



Kuros Biosciences Announces Completion of Enrollment in the Fibrin-PTH Phase 2 Trial

July 13, 2023

- **First investigational trial of drug-biologic bone graft for spinal fusion**
- **50 patients have been enrolled in the Phase 2 trial**
- **Potential to address \$2.2B market opportunity**

Schlieren (Zurich), Switzerland, July 13, 2023 – Kuros Biosciences (“Kuros” or the “Company”), a leader in next generation bone graft technologies, announced today the completion of enrollment in the STRUCTURE trial, which is investigating the safety and efficacy of Fibrin-PTH (KUR-113) in single-level transforaminal lumbar interbody fusion (TLIF) procedures in patients with degenerative disc disease (DDD).

Fibrin-PTH is a novel parathyroid hormone-based healing matrix allowing targeted, controlled bone generation. “This first-of-its-kind, drug-biologic combination product has the potential to transform the way spinal fusions are performed” agreed Dr R. Todd Allen from UCSD, one of the investigators of the study. Due to its injectable formulation, it is particularly well suited for minimally invasive approaches.

Fibrin-PTH targets a substantial clinical need and, upon approval, will address the large musculoskeletal growth factor market projected to reach \$2.2B by 2030.

The coordinating investigator of the STRUCTURE study, Dr John Chi from Brigham and Women’s Hospital, commented: “Fibrin PTH is a keystone technology for promoting bone health and I’m excited to see it being used for spinal fusion, which is one of the hardest areas to fuse. I’m so pleased to see this product progressing through clinical development and we are now one step closer to treating many patients.”

Joost de Bruijn, Chief Executive Officer of Kuros, said: “This is a major milestone for the company as well as the patients and surgeons we serve across the globe. We look forward with great anticipation to the initial readout from the Phase 2 trial, which we estimate will be in December of this year.”

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 has enrolled 50 patients with DDD requiring single-level interbody fusion with concomitant posterolateral fusion (PLF). The primary endpoint of the trial is radiographic interbody fusion using CT scans at 12 months, as determined by an independent radiology expert panel. Upon successful completion of the Phase 2 study, the Phase 3 program will be initiated.

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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 U.S. & 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 product candidate 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](http://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.*