Albireo Announces Exclusive Licensing Agreement with Jadeite Medicines for Bylvay™ (odevixibat) in Japan

October 12, 2021

– Agreement to accelerate commercialization of Bylvay ™(odevixibat) in Japan, a significant market for PFIC, Alagille syndrome and biliary atresia –

– Albireo to receive upfront payment of $15M and up to $120M in milestones and double-digit royalties –

– Bylvay approved in U.S., EU and UK with global prescriptions already generated –

BOSTON, Oct. 12, 2021 (GLOBE NEWSWIRE) -- Albireo Pharma, Inc. (Nasdaq: ALBO), a rare liver disease company developing novel bile acid modulators, entered into an exclusive licensing agreement with Jadeite Medicines, Inc. for the development and commercialization of Bylvay (odevixibat) in Japan for progressive familial intrahepatic cholestasis (PFIC), Alagille syndrome (ALGS) and biliary atresia.

Under the terms of the agreement, Albireo will receive an upfront payment of $15M and will be eligible to receive up to $120M in milestones as well as double-digit royalties. Jadeite Medicines, a biopharmaceutical platform company focused on developing global innovative pharmaceutical products for Japan, will be responsible for clinical development, regulatory approval and commercialization of Bylvay in Japan, where there is significant market opportunity. Jadeite Medicines is backed by CBC Group (www.cbridgecap.com), who has partnered with the world's top entrepreneurs and scientists and, leveraging its unique "investor-operator" approach, has empowered global leading healthcare companies to widen access to affordable medical care, catalyze innovations and improve efficiency in fulfilling unmet medical needs worldwide.

"This agreement exemplifies Albireo's commitment to providing global availability of Bylvay, particularly in areas like Japan where high prevalence translates to a sizable number of patients who currently have no approved treatment option. Jadeite Medicines entrepreneurial, biotech approach makes them the right type of partner to successfully commercialize Bylvay in Japan," said Ron Cooper, President and Chief Executive Officer of Albireo. "The agreement allows for success of both companies, while strengthening Albireo's financial position with the $15M payment added to our strong balance sheet."

Bylvay is the first drug approved in Europe for the treatment of all types of PFIC and in the U.S. for the treatment of pruritus in all types of PFIC. A potent, non-systemic ileal bile acid transport inhibitor (IBATi), Bylvay is administered as a once-daily capsule or opened and sprinkled onto soft foods. Bylvay is currently being evaluated in the ASSERT Phase 3 study for ALGS, the BOLD Phase 3 study for patients with biliary atresia and the ongoing PEDFIC 2 open-label trial in patients with PFIC.

"We are excited to partner with Albireo to accelerate delivery of odevixibat to children living with rare liver diseases, initially targeting PFIC, followed by potentially biliary atresia and Alagille syndrome, which all represent significant unmet medical needs in Japan," said Eiichi Takahashi, M.D., Ph.D., Chief Executive Officer of Jadeite Medicines. "This agreement reinforces Jadeite's commitment and vision to develop highly differentiated and innovative medicines to improve the health and quality of life of patients in Japan."

"CBC remains steadfast in our commitment to widening access to medical care globally, and Jadeite is our cornerstone in Japan, and the partnership with Albireo represents important progress toward that goal by expanding more cure options, initially for children living with rare liver diseases in Japan," said Sean Cao, Ph.D., Managing Director of CBC Group. "By leveraging our extensive investor-operator experience in Asia, we will continue to partner with the world's top pharmaceutical companies and scientists and identify opportunities to broaden global reach for patients with unmet medical needs."

About Bylvay (odevixibat)
Bylvay is the first drug approved in the U.S. for the treatment of pruritus in patients 3 months of age and older 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 for the treatment of PFIC in patients aged 6 months or older. 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.

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. Bylvay is being evaluated in the ongoing PEDFIC 2 open-label trial in patients with PFIC, in the BOLD Phase 3 study for patients with biliary atresia and the ASSERT Phase 3 study for Alagille syndrome.

About Jadeite
Jadeite Medicines is a biopharmaceutical company focused on developing and commercializing innovative pharmaceutical products that address critical unmet medical needs for patients in Japan. The management team of Jadeite Medicines has deep expertise and an extensive track record of high-quality clinical development, regulatory affairs, CMC, business development and operations in Japan and with leading global pharmaceutical companies. Jadeite Medicines plans to build a portfolio of global first-in-class or best-in-class molecules, many of which are in late-stage clinical development. For more information, please visit its website at www.jadeitemedicines.co.jp.

About CBC

CBC Group, Asia's largest healthcare-dedicated investment firm, commits to creating value and integrating global resources. In partnering with the world's top entrepreneurs and scientists, our unique "investor-operator" approach has empowered global leading healthcare companies to widen access to affordable medical care, catalyze innovations, and improve efficiency in fulfilling unmet medical needs worldwide. Founded in 2014, CBC has a leading team of investment, industry and portfolio management professionals headquartered in Singapore with global offices in Shanghai, Beijing, Hong Kong and New York, and presence in Boston, San Diego, San Francisco, and Tokyo. CBC focuses on platform-building, buyout, credit and growth-focused opportunities across multiple core areas within the healthcare sector, including pharmaceutical and biotech, medical technology and healthcare services. For more information, please visit www.cbridgecap.com.

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 lead product, Bylvay, was approved by the U.S. FDA as the first drug for the treatment of pruritus in all types of progressive familial intrahepatic cholestasis (PFIC), and it is also being developed to treat other rare pediatric cholestatic liver diseases with Phase 3 trials in Alagille syndrome and biliary atresia, as well as an Open-label Extension (OLE) study for PFIC. In Europe, Bylvay has been approved for the treatment of PFIC and has been submitted for pricing and reimbursement approval. 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 and Japan; estimates of the number of patients impacted by PFIC; expectations about Bylvay's acceptance by healthcare practitioners to treat PFIC patients; 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; the potential benefits of an orphan drug designation; the length of time for which Albireo's cash resources are expected to be sufficient, and the milestones and activities to be funded with those cash resources; 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," 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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