

Sanofi and Denali Therapeutics to develop treatments for neurological and inflammatory diseases

- * Candidate molecules have the potential to treat multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Alzheimer's disease, and systemic inflammatory diseases
- * Denali to receive \$125 million upfront payment and future milestone payments that could exceed \$1 billion

PARIS – November 1, 2018 – Sanofi plans to collaborate with Denali Therapeutics Inc. on the development of multiple molecules with the potential to treat a range of neurological and systemic inflammatory diseases.

The two lead molecules (DNL747 and DNL758) target a critical signaling protein known as the receptor-interacting serine/threonine-protein kinase 1 (RIPK1) in the TNF receptor pathway, which regulates inflammation and cell death in tissues throughout the body. The companies plan to study DNL747 in multiple sclerosis (MS), Alzheimer's disease, and amyotrophic lateral sclerosis (ALS), and DNL758 in systemic inflammatory diseases such as rheumatoid arthritis and psoriasis.

Under the terms of the agreement, Sanofi will make an upfront cash payment to Denali of \$125 million, with future development and commercial milestone payments that could exceed \$1 billion. Sanofi and Denali will share commercial profits and losses from DNL747 in the U.S. and China equally, while Denali will receive a royalty from Sanofi for other territories for DNL747 and worldwide for DNL758.

Phase 1b and 2 clinical development costs for DNL747 will be fully funded by Sanofi for MS, ALS, and other neurological indications, except in Alzheimer's disease, which will be funded by Denali. Phase 3 trials for all neurological indications will be jointly funded by Sanofi (70%) and Denali (30%). Sanofi will fully fund the clinical development costs for DNL758 in systemic inflammatory diseases.

“This collaboration with Denali is yet another example of Sanofi’s commitment to accelerate the development of transformative and best-in-class treatments for patients living with serious illnesses,” said Rita Balice-Gordon, Ph.D., Global Head of Rare and Neurologic Diseases Research at Sanofi. *“We look forward to working with Denali on the RIPK1 program as we explore the potential of this mechanism in neurologic and inflammatory diseases.”*

“RIPK1 is a promising target with the potential to bring disease modifying medicines to patients suffering from neurodegenerative diseases as well as systemic inflammatory diseases. We are very excited to partner with Sanofi and expand our RIPK1 program into new indications,” said Ryan Watts, Ph.D., CEO of Denali. *“With its considerable infrastructure and experience in both clinical development and commercial functions, Sanofi is an ideal partner for Denali to maximize the clinical and commercial success of our RIPK1 program.”*

RIPK1 Molecules

- **DNL747**, a brain-penetrant small molecule, is currently being evaluated in early clinical stage trials, known as Phase 1. Phase 1b studies in Alzheimer’s disease and ALS patients are expected to commence in the near-term and will inform the subsequent clinical development. Denali will lead the Phase 2 clinical trials in Alzheimer’s disease while Sanofi will lead the Phase 2 clinical trials in MS and ALS, as well as future Phase 3 trials in all neurological indications.
- **DNL758** is a small molecule that does not penetrate the brain. Sanofi will lead clinical development activities for all systemic inflammatory diseases. The clinical trials are expected to begin in 2019.

The collaboration also includes additional pre-clinical RIPK1 inhibitor molecules.

The transaction is expected to close in the coming months in accordance with customary regulatory approvals.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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ir@sanofi.com**Sanofi Forward-Looking Statements**

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Forward-looking statements expressed or implied in this press release include, but are not limited to, the potential benefits of the collaboration with Denali; the expected closing date of the transaction, plans to commence Phase 1b clinical testing of DNL747 in ALS and Alzheimer's patients in the near-term; expectations for future Phase 2 clinical trials, commencement of Phase 3 clinical trials in all neurological indications, expectations for future clinical testing of DNL758, and statements made by Sanofi's Global Head of Rare and Neurologic Diseases Research. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions, and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the ability of Sanofi's partners to execute their obligations under any partnership or collaboration agreement, as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.