Versameb AG Announces FDA Clearance of IND Application for VMB-100 in the Treatment of Stress Urinary Incontinence

BASEL, Switzerland, Nov. 16, 2023: Versameb AG ("Versameb"), a pre-clinical stage company focused on transforming RNA therapeutics to treat unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application of VMB-100, a potency enhanced messenger ribonucleic acid (mRNA) encoding human insulin-like growth factor-1 (IGF-1), for the treatment of stress urinary incontinence (SUI).

Following this clearance, Versameb plans to launch a Phase 2a open label, first-in-human dose ascending study in the first half of 2024. The study will evaluate the safety, tolerability, and efficacy of VMB-100 in female subjects with stress urinary incontinence, a highly common condition resulting in involuntary leakage of urine due to a weakened urinary sphincter muscle.

"The IND clearance by the FDA represents a significant milestone for the VMB-100 development program and for Versameb," said Klaas Zuideveld, Chief Executive Officer of Versameb AG. "This brings us a step closer to providing an effective therapeutic option to patients suffering from SUI. Our proprietary VERSagile platform is uniquely designed to improve potency of mRNA therapeutics and we believe VMB-100 can potentially become a game changer for SUI treatment. We look forward to initiating this trial in the first half of 2024 to evaluate the potential clinical benefits of VMB-100 in SUI."

"Stress urinary incontinence significantly impacts the quality of life of millions of women globally and is a major unmet medical need with no approved therapeutics available currently," said Professor Roger Dmochowski, Chief Medical Officer of Versameb AG. "IGF-1 plays a key role in promoting muscle regeneration and re-establishment of muscle function. We believe VMB-100 has the potential to fill the current therapeutic gap as a first-in-class mRNA therapy that can restore muscle function and thereby effectively treat incontinence."

About VMB-100

VMB-100 is an intramuscularly locally delivered, sequence engineered messenger ribonucleic acid (mRNA) encoding for human insulin-like growth factor-1 (IGF-1) under investigation for the treatment of stress urinary incontinence (SUI). VMB-100 has the potential to become first-and best-in-class in sustained muscle regeneration following short-term treatment. In preclinical studies, it has been demonstrated that VMB-100 induced the expression of IGF-1 levels in human muscle cells. In animals models of SUI, VMB-100 accelerated regeneration of the urinary sphincter muscle and restored urinary sphincter function after a single dose of treatment. Versameb plans to launch a Phase 2a open label, first-in-human dose ascending study of VMB-100 in female subjects with moderate stress urinary incontinence in the first half of 2024.

About Stress Urinary Incontinence

Stress urinary incontinence is a common condition amongst women in which a leakage of urine occurs during moments of physical activity due to a weakened urinary sphincter muscle. SUI is the most common type of urinary incontinence, affecting 86% of incontinent women. Despite the prevalence of SUI, there are currently no approved pharmacological therapies available in the United States. Current standard of

care protocol includes short-term solutions like pelvic floor therapy or a highly invasive surgical procedure in which a sling is permanently implanted into the urethra or bladder neck.

About Versameb AG

Versameb AG is a privately held biotechnology company focusing on discovering and developing innovative RNA-based drugs for modulation of protein expression, including the ability to simultaneously influence several therapeutic targets, in a controlled manner, with one molecular construct, and cellular targeting. Based in Basel and fully operational since 2018, the company is led by an experienced scientific and leadership team with proven expertise in drug discovery and development from lab bench to patient. Versameb's proprietary technology platform, VERSagile, optimizes the application of functional RNA in different disease contexts. The pipeline includes lead candidate programs in stress urinary incontinence (SUI), solid tumors and rare diseases. Versameb is working towards the completion of a first in-human proof-of-concept clinical study while advancing its platform. More information on Versameb can be found at www.versameb.com as well as on LinkedIn.

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