Ad hoc announcement pursuant to Article 53 of the SIX listing rules

Kuros Biosciences Announces Results from Two Prospective Randomized Clinical Trials: STRUCTURE and MAXA

- **In the MAXA trial, standalone MagnetOs outperformed the gold standard autograft by 73% in posterior spinal fusion in a difficult-to-treat real life patient population (20% smokers). In the STRUCTURE trial, MagnetOs mixed with autograft showed posterolateral fusion rates comparable to autograft fusion rates in the less challenging interbody space**
- **In the STRUCTURE trial, according to an interim analysis, Fibrin-PTH did not outperform autograft for interbody fusion, although patients showed excellent clinical outcomes**
- **Considering the outstanding clinical results of MagnetOs in the MAXA and STRUCTURE trials, and the recent FDA interbody clearance, Kuros has decided not to proceed to Phase 3 with Fibrin-PTH and focus its resources on MagnetOs**
- **Focusing on the MagnetOs program will result in lower development costs and lower expenses in the near-term, extending Kuros' cash runway, while still addressing a $2.4Bn annual bone graft market similar to that originally anticipated for both MagnetOs and Fibrin-PTH together**

Schlieren (Zurich), Switzerland, December 27, 2023 – Kuros Biosciences, a leader in next generation bone graft technologies, today announced results from two prospective, randomized clinical studies – the STRUCTURE and MAXA trials. In the MAXA trial, MagnetOs showed a 73% higher fusion rate relative to autograft in the challenging posterolateral space. In the STRUCTURE trial, Fibrin-PTH, while demonstrating excellent clinical outcomes, showed fusion rates comparable to autograft in the less challenging interbody space. As a result, Kuros will focus its resources to amplify the continued commercialization of its MagnetOs bone graft family of products.

The MAXA trial is an observer-blinded, randomized, intra-patient controlled, multi-center clinical trial which compared MagnetOs standalone to autograft for posterolateral fusion. The STRUCTURE trial is investigating the safety and efficacy of Fibrin-PTH (KUR-113) in single-level transforaminal lumbar interbody fusion (TLIF) procedures, compared to local autograft in the interbody space. Both treatment groups underwent concomitant posterolateral fusion with MagnetOs mixed with local autograft.

MAXA Study Results

The MAXA study is designed as a 100-patient, multi-center, observer-blinded, randomized, controlled, non-inferiority trial with intrapatient comparisons. This study compared MagnetOs standalone to autograft for posterolateral fusion. Patients requiring up to four-level instrumented posterolateral fusion (T10 – S2) were included, and lumbar/thoracolumbar fusion was assessed by CT-scan 12 months after surgery. Patients were randomized to have either MagnetOs or the gold standard autograft (at least 50% bone harvested from the iliac crest of the greater pelvis) implanted on one side of the spine.

In the study, MagnetOs showed a 73% higher fusion rate relative to autograft in the challenging posterolateral space. MagnetOs outperformed autograft in a difficult-to-treat, real-life patient population, containing 20% smokers.

Considering the very strong MagnetOs data and in order to most effectively allocate the Company's capital, Kuros Biosciences has decided not to proceed to Phase 3 with Fibrin-PTH and focus on continuing investment in its MagnetOs program and related initiatives for commercial advancement, while still addressing a USD 2.4 billion bone graft market similar to that originally anticipated for both MagnetOs and PTH together. This decision will result in lower development costs and lower expenses, extending the Company's cash runway in the near term. The Company expects to provide further financial guidance when presenting its financial statements for 2023.

Chris Fair, Chief Executive Officer of Kuros, said: "We are encouraged by the excellent results obtained with MagnetOs in both trials, and this, coupled with a recent interbody FDA clearance of MagnetOs, means that we now have level one clinical evidence of a best-in-class product to treat even difficult-to-heal patients. As a result, we have made the decision not proceed to Phase 3 with Fibrin-PTH and focus our investment and resources on the MagnetOs bone graft family of products. We are fortunate to have growing robust sales from MagnetOs to readily support our ongoing commercial and clinical operations."

