



Kuros Biosciences Completes Enrollment of Randomized Stage of Phase 2 Trial for Fibrin-PTH

November 23, 2022

- **First investigational trial of drug-biologic bone graft for spinal fusion**
- **No drug-related Serious Adverse Events (SAEs) reported in randomized stage of the trial**
- **Enrollment of additional 20 patients for second non-randomized stage underway**
- **Potential to address a major commercial opportunity**

Schlieren (Zurich), Switzerland, 23 November, 2022 – Kuros Biosciences (“Kuros” or the “Company”), a leader in next generation bone graft technologies, announced today the completion of enrollment in the randomized stage of the STRUCTURE trial, which is investigating the safety and efficacy of Fibrin-PTH (KUR-113) in transforaminal lumbar interbody fusion (TLIF) procedures in patients with degenerative disc disease (DDD).

No drug-related SAEs were reported in the first stage of the Phase 2 randomized, dose-finding, multi-center study. The STRUCTURE trial is being conducted under an open Investigational New Drug (IND) program for spinal fusion, which was filed with the U.S. Food and Drug Administration (FDA) in 2020. STRUCTURE will enroll 50 patients with DDD requiring single-level interbody fusion with concomitant posterolateral fusion (PLF).

In the first stage of the trial, 30 patients were randomized into two arms, the first receiving Fibrin-PTH and the second receiving local autograft, which serves as control. Fibrin-PTH or local autograft were applied in and around FDA-cleared polyether-etherketone (PEEK) cages, respectively. Enrollment is underway for the remaining 20 patients for the second, non-randomized part of the trial, in which all subjects will receive Fibrin-PTH at a higher concentration. The primary endpoint of the trial is radiographic interbody fusion using CT scans at 12 months, as determined by an independent radiology expert panel.

Joost de Bruijn, Chief Executive Officer of Kuros, said: “We are very pleased with the progress we are making in this investigational trial, which is the first time a drug-biologic combination product candidate is being tested as a bone graft for the treatment of DDD in a controlled clinical setting. Fibrin-PTH has the potential to transform the way spinal fusions are performed and, as such, we see a substantial commercial opportunity around this product candidate. We are pressing ahead with the next stage of this trial and are looking forward to full enrollment of the study and primary endpoint read out of the randomized part of the study due next year.”

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About Fibrin-PTH (KUR-113)

Fibrin-PTH (KUR-113) consists of a natural fibrin-based healing matrix with an immobilized targeted bone growth factor (truncated human parathyroid hormone (PTH) analog. Fibrin-PTH (KUR-113) is designed to be applied directly into and around an intervertebral body fusion device as a gel, where it polymerizes in situ. Fibrin-PTH (KUR-113) functions via the well-established mechanism of action of parathyroid hormone; has been demonstrated in animal models of spinal fusion to be comparable to rhBMP-2; and has been shown in preclinical studies to be easy to use and ideal for open or minimally invasive techniques^{1}. The safety & efficacy of Fibrin-PTH (KUR-113) has not yet been evaluated for spinal fusion in humans.*

About Spinal Fusion

Lumbar fusion surgery is designed to create solid bone between adjoining vertebrae of the spine, eliminating any movement between the bones. Spinal fusion may be recommended for conditions such as spondylolisthesis, degenerative disc disease or recurrent disc herniations. The goal of fusion surgery is to reduce pain and nerve irritation. Surgeons perform lumbar fusion using several techniques. One such technique – Transforaminal Lumbar Interbody Fusion (TLIF) – is used to stabilize the spinal vertebrae. This definition is adapted from www.spine-health.com. It is estimated that the orthobiology market for spinal fusion is growing to \$2.2 billion in 2030, while currently over 800,000 spinal fusion procedures are performed annually in the US & EU.

About Kuros Biosciences

Kuros Biosciences is a fast-growing leader in the development of spinal fusion biologics that ease the burden of back pain. With locations in the United States, Switzerland and the Netherlands, the company is listed on the SIX Swiss Exchange. The company's first commercial product, MagnetOs, is a unique synthetic bone graft that has already been used successfully across

three continents and in over 10,000 spinal fusion surgeries. The next candidate in the Kuros pipeline is Fibrin-PTH – the first drug-biologic combination for interbody spinal fusions, currently undergoing a Phase 2 clinical trial in the U.S. For more information on the company, its products and pipeline, visit kurosbio.com.

Forward Looking Statements

This media release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. You are urged to consider statements that include the words “will” or “expect” or the negative of those words or other similar words to be uncertain and forward-looking. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward-looking statements include scientific, business, economic and financial factors. Against the background of these uncertainties, readers should not rely on forward-looking statements. The Company assumes no responsibility for updating forward-looking statements or adapting them to future events or developments.

1. *Data on file*

**Results from in vivo laboratory testing may not be predictive of clinical experience in humans.*