Albireo Recognizes PFIC Awareness Day 2021

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BOSTON, Oct. 05, 2021 (GLOBE NEWSWIRE) -- Albireo Pharma, Inc. (Nasdaq: ALBO), a rare pediatric liver disease company developing novel bile acid modulators, joins the PFIC Advocacy and Resource Network (PFIC Network) in recognition of PFIC Awareness Day 2021, a global effort to support patients and families affected by progressive familial intrahepatic cholestasis (PFIC). 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.

PFIC is a rare disorder that causes progressive, life-threatening liver disease. Patients 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. Other symptoms include jaundice, poor weight gain and slowed 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.

Every year the PFIC Network recognizes, shares, and supports the PFIC community in hopes for a better future for those impacted by PFIC (events.pfic.org/awareness-day-2021/). This year, PFIC Network is working with the global community to recognize PFIC Awareness Day around the world through a variety of initiatives, including:

- **Raising Awareness:** Share your story and photos with the #ItchingForACure hashtag and your journey will help spread awareness around the world. To learn more about how you can participate, visit events.pfic.org/raise-awareness/.
- **Fundraising:** Join a team, pick a cause and help raise money for resources that have direct impact on the PFIC community. For information on how to support, visit events.pfic.org/fundraising/.
- **Advocacy:** Get involved and help connect the PFIC community with available information and resources. To learn more about how to get involved, visit events.pfic.org/advocacy/.

Albireo is committed to advancing research in PFIC and other rare pediatric and adult liver diseases. The Company recently launched a new treatment option for PFIC and is working with the community and patient advocacy groups like the PFIC Network and Children's Liver Disease Foundation to raise awareness of PFIC and support families managing the burden of this devastating disease.

"Guided by our mission of providing hope to families, we stand with the PFIC community in recognizing PFIC Awareness Day," said Ron Cooper, President and Chief Executive Officer of Albireo. "While we are thrilled that we are now able to provide a drug treatment option to patients with PFIC, there is still more work to be done to ensure access and to elevate the important perspectives of the patients and families that have been impacted by this devastating disease."

About Albireo
Albireo Pharma is a rare disease company focused on the development of novel bile acid modulators to treat rare pediatric and adult liver diseases. Albireo's first product, Bylvay™ (odevixibat) is the first drug treatment approved in theU.S. for the treatment of pruritus in all types of progressive familial intrahepatic cholestasis (PFIC). The European Commission (EC) and UK Medicines and Healthcare Products Regulatory Agency (MHRA) have also granted marketing authorization of Bylvay in PFIC. Bylvay is available for sale in Germany and will be available for sale in other European countries following pricing and reimbursement approval. A potent, once-daily, non-systemic ileal bile acid transport inhibitor, Bylvay acts locally in the small intestine. Bylvay can be taken as a capsule for older children, or opened and sprinkled onto food, which are factors of key importance for adherence in a pediatric patient population. The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the management of PFIC. For more information about using Bylvay, see the package leaflet or contact your doctor or pharmacist. For full prescribing information, visit www.bylvay.com.

Bylvay is being evaluated in the ongoing PEDFIC 2 open-label trial in patients with PFIC. It is also being developed to treat other rare pediatric cholestatic liver diseases with the BOLD Phase 3 study for patients with biliary atresia and the ASSERT Phase 3 study for Alagille syndrome. In the U.S. and Europe, Bylvay has orphan exclusivity for its approved PFIC indications, and orphan designations for the treatment of Alagille syndrome, biliary atresia and primary biliary cholangitis. The Company has also initiated a Phase 1 clinical trial for A3907 to advance development in adult cholestatic liver disease, with IND-enabling studies moving ahead with A2342 for viral and cholestatic liver disease. Albireo was spun out from AstraZeneca in 2008 and is headquartered in Boston, Massachusetts, with its key operating subsidiary in Gothenburg, Sweden. The Boston Business Journal named Albireo one of the 2020 Best Places to Work in Massachusetts for the second consecutive year. 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: Albireo's commercialization plans and expectations for commercializing Bylvay in the U.S. and Europe; the plans for, or progress, scope, cost, initiation, duration, enrollment, results or timing for availability of results of, development of Bylvay, A3907, A2342 or any other Albireo product candidate or program; the pivotal trial for Bylvay in biliary atresia (BOLD), and the pivotal trial for Bylvay in Alagille syndrome (ASSERT); the Phase 1 trial for A3907; 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

Bylvay in PFIC, and the BOLD and ASSERT trials; discussions with the FDA or EMA regarding our programs; the potential benefits or competitive position of Bylvay or any other Albireo product candidate or program or the commercial opportunity in any target indication; the potential effects of Bylvay of the treatment of PFIC patients and its potential to improve the current standard of care; or the potential benefits of an orphan drug designation. Albireo often uses words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “planned,” “continue,” “guidance,” or the negative of these terms or other 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: there are no guarantees that Bylvay will be commercially successful; we may encounter issues, delays or other challenges in launching or commercializing Bylvay; whether Bylvay receives adequate reimbursement from third-party payors; the degree to which Bylvay receives acceptance from patients and physicians for its approved indication; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in Bylvay in the treatment of patients with PFIC once we have launched the product may be different than observed in clinical trials, and may vary among patients; other potential 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 Bylvay to date, including findings in indications other than PFIC, will be predictive of results from other clinical trials of Bylvay; 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 Bylvay, including BOLD and ASSERT, and the Phase 1 clinical trial of A3907, and the outcomes of such trials; Albireo’s ability to obtain coverage, pricing or reimbursement for approved products in the United States or Europe; delays or other challenges in the recruitment of patients for, or the conduct of, Company’s clinical 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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