



Takeda and Denali Therapeutics Collaborate to Develop and Commercialize Therapies for Neurodegenerative Diseases

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Collaboration includes three named programs for the treatment of Alzheimer's disease and other neurodegenerative diseases, utilizing Denali's Antibody Transport Vehicle (ATV) technology to enhance blood-brain barrier (BBB) penetration.

OSAKA, Japan & SOUTH SAN FRANCISCO, CA--(BUSINESS WIRE)--Jan. 5, 2018-- Takeda Pharmaceutical Company Limited ([TSE: 4502](#)) and Denali Therapeutics (NASDAQ: DNLI) today announced that they have entered into a strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases. Each program is directed to a genetically validated target for neurodegenerative disorders, including Alzheimer's disease and other indications, and incorporates Denali's ATV platform for increased exposure of biotherapeutic products in the brain.

This press release features multimedia. View the full release here: <http://www.businesswire.com/news/home/20180105005161/en/>

"This partnership further exemplifies Takeda's continued commitment to developing genetically validated therapies for neurodegenerative diseases through an enhanced portfolio comprised of new modalities," said Emiliangelo Ratti, Head of the Neuroscience Therapy Area at Takeda. "We are excited to partner with the Denali team, whose innovative technology is uniquely poised to deliver the next generation of antibody therapeutics for patients."

"We are impressed with Takeda's commitment to developing treatments for difficult to treat neurodegenerative diseases and look forward to partnering with them to bring medicines to patients," said Denali CEO Ryan Watts, Ph.D. "Takeda has a great track record of partnering with biotech firms in addition to unique development expertise and a strong global commercial presence."

Terms of Collaboration

Under the terms of the agreement, Takeda will make an initial payment to Denali of \$150 million through a combination of cash upfront payments and the purchase of Denali equity. In addition, Denali is eligible to receive development and commercial milestone payments, including \$90 million in preclinical milestones and opt-in payments.

Denali will be responsible for all development activities and costs prior to IND filing for each of the three programs. Takeda has the option to co-develop and co-commercialize each of the three programs. If Takeda exercises the option, the parties will then jointly conduct clinical development and share all costs equally. Denali will lead early clinical development activities and Takeda will lead late stage clinical development activities. Takeda and Denali will jointly commercialize products in the United States and China, and Takeda will have exclusive commercialization rights in all other markets. The parties will share global profits equally. The agreement will become effective when the requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 have been satisfied.

About Takeda Pharmaceutical Company

Takeda Pharmaceutical Company Limited ([TSE: 4502](#)) is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and neuroscience therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as Takeda's presence in emerging markets, are currently fueling the growth of Takeda. Approximately 30,000 Takeda employees are committed to improving quality of life for patients, working with Takeda's partners in health care in more than 70 countries. For more information, visit <https://www.takeda.com/newsroom/>.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, www.takedaoncology.com.

About Denali Therapeutics

Denali is a biopharmaceutical company developing a broad portfolio of therapeutic candidates for neurodegenerative diseases. Denali is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

Cautionary Note Regarding 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, the potential benefits of the collaboration; plans to conduct clinical development activities and commercialize products; the expectation as to when the agreement will become effective; and other information relating to the transaction between Takeda and Denali. 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: the risk that the agreement may not become effective in a timely manner or at all; risks related to obtaining the requisite regulatory approvals; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of the agreement (including without limitation the failure to timely obtain requisite regulatory approvals); risks related to the effect of the announcement of the transaction on Denali's business relationships, operating results and business generally; and other risks, including those described in Denali's Prospectus filed with the SEC on December 8, 2017. The forward-looking statements in this press release are based on information available to Denali as of the date hereof. Denali and Takeda disclaim any obligation to update any forward-looking statements, except as required by law.

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Source: Takeda Pharmaceutical Company

Takeda Contact:

Kelly Schlemm, +1-617-551-8865

kelly.schlemm@takeda.com

or

Denali Therapeutics Contact:

Morgan Warners, +1-202-295-0124

mwarners@gpg.com