families affected by progressive familial intrahepatic cholestasis (PFIC). PFIC is a rare genetic disorder that causes progressive, life-threatening liver disease characterized by an intense form of itching called pruritus, jaundice and difficulties gaining weight and maintaining proper nourishment.

“PFIC Awareness Day is one of the many efforts PFIC Network is undertaking to lift up the research, educational and advocacy needs for this devasting and life-threatening disease,” said Emily Ventura, executive director and co-founder of the PFIC Network. “We are grateful for the global community’s support of people with PFIC and their families on PFIC Awareness Day and every day, and appreciate the research commitment of companies like Albireo.”

Established in 2019, PFIC Awareness Day aims to highlight the impact of this disease on patients and families, and to call for new levels of support, including research, advocacy, education and opportunities to connect and share information. This year, members of the PFIC community from countries around the world will come together virtually by using the hashtag #ItchingForACure on social media. PFIC Network is also offering additional ways to support families, including the PFIC Network Lemonade Stand Fundraiser and #ItchingForACure campaign apparel for purchase at www.pfic.org.

“Patients and families are our north star aligned to the mission of providing hope to families by continuing to advance research for a new drug treatment option for PFIC,” said Ron Cooper, President and Chief Executive Officer of Albireo. “PFIC Awareness Day is an opportunity for us to shine a light on patient voices, salute their strength and perseverance, and show that we’re in this fight together.”

To recognize PFIC Awareness Day, Albireo is supporting #ItchingForACure with a social media campaign highlighting PFIC families from around the world, including messages from families in the United States, Canada, the United Kingdom and Australia. The Company also continues to share patient perspectives about the impact of PFIC through www.PFICVoices.com, an online platform for information and support.

About PFIC

PFIC is a rare genetic disorder that causes progressive, life-threatening liver disease. People diagnosed with PFIC have impaired bile flow, or cholestasis, caused by genetic mutations. The resulting bile build-up in liver cells causes liver disease and symptoms. The most prominent and problematic ongoing manifestation of the disease is pruritus, or intense itching, which often results in a severely diminished quality of life. PFIC is also characterized by jaundice, and poor weight gain and growth. In many cases, PFIC leads to cirrhosis and liver failure within the first 10 years of life, and nearly all people with PFIC require treatment before age 30. There are no drugs currently approved for PFIC, only surgical options, including a procedure known as partial external biliary diversion (PEBD) and liver transplantation. These options carry substantial risks. Additional information on PFIC is available at PFICvoices.com.

About Albireo

Albireo Pharma is a clinical-stage biopharmaceutical company focused on the development of novel bile acid modulators to treat orphan pediatric liver diseases, and other adult liver diseases and disorders. Albireo’s lead product candidate, odevixibat, is being developed to treat rare pediatric cholestatic liver diseases and has the potential to become the first approved drug treatment for patients with PFIC. Albireo recently reported positive results from PEDFIC 1, a global Phase 3 clinical trial evaluating the efficacy and safety of odevixibat, which was the first and largest study ever conducted in PFIC1 and PFIC2. The Company intends to complete regulatory filings in the EU and U.S. no later than early 2021, in anticipation of potential regulatory approval, issuance of a rare pediatric disease priority review voucher and launch in the second half of 2021. The Company also plans to initiate a pivotal Phase 3 trial of odevixibat in Alagille syndrome by the end of 2020, and continues enrolling patients in the BOLD pivotal Phase 3 trial of odevixibat in biliary atresia. 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, among other things: the plans for, or progress, scope, cost, initiation, duration, enrollment, results or timing for availability of results of, development of odevixibat or any other Albireo product candidate or program, including regarding expectations regarding the impact of COVID-19 on our business and our ability to adapt our approach as appropriate; the Phase 3 clinical program for odevixibat in patients with PFIC, the pivotal trial for odevixibat in biliary atresia (BOLD), and the planned pivotal trial for odevixibat in Alagille syndrome; the target indication(s) for development or approval, the size, design, population, location, conduct, cost, objective, enrollment, duration or endpoints of any clinical trial, or the timing for initiation or completion of or availability or reporting of results from any clinical trial, including the long-term open-label extension study for odevixibat in PFIC, the pivotal trial for odevixibat in biliary atresia, the planned pivotal trial for odevixibat in Alagille syndrome; the potential approval and commercialization of odevixibat; discussions with the FDA or EMA regarding our programs; the potential benefits or competitive position of odevixibat, elobixibat, or any other Albireo product candidate or program or the commercial opportunity in any target indication; the potential effects of odevixibat of the treatment of PFIC patients and its potential to improve the current standard of care; the potential benefits of an orphan drug designation; the potential issuance of a rare pediatric disease priority review voucher; the period for which Albireo’s cash resources will be sufficient to fund its operating requirements (runway); 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, uncertainties and other factors, including, but not limited to: negative impacts of the COVID-19 pandemic, including on manufacturing, supply, conduct or initiation of clinical trials, or other aspects of our business; whether favorable findings from clinical trials of odevixibat to date, including findings in indications other than PFIC, will be predictive of results from other clinical trials of odevixibat; whether either or both of the FDA and EMA will determine that the primary endpoint for their respective evaluations and treatment duration of the double-blind Phase 3 trial in patients with PFIC are sufficient to support approval of odevixibat in the United States or the European Union, to treat PFIC, a symptom of PFIC, a specific PFIC subtype(s) or otherwise; the outcome and interpretation by regulatory authorities of the ongoing third-party study pooling and analyzing of long-term PFIC patient data; the timing for initiation or completion of, or for availability of data from, clinical trials of odevixibat, including the pivotal program in biliary atresia or the planned pivotal program in Alagille syndrome, and the outcomes of such trials; Albireo’s ability to obtain coverage, pricing or reimbursement for approved products in the United States or European Union; delays or other challenges in the recruitment of patients for, or the conduct of, the double-blind Phase 3 trial or other pivotal trials; and Albireo’s critical accounting policies. 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 or in subsequent 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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