Wave Life Sciences Announces Initiation of Phase 1 INLIGHT Clinical Trial of WVE-007 in Obesity

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WVE-007 is a novel, long-acting GalNAc-siRNA targeting INHBE mRNA – a genetically validated target that provides a new approach for healthy, sustainable weight loss (fat loss with muscle preservation)

Proof-of-concept clinical data from INLIGHT are expected in 2025

CAMBRIDGE, Mass., Feb. 06, 2025 (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 clinical trial application (CTA) approval and initiation of the Phase 1 INLIGHT clinical trial of WVE-007 in obesity. WVE-007 is a long-acting GalNAc-conjugated small interfering RNA (siRNA) that targets INHBE messenger RNA. INHBE is a genetically validated target that provides a novel approach for healthy weight loss. Wave expects to deliver proof-of-concept clinical data in 2025.

“WVE-007 is designed to treat obesity in an entirely new way by directly impacting fat cells to drive weight reduction, maintain muscle mass, and improve cardiometabolic health outcomes. With the potential for once- or twice-yearly dosing, WVE-007 is uniquely positioned to address more than 1 billion people living with obesity globally,” said Paul Bolno, MD, MBA, President and Chief Executive Officer at Wave Life Sciences. “WVE-007 is also Wave’s first siRNA to enter clinical development and utilizes our state-of-the art chemistry delivering potentially best-in-class silencing and durability. We are excited to continue advancing WVE-007 as we enter a new era for RNA interference and its application in common diseases.”

INLIGHT is a Phase 1, first-in-human clinical trial, which is designed to enroll adults living with overweight or obesity and assess safety, tolerability, pharmacokinetics, biomarkers for target engagement, body weight and composition, and metabolic health. Assessments of healthy weight loss, or fat loss with lean mass preservation, are consistent with recently issued FDA draft guidance on developing therapeutics for weight reduction. Proof-of-concept clinical data from INLIGHT, including safety, tolerability, and biomarkers reflective of healthy weight loss, are expected in 2025.

About WVE-007
WVE-007 is a GalNAc-conjugated small interfering RNA (GalNAc-siRNA) that targets inhibin βE (“INHBE”) messenger RNA. INHBE mRNA encodes a protein called Activin E that is secreted from the liver and acts directly on fat cells to block fat burning (“lipolysis”); therefore, silencing of INHBE would restart and maintain lipolysis. Human genetics also provide strong evidence for INHBE as a therapeutic target. Individuals who have a protective loss-of-function mutation in one copy of 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, leading to fat burning, muscle preservation, and improvements in metabolic health. Preclinical data using a mouse model of diet induced obesity (DIO) demonstrate WVE-007’s potential in multiple treatment settings, including as a monotherapy, as an add-on to GLP-1s, and as a maintenance treatment to prevent weight regain upon discontinuation of GLP-1 treatment.

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 common 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 Alpha-1 antitrypsin deficiency, Duchenne muscular dystrophy, Huntington’s disease, and Obesity, as well as several preclinical programs utilizing the company’s broad RNA therapeutics toolkit. 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 of the proof-of-concept data from our INLIGHT clinical trial of WVE-007; the novelty of our approach to silence INHBE in order to achieve healthy, sustainable weight loss and the potential for once- or twice-yearly 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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