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Stock exchange listing: Tokyo Stock Exchange
Code number: 4883
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Strategic Development Progress Update for MDL-101: Clinical Readiness Advancement and Program Optimization

TOKYO & Waltham, Mass – Modalis Therapeutics Corporation (Tokyo Stock Exchange: 4883), a pioneering company developing innovative therapeutics for rare genetic diseases utilizing its proprietary CRISPR-GNDM® epigenome editing technology, today announced continued strategic advancement of MDL-101 toward clinical-stage readiness, supported by consistent biological validation and ongoing development optimization initiatives.

1. Biological Validation and Nonclinical Development Progress
IND-enabling studies conducted in disease model mice have consistently demonstrated clear survival benefit compared with control groups, supporting the underlying therapeutic concept and pharmacological mechanism of action of MDL-101. These findings continue to reinforce the biological rationale of the program.
As part of ongoing development progression toward clinical-stage readiness, the Company is conducting further analyses to refine development parameters and enhance overall program robustness. Importantly, no new safety concerns have been identified to date.

2. Development Optimization Toward Clinical Transition
The Company is prioritizing optimization of biological and clinical readiness to enhance the probability of long-term clinical success. Current activities are focused on strengthening translational robustness and execution certainty as the program advances toward clinical-stage transition, rather than reflecting any change in the underlying therapeutic concept.

3. IND Submission Timing
In alignment with this disciplined development approach, the anticipated timing of IND submission is currently under reassessment to ensure optimal preparation for clinical development. At this time, we are considering the IND application timing, including the possibility of a delay beyond the initial plan, based on optimizing preparations for clinical transition. The specific timing is currently under review.

4. Platform and Pipeline Impact
At this time, the Company believes the ongoing development optimization is specific to MDL-101 and does not indicate broader limitations of the CRISPR-GNDM® platform technology or other pipeline programs.

5. Strategic Partnership Progress
In parallel, the Company has reached a term sheet-level strategic understanding with a third party regarding regional clinical development and future commercialization rights in a specific territory. This agreement reflects external validation of the program's potential and supports the Company's strategy to enhance global development execution and long-term commercial value. Further details will be disclosed as appropriate.

6. Forward Strategy
Consistent with our development philosophy, we prioritize achieving optimal biological and clinical readiness over adhering to predetermined timelines. We believe that a disciplined, data-driven approach at this stage enhances the probability of long-

term clinical success and strengthens the overall value of the program.
The Company will continue to:

- Complete ongoing analyses
- Optimize development planning
- Maintain ongoing dialogue with regulatory authorities

Further updates will be provided as appropriate.

7. Financial Impact

The Company is currently evaluating potential impacts on financial forecasts and will disclose any material updates as appropriate.

Importantly, based on currently available data, the Company does not believe that the ongoing development optimization reflects any fundamental limitations of the underlying therapeutic concept or biological mechanism, but rather represents a disciplined step toward enhancing clinical-stage readiness. Taken together, the Company views the current development stage as a natural evolution toward clinical execution rather than a deviation from the program's intended trajectory.

About Modalis

Modaris Corporation (TSE: 4883), established in 2016, has a research and development base in Massachusetts, USA, and is a leading company in the development of therapeutic drugs using CRISPR-based epigenome editing technology. Based on our scalable platform technology, we develop therapeutics for patients suffering from serious genetic disorders such as muscle diseases, CNS diseases and cardiomyopathies. For more information, please visit our website at (www.modalistx.com/jp/)