Resalis Therapeutics Announces Initiation of Phase 1 Clinical Trial for RES-010 in Obesity

Torino, Italy, December 03, 2024 – Resalis Therapeutics today announced the initiation of its first-in-human, Phase 1 study for RES-010, a non-coding RNA-based compound designed to provide a disease-modifying approach to obesity treatment. Preclinical studies have demonstrated that RES-010 reduces fat mass, preserves lean body mass, and enhances energy expenditure. By targeting fat reduction across various regions of the body, including visceral and hepatic stores, RES-010 has the potential to complement existing therapies such as GLP-1 receptor agonists, and support sustainable, long-term weight management. The Phase 1 trial (EUCT No: 2024-514871-17-00) will explore the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of RES-010 in healthy, overweight, and moderately obese volunteers.

"The initiation of our Phase 1 trial with RES-010 marks a significant milestone in our commitment to address obesity's complex biological roots. By targeting the miR-22 pathway, a key metabolic regulator, RES-010 is designed to selectively reduce fat while preserving muscle mass. This unique mechanism of action can potentially improve and extend the effectiveness of current obesity treatments," said **Almut Nitsche, Chief Medical and Development Officer of Resalis Therapeutics**. "The trial is an essential step toward translating our preclinical insights into clinical advancements, paving the way toward a new generation of long-term obesity management treatments."

"Resalis has achieved the clinical development stage for RES-010 based on robust preclinical evaluation and a deep understanding of metabolic diseases, the non-coding RNA space, and RNA medicines. With RES-010, we expect to shift the focus from managing symptoms in the short term to achieving durable, long-term impact on obesity," said **Alessandro Toniolo, Chief Executive Officer of Resalis Therapeutics.** "With this trial, we are committed to validating our approach and moving closer to a transformative solution for people living with metabolic diseases."

The Phase 1 trial is a randomized, double-blind, placebo-controlled study conducted in the Netherlands. It consists of two parts: a single ascending dose (SAD) phase and a multiple ascending dose (MAD) phase. In the SAD phase, up to 48 healthy male and female participants will receive incremental single doses of RES-010 to evaluate safety and pharmacokinetics. The subsequent MAD phase will involve 24 overweight and 8 moderately obese participants who will receive multiple doses to further assess RES-010's safety and tolerability. The trial's primary objective is to assess the safety and tolerability of RES-010, while also evaluating its pharmacokinetics profile. Additionally, exploratory endpoints include assessing the effect of RES-010 on specific metabolic markers, change in lipid metabolism, body weight, appetite, and glucose tolerance. Data from the combined SAD/MAD study, which involves multiple phases of dose escalation and extensive safety evaluation, are expected by mid-2026.

About RES-010

RES-010 is designed to reprogram metabolic pathways, providing a potential disease-modifying therapeutic impact that could include high-quality, sustained weight loss. By specifically targeting miR-22, a master regulator of lipid biosynthesis, mitochondrial function, and adipose tissue transformation, RES-010 has the potential to go beyond conventional obesity treatments that

focus solely on appetite reduction. This targeted approach has the potential to offer a more durable solution, addressing the complex biological underpinnings of obesity. The regulation of these pathways may result in a reduction of fat mass across various body districts, including visceral fat and hepatic stores. With its robust preclinical results, RES-010 has the potential to complement and enhance the efficacy of existing anti-obesity drugs, such as GLP-1 receptor agonists, and may extend their impact by providing a more comprehensive therapeutic solution.

About Resalis Therapeutics

Resalis Therapeutics is dedicated to developing RNA-based therapies that tackle the root causes of complex metabolic disorders. With its deep expertise in non-coding RNA and lipid metabolism, Resalis Therapeutics is advancing RES-010 as a safe, effective, and disease-modifying therapy, offering sustained weight loss and improved metabolic health. With strong preclinical data supporting its development, RES-010 is now entering clinical trials, positioning Resalis Therapeutics as a key company in the evolving landscape of obesity treatment.

For more information visit our website www.resalistherapeutics.com.

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