January 7, 2022
Modalis Therapeutics Corporation
Stock exchange listing: Tokyo Stock Exchange (4883)
Representative: Haruhiko Morita

Modalis Announces Termination of Research Collaboration on MDL-204

7-January-2022 TOKYO & Waltham, Mass.- Modalis Therapeutics Corporation (Tokyo Stock Exchange T.4883) (hereinafter “Modalis” or “the Company"), a leading company developing innovative products for the treatment of rare genetic diseases utilizing its proprietary CRISPR-GNDM epigenetic gene modulation technology, today announced the expiration of its research collaboration with Astellas Pharma Inc. (hereinafter “Astellas”), a global pharmaceutical company, for the development of MDL-204.

Modalis and Astellas have been pursuing their collaboration program through discovery activities with Modalis’ proprietary technology, CRISPR-GNDM. Astellas has notified us today of its decision not to extend the joint research program for MDL-204 or exercise its right to negotiate a license agreement for the pipeline for strategic reasons.

MDL-204 targeted a disease of the central nervous system. The collaboration began 2019. After evaluation by both parties, it was determined that the CRISPR-GNDM® platform could not deliver a differentiated approach for this target, and therefore, the parties have agreed not to extend the collaboration beyond the current expiration date at the end of December 2021.

Although the advantage of the CRISPR-GNDM® technology was not fully realized in this program, we believe it is due to the highly competitive landscape for this specific target. Astellas continues to explore the existing programs licensed to it, MDL-201 and MDL-202, currently in the pre-clinical stage.

With the removal of MDL-204 from the collaborative pipeline, the Company's collaboration pipeline is reduced to three products. Together with the four products that are being developed in-house, the Company will have a total of seven products.

The impact of this matter on the Company's consolidated financial results for the fiscal year ending December 31, 2021, is expected to be minimal.

"While the agreement not to extend the joint research for MDL-204 was based on an overall assessment that it was not sufficiently superior or reasonable, we have several new pipeline candidates, including those that we are currently exploring the possibility of collaboration and those that we are incubating in-house. We plan to promote them to the pipeline at an appropriate stage." said Haru Morita, President and CEO of Modalis. "Making such appropriate decisions for revision or discontinuation on a program-by-program basis is a routine decision for the portfolio of any pharmaceutical or biotech company, including us, and we believe that it is reasonable to optimize the size and quality of the pipeline through appropriate metabolism. We also believe that making such decisions at an early stage, especially in the research stage, is effective in increasing the likelihood of success in the costly development in later stage."

About Modalis:

Modalis Therapeutics is developing precision genetic medicines through epigenetic gene modulation. Modalis is pursuing therapies for orphan genetic diseases using its proprietary CRISPR-GNDM technology which enables the locus specific modulation of gene expression or histone modification without the need for double-stranded DNA cleavage, gene editing or base editing. Modalis is focusing initially on genetic disorders caused by loss of gene regulation – resulting in excess or insufficient protein production – which includes more than 660 genes that are currently estimated to cause human disease due to haploinsufficiency. Headquartered in Tokyo with laboratories and facilities in Cambridge, Massachusetts. For additional information, visit www.modalistx.com.

Forward-Looking Statements:

This document has been prepared by Modalis Therapeutics corporation and Modalis Therapeutics Inc. (the "Companies") solely for information purpose only. This document does not constitute or form part of and should not be construed as, an offer to sell or issue or the solicitation of an offer to buy or acquire securities of the Companies in Japan, the United States or any other jurisdictions. The information contained herein is based on current economic, regulatory, market trends and other conditions. The Companies make no representation or guarantee with respect to the credibility, accuracy or completeness of the information herein. The information contained herein may change without prior notice. You may not publish or use this document and the contents thereof for any other purpose without a prior written consent of the Companies. Furthermore, the information on future business results are forward-looking statements. Forward-looking statements include but not limited to expressions such as "*believe*", "*expect*", "*plan*", "*strategic*", "*expect*", "*anticipate*", "*predict*" and "*possibility*", as well as other similar expressions to explain future business activities, achievements, events and future conditions. Forward-looking statements are predictions about the future that reflect management's judgment based on currently available information. As such, these forward-looking statements are subject to various risks and uncertainties that could cause actual results to differ materially from those expressed in or suggested by the forward-looking statements. Therefore, you may not rely entirely on forward-looking statements. The Companies do not assume any obligation to change or correct any forward-looking statements in light of new information, future events or other findings. This document and its contents are confidential and are being provided to you solely for your information and may not be retransmitted. This presentation is being furnished to you solely for your information and may not be reproduced or redistributed to any other person. In giving this presentation, the Companies do not undertake any obligation to provide the recipient with access to any additional information or to update this presentation or any additional information or to correct any inaccuracies in any such information which may become apparent. Information on companies other than the Companies and information provided from third parties are based on public information or sources. The Companies have not independently verified the accuracy and appropriateness of such data and indicators used herein, nor assume any responsibility for the accuracy and appropriateness of such data and indicators presented in this document.

Contacts

Modalis Therapeutics
Sawako Nakamura
media@modalistx.com