Interim STRUCTURE Study Results

Interim analysis of the randomized part of the STRUCTURE study showed a good safety profile in both experimental groups, one treated with Fibrin-PTH (KUR-113) in single-level transforaminal lumbar interbody fusion (TLIF), and one treated with local autograft in the interbody space. Observed adverse events were those typical for spinal fusion surgeries. There were no Fibrin-PTH-related serious adverse events. Both study groups did well in terms of clinical parameters. The Oswestry disability score (ODI) was improved by 44 points in the Fibrin-PTH group and by 40 points in the autograft control group. Likewise, visual analog scale (VAS) scores improved by 50 points for the Fibrin-PTH group and by 36 points for the autograft control group. In this limited population of patients, the interbody fusion outcome with Fibrin-PTH did not outperform the autograft control group. MagnetOs mixed with autograft, which was used in both study groups for the more challenging to fuse posterior fusion, showed fusion outcomes that were comparable to the autograft group in the interbody space.

About the MAXA Trial

The MAXA study is a 100-patient multicenter, observer blinded, randomized, intra-patient controlled, non-inferiority trial with intra-patient comparisons. Adult patients qualifying for instrumented posterolateral spinal fusion of one to six levels in the thoracolumbar and lumbosacral region (T10-S2) with the use of autograft were included and posterolateral lumbar/thoracolumbar fusion was assessed by CT-scan 12 months after surgery. According to a randomization scheme, MagnetOs was implanted on one side of the spine and the gold standard autograft (at least 50% bone harvested from the iliac crest mixed with local bone) was implanted on the other side of the spine. Thereby, each patient serves as its own control. More details can be found at www.clinicaltrials.gov (NCT03625544).

About the STRUCTURE Phase 2 Clinical Trial

The STRUCTURE trial is investigating the safety and efficacy of Fibrin-PTH (KUR-113) in single-level transforaminal lumbar interbody fusion (TLIF) procedures with concomitant posterolateral fusion (PLF) in patients with degenerative disc disease (DDD). It is a dose-finding, multi-center, two-part trial, divided into a single-blind (randomized) first stage and an open-label (non-randomized) second stage. In the single-blind stage, 20 patients were randomized to Fibrin-PTH (0.4 mg TGplPTH1-34/mL Fibrin) and 10 patients to the gold standard local autograft which serves as a control. In the open-label stage, 20 patients received Fibrin-PTH at a higher concentration of TGplPTH1-34 (0.7 mg TGplPTH1-34/mL Fibrin). For the posterolateral fusion both experimental groups were treated with MagnetOs mixed with autograft. The primary endpoint of the trial is radiographic interbody fusion (defined by evidence of bridging trabeculae or continuous bony connection between superior and inferior vertebrae) using CT scans at 12 months, as determined by an independent radiology expert panel. In addition, clinical and safety parameters are being assessed. This study intends to demonstrate the safety and efficacy of Fibrin-PTH (KUR-113) www.clinicaltrials.gov (NCT04294004). The STRUCTURE clinical trial is not statistically powered to detect non-inferiority.

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About MagnetOs

MagnetOs is a bone graft like no other: thanks to its NeedleGrip™ surface technology, it grows bone even in soft tissues. This surface technology provides traction for our body's vitally important 'pro-healing' immune cells (M2 macrophages).†‡1,2 This in turn, unlocks previously untapped potential to stimulate stem cells - and form new bone throughout the graft.†§3-6 The growing body of science behind NeedleGrip™ is called osteoimmunology. But for surgeons and their patients we seek a more predictable fusion. †¶5,6*

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 Netherlands, Switzerland and the United States, the company is listed on the SIX Swiss Exchange. The company's main commercial product, MagnetOs, is a unique synthetic bone graft that has already been used successfully across three continents and in over 15,000 fusion surgeries. 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. *Duan, et al. eCM. 2019;37:60-73*
2. *Van Dijk, et al. eCM. 2021;41:756-73*
3. *Van Dijk, et al. JOR Spine. 2018;e1039*
4. *Van Dijk, et al. J Biomed Mater Res. Part B: Appl Biomater. 2019;107(6):2080-2090*
5. *Van Dijk, et al. Clin Spine Surg. 2020;33(6):E276–E287*
6. *Data on file*

**In large animal models*

†Results from in vivo laboratory testing may not be predictive of clinical experience in humans. For important safety and intended use information please visit kurosbio.com

‡MagnetOs is not cleared by the FDA or TGA as an osteoinductive bone graft

§For a 510(k)-cleared synthetic bone graft.

¶MagnetOs has been proven to generate more predictable fusions than two commercially available alternatives in an ovine model of posterolateral fusion.