PRESS RELEASE

SERDA therapeutics submits IND for its lead product, an innovative wound debridement agent.

AMSTERDAM, THE NETHERLANDS. SERDA therapeutics, a biopharmaceutical company, announces that it has submitted an Investigational New Drug Application (IND) to the US FDA on the 17th February 2023 for its lead product SN514 hydrogel, an innovative enzymatic wound debriding agent. Clinical studies are expected to start in Q2 2023.

SN514 hydrogel is a topical debridement product designed to remove eschar rapidly and effectively from severe burn wounds and chronic ulcers, including pressure injury ulcers, venous leg ulcers (open leg) and diabetic foot ulcers. It will be the first clinical development in many years of an innovative enzymatic debriding agent with the potential of becoming a product of first choice in wound care.

In preclinical studies, SN514 hydrogel showed superior efficacy and speed of action over the current market leader and showed much better tolerability and ease of use than other debriding products. Application of the hydrogel will not require a surgery room or anesthesia, as is required for several other debriding products and methods.

Healing of severe wounds and ulcers is very often hampered by the formation of slough and eschar, which inhibit and interfere with the healing process. Removal of slough and eschar also has the potential to reduce the likelihood of local wound infection.

SN514 hydrogel is easy to apply. It does not require expert medical professionals and can be self-administered or applied by caregivers. As a result, SN514 hydrogel is expected to reduce the cost-of-care associated with severe burn wounds and chronic ulcers.

“We are very excited about this IND submission to initiate the clinical development of the SN514 hydrogel - a novel and promising debridement product for the treatment of severe burns and chronic wounds,” says Lucio van Rooijen, CEO of SERDA therapeutics.

About SERDA therapeutics

SERDA therapeutics is a biopharmaceutical company founded in 2020 as a spin-off from one of the leading wound care companies, Smith & Nephew, with NLC, the European Healthtech Venture Builder.

The name SERDA originated as an acronym of Stable Enzymatic Rapid Debridement Agent. Smith & Nephew granted an exclusive license to its preclinically developed product to SERDA therapeutics. SERDA is developing a proprietary best-in-class fast and effective therapeutic product for wound debridement in treatment of severe burn injuries and chronic ulcers, like pressure injuries, venous leg ulcers and diabetic foot ulcers.

In collaboration with the Metis Foundation, SERDA is planning to perform a Phase 1 Clinical Trial Utilizing SN514 for Enzymatic Debridement of Burns, which will be supported by the United States Army Medical Research Acquisition Activity (USAMRAA) under Contract No. W81XWH22C0143.

SERDA therapeutics is currently in the process of raising Series A funding.

The terms “SERDA” and “SERDA therapeutics” are used to refer to SERDA bv.

For more information about SERDA therapeutics, please visit www.serda-therapeutics.com.

Forward-looking Statements

This document may contain forward-looking statements that may or may not prove accurate. For example, statements regarding expected revenue growth, market trends and our product pipeline are forward-looking statements. Phrases such as "aim", "plan", "intend", "anticipate", "well-placed", "believe", "estimate", "expect", "target", "consider" and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from what is expressed or implied by the statements. For SERDA, these factors include: risks related to government actions and other restrictive measures taken in response, reduced procedure capacity at medical facilities, or our ability to execute business continuity plans, economic and financial conditions in the markets, especially those affecting health care providers, price levels for pharmaceutical products, developments in therapeutic standard, regulatory approvals, reimbursement decisions or other government actions, product defects or recalls or other problems with quality management systems or failure to comply with related regulations; litigation relating to patent or other claims; legal compliance risks and related investigative, remedial or enforcement actions; disruption to our supply chain or operations or those of our suppliers, competition for qualified personnel; strategic actions, including acquisitions and dispositions, our success in performing due diligence, valuing and integrating acquired businesses; disruption that may result from transactions or other changes we make in our business plans or organization to adapt to market developments, and numerous other matters that affect us or our markets, including those of a regulatory, political, economic, business, competitive or reputational nature. Any forward-looking statement is based on information available to SERDA as of the date of the statement. All written or oral forward-looking statements attributable to SERDA are qualified by this caution. SERDA does not undertake any obligation to update or revise any forward-looking statement to reflect any change in circumstances or in SERDA's expectations. Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the United States Army Medical Research Acquisition Activity (USAMRAA).

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