



NEWS RELEASE

bridgebio pharma and sentynl therapeutics announce asset purchase agreement for bridgebio pharma's nulibry™ (fosdenopterin)

2022-03-08

PALO ALTO and SOLANA BEACH, Calif., March 08, 2022 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio), a commercial-stage biopharmaceutical company that focuses on genetic diseases and cancers, and Sentynl Therapeutics, Inc. (Sentynl), a U.S.-based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases owned by Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.), today announced the execution of an asset purchase agreement (the Agreement) for the sale of BridgeBio's NULIBRY™ (Fosdenopterin) for Injection. NULIBRY is approved by the U.S. Food and Drug Administration (FDA) to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A, an ultra-rare, life-threatening pediatric genetic disorder. The closing of the asset purchase is subject to customary closing conditions.

"Sentynl's focus on meaningful treatments for serious rare diseases is further enhanced by the acquisition of Fosdenopterin. We will leverage our existing platform of ultra-rare pediatric disease initiatives to facilitate early diagnosis and treatment by enhancing awareness, newborn screening, genetic testing and patient support across multiple products and rare diseases. By partnering with BridgeBio, we hope to reach even more patients born with MoCD Type A as quickly as possible with the hope of reducing the risk of mortality and progression of this devastating disease," said Matt Heck, CEO of Sentynl.

Under the Agreement, Sentynl will acquire global rights to NULIBRY and will be responsible for the ongoing development and commercialization of NULIBRY in the United States and developing, manufacturing and

commercializing Fosdenopterin globally. BridgeBio will share development responsibilities for Fosdenopterin through approval of the marketing authorization application already under accelerated assessment with the European Medicines Agency and through approval of its regulatory submission with the Israeli Ministry of Health. Sentyln will provide cash payments upon the achievement of certain regulatory milestones. BridgeBio will be eligible to receive commercial milestone payments as well as tiered royalties on adjusted net sales of NULIBRY.

“Sentyln is an ideal partner given its expertise in the rare pediatric neurodevelopment space and its relationships with physicians who diagnose and treat children with MoCD Type A,” said Neil Kumar, Ph.D., founder and CEO of BridgeBio. “Focused execution means reducing the scope of our internal activity. We will continue to advance high-quality programs in our pipeline while expanding our reach to patients in need of options.”

About Molybdenum Cofactor Deficiency (MoCD) Type A

MoCD Type A is an autosomal recessive, inborn error of metabolism caused by mutations in the molybdenum cofactor synthesis 1 gene and characterized by a deficiency in molybdenum cofactor production, leading to a lack of molybdenum-dependent enzyme activity.^{1,2} The lack of activity leads to decreased sulfite oxidase activity with buildup of sulfite and secondary metabolites (such as S-sulfocysteine) in the brain, which causes irreversible neurological damage.²

MoCD Type A is an ultra-rare disease. The incidence and prevalence of MoCD Type A in the United States are not known, but the estimated incidence is 1 per 342,000 to 411,000 live births (0.24 and 0.29 per 100,000).³ Based on these estimates, MoCD Type A is likely to be underdiagnosed, with an estimated 22 to 26 missed diagnoses per year in the United States and European Union.

The most common presenting symptoms of MoCD Type A are seizures, feeding difficulties and encephalopathy. Patients with MoCD Type A who survive beyond infancy typically suffer from progressive brain damage, which presents in characteristic patterns on magnetic resonance imaging (MRI). This damage leads to severe psychomotor impairment and an inability to make coordinated movements or communicate with their environment.

About NULIBRY™ (Fosdenopterin) for Injection

NULIBRY™ (Fosdenopterin) for Injection is a substrate replacement therapy that provides an exogenous source of cPMP, which is converted to molybdopterin. Molybdopterin is then converted to molybdenum cofactor, which is needed for the activation of molybdenum-dependent enzymes, including sulfite oxidase, an enzyme that reduces levels of neurotoxic sulfites. It is the first and only FDA-approved therapy indicated to reduce the risk of mortality in patients with MoCD Type A, and clinical trials have demonstrated that patients treated with NULIBRY or rcPMP had an improvement in overall survival compared to the untreated, genotype-matched, historical control group.

References

¹Mechler K et al. Genet Med. 2015;17(12):965-970.

²Schwarz G. Cur Op in Che Bio. 2016;31:179-187.

³Mayr SJ, et al. Forecasting the incidence of rare diseases: an iterative computational and biochemical approach in molybdenum cofactor deficiency type A. Presented at the 2019 SSIEM meeting; September 3-6, 2019; Rotterdam, The Netherlands.

About Sentyln Therapeutics

Sentyln Therapeutics is a U.S.-based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases. The company was acquired by the Zydus Group in 2017. Sentyln's highly experienced management team has previously built multiple successful pharmaceutical companies. With a focus on commercialization, Sentyln looks to source effective and highly differentiated products across a broad spectrum of therapeutic areas to address unmet needs. Sentyln is committed to the highest ethical standards and compliance with all applicable laws, regulations, and industry guidelines. For more information, visit www.sentyln.com.

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (BridgeBio) is a commercial-stage biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. BridgeBio's pipeline of over 30 development programs ranges from early science to advanced clinical trials and its commercial organization is focused on delivering the company's first two approved therapies. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information visit bridgebio.com and follow us on [LinkedIn](#) and [Twitter](#).

About Zydus

The Zydus Group, with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is driven by its mission to unlock new possibilities in life-sciences through quality healthcare solutions that impact lives. The group aspires to become a global life-sciences company transforming lives through pathbreaking discoveries. For more information, visit <https://www.zyduslife.com/zyduslife/>.

BridgeBio Pharma, Inc. Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are usually identified by the use of words such as "anticipates," "believes," "estimates,"

“expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions. BridgeBio Pharma, Inc. (“BridgeBio,” “we,” “us” or “our”) intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements, including statements relating to the clinical and therapeutic potential of our programs and product candidates, expectations, plans and prospects regarding clinical development plans; regulatory status and commercial strategy; the success of BridgeBio’s relationship with Sentynl and Zydus pursuant to the Agreement, including the parties’ development responsibilities; Sentynl’s ability to successfully develop, manufacture, commercialize and continue to increase market acceptance and uptake of Fosdenopterin pursuant to the Agreement; BridgeBio’s eligibility to receive future payments upon the achievement of certain regulatory and commercial milestones and tiered royalties on adjusted net sales from Sentynl and the timing of these events; and BridgeBio’s faith in the long-term prospects of its pipeline, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, initial and ongoing data from our preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations our product candidates are designed to treat not being as large as anticipated, the design and success of ongoing and planned clinical trials, future regulatory filings, approvals and/or sales, despite having ongoing and future interactions with the FDA or other regulatory agencies to discuss potential paths to registration for our product candidates, the FDA or such other regulatory agencies not agreeing with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of BridgeBio’s collaborations, potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, as well as those risks set forth in the Risk Factors section of BridgeBio’s Annual Report on Form 10-K for the year ended December 31, 2021 and our other filings with the U.S. Securities and Exchange Commission. Moreover, BridgeBio operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of BridgeBio’s management as of the date of this release and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information:

BridgeBio Media Contact:

Grace Rauh

Grace.rauh@bridgebio.com

(917) 232-5478

BridgeBio Investor Contact:

Katherine Yau

katherine.yau@bridgebio.com

(516) 554-5989

Sentynl Therapeutics Contact:

Michael Hercz

ir@sentynl.com

888-507-5296