Wave Life Sciences Announces Submission of First Clinical Trial Application for WVE-007 (siRNA Targeting INHBE) in Obesity

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WVE-007 is a novel approach for treating obesity and is designed to silence INHBE to achieve healthy, sustainable weight loss through fat burning, muscle maintenance and the potential for once or twice-annual administration

WVE-007 is Wave's first siRNA program to enter clinical development and uses best-in-class oligonucleotide chemistry and GalNAc delivery

Wave expects to initiate the first-in-human study of WVE-007 in 1Q 2025

CAMBRIDGE, Mass., Dec. 23, 2024 (GLOBE NEWSWIRE) -- Wave Life Sciences Ltd. (Nasdaq: WVE), a clinical-stage biotechnology company focused on unlocking the broad potential of RNA medicines to transform human health, today announced the submission of its first clinical trial application (CTA) for WVE-007 in obesity. WVE-007 is an investigational GalNAc-conjugated small interfering RNA (siRNA) designed to silence Inhibin βE (INHBE) gene expression, which would induce fat burning (lipolysis) to decrease body weight without impacting muscle mass. Wave expects CTA approval and initiation of the first-in-human study of WVE-007 in the first quarter of 2025.

"Our WVE-007 program, which uses Wave's best-in-class GalNAc-siRNA capabilities with proprietary chemistry, has potential to be dosed once or twice annually and may ultimately be used across the obesity treatment continuum for sustainable weight loss and cardiometabolic risk reduction," said Paul Bolno, MD, MBA, President and Chief Executive Officer at Wave Life Sciences. "With a growing understanding of human genetics and opportunities to directly impact adipose tissue, INHBE has emerged as an exciting, novel therapeutic target to address obesity, without the challenges of current standard-of-care therapeutics."

Human genetics provide strong evidence for INHBE as a therapeutic target. Individuals who have a protective loss-of-function mutation in the INHBE gene have a healthier cardiometabolic profile, including less abdominal fat, lower triglycerides, and lower risk of type 2 diabetes and cardiovascular disease. WVE-007 is designed to induce this healthy phenotype through INHBE gene silencing, leading to fat burning and improvements in metabolic health. In preclinical studies using a mouse model of diet induced obesity (DIO), a single dose of Wave's INHBE siRNA led to weight loss on par with semaglutide, with no muscle loss. When administered as an add-on to semaglutide, a single dose doubled the amount of weight loss. In another study, Wave's INHBE siRNA also prevented weight regain when semaglutide treatment was discontinued.

Wave's first-in-human study of WVE-007 is a Phase 1 clinical trial in adults living with overweight or obesity. The trial is designed to assess safety, tolerability, pharmacokinetics, and biomarkers for target engagement, as well as body composition and metabolic health.

About Wave Life Sciences
Wave Life Sciences (Nasdaq: WVE) is a biotechnology company focused on unlocking the broad potential of RNA medicines to transform human health. Wave's RNA medicines platform, PRISM ®, combines multiple modalities, chemistry innovation and deep insights in human genetics to deliver scientific breakthroughs that treat both rare and prevalent disorders. Its toolkit of RNA-targeting modalities includes editing, splicing, RNA interference and antisense silencing, providing Wave with unmatched capabilities for designing and sustainably delivering candidates that optimally address disease biology. Wave's diversified pipeline includes clinical programs in Duchenne muscular dystrophy, Alpha-1 antitrypsin deficiency and Huntington's disease, as well as a preclinical program in obesity. Driven by the calling to "Reimagine Possible", Wave is leading the charge toward a world in which human potential is no longer hindered by the burden of disease. Wave is headquartered in Cambridge, MA. For more information on Wave's science, pipeline and people, please visit www.wavelifesciences.com and follow Wave on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations for WVE-007, our investigational GalNAc-conjugated small interfering RNA (siRNA) designed to silence Inhibin βE (INHBE) gene expression and the anticipated therapeutic benefits thereof, including the potential of WVE-007 to treat obesity; the anticipated timing to initiate the first-in-human clinical program with WVE-007; the novelty of our approach to silence INHBE in order to achieve healthy, sustainable weight loss through fat burning, muscle maintenance and the potential for once or twice-annual dosing; and the potential benefits of WVE-007 compared with other investigational obesity treatments and current standard-of-care obesity therapeutics. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release and actual results may differ materially from those indicated by these forward-looking statements as a result of these risks, uncertainties and important factors, including, without limitation, the risks and uncertainties described in the section entitled "Risk Factors" in Wave's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), as amended, and in other filings Wave makes with the SEC from time to time. Wave undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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