Denali Therapeutics Announces Early Exercise of Its Option to Acquire F-star Gamma

May 30, 2018

SOUTH SAN FRANCISCO, May 30, 2018 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (NASDAQ:DNLI), a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases, today announced that it has exercised its option to acquire all outstanding shares in F-star Gamma pursuant to the Option Agreement dated August 24, 2016 and expanded its collaboration with F-star on Denali's biologics Transport Vehicle ("TV") blood-brain barrier ("BBB") platform technology.

Denali entered into a License and Collaboration Agreement with F-star in August 2016 to support the development of and provide rights to intellectual property for Denali's proprietary TV platform technology to deliver therapeutics across the BBB. Based on compelling preclinical proof of concept data for the TV platform technology and substantive progress with Denali's lead program enabled by this technology, Denali has decided to exercise its option to acquire F-star Gamma, a private limited liability company incorporated under the laws of England and Wales. F-star Gamma holds certain intellectual property rights to F-star's Modular Antibody Technology™ which has been used to generate Fcabs against a transporter in the BBB. In addition, Denali has expanded certain rights under the existing License and Collaboration Agreement and has exercised its right to nominate two additional BBB transporter Fcab™ (constant Fc-domains with antigen-binding activity) targets.

"Our decision to exercise the option to buy F-star Gamma reflects the progress in our collaboration with F-star and the generation of preclinical data showing that our proprietary TV platform technology may enable us to deliver biologics across the BBB and into the brain. Specifically, recent data demonstrated robust and sustained peripheral and brain activity for our ETV:IDS program for Hunter Syndrome and hence preclinical proof of concept. Furthermore, the expanded collaboration allows us to deepen and broaden our research efforts supporting our TV platform technology," said Ryan Watts, Ph.D., CEO of Denali Therapeutics.

"With the growing number of patients affected by neurological disorders, there is an urgent need to efficiently deliver medicines into the brain. Denali's approach is well positioned to tackle this challenge and we firmly believe that its TV platform technology, enabled by F-star's Modular Antibody Technology has the potential to create a new class of disruptive CNS-targeting biological therapeutics," said John Haurum, CEO of F-star.

The total consideration for the option exercise and expanded collaboration amounts to $24 million, plus any net cash held by F-star Gamma at closing of the transaction. In addition, Denali may make future contingent payments up to a maximum of $447 million upon the achievement of defined preclinical, clinical, regulatory and commercial milestones. There are no royalty payments on net sales from future products. Through the acquisition of F-star Gamma, Denali obtains exclusive rights to discover, develop and commercialize an unlimited number of therapeutic products enabled by F-star's intellectual property and utilizing any of the three BBB transporter Fcab targets nominated by Denali.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the blood-brain barrier and guiding development with biomarker monitoring to demonstrate target engagement and select patients. Denali is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding Denali's progress, expectations and business plans; expectations regarding, and potential benefits of, the F-star collaboration and the acquisition of F-star Gamma; and statements made by Denali's CEO and F-star's CEO. Actual results are subject to risks and uncertainties and may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not limited to, risks related to: Denali's early stages of clinical drug development; Denali's ability to complete the development of, and if approved, commercialization of its product candidates; Denali's dependence on successful development of its TV platform technology and product candidates currently in its core program; Denali's ability to conduct or complete clinical trials on expected timelines; the uncertainty that any of Denali's product candidates will receive regulatory approval necessary to be commercialized; Denali's ability to continue to create a pipeline of product candidates or develop commercially successful products; Denali's ability to obtain, maintain, or protect intellectual property rights related to its product candidates and TV platform technology; implementation of Denali's strategic plans for its business, product candidates and TV platform technology; and other risks, including those described in Denali's Annual Report on Form 10-K filed with the SEC on March 19, 2018, Denali's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2018 and Denali's future reports to be filed with the SEC. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali disclaims any obligation to update any forward-looking statements, except as required by law.

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