



## Kuros Biosciences Announces Peer-Reviewed Publication of MagnetOs MAXA Level 1 Study Outcomes in Spine, Indicating Superiority Over Autograft

June 25, 2024

**Schlieren (Zurich), Switzerland, June 25, 2024** – Kuros Biosciences, a leader in next generation bone healing technologies, today announced the publication of a peer-reviewed manuscript that details the clinical data of its MAXA Level 1 prospective, multi-center, randomized, intra-patient controlled clinical study in Spine<sup>1</sup>.

Published clinical results of “Efficacy of Biphasic Calcium Phosphate Ceramic with a Needle-shaped Surface Topography Versus Autograft in Instrumented Posterolateral Spinal Fusion: A Randomized Trial” include fusion data on 91 patients and 128 segments with 1-year follow-up after surgery. As previously reported and now detailed in the peer-reviewed publication, the data demonstrates:

- MagnetOs™ effectiveness as a standalone\* alternative to autograft in challenging posterolateral fusions (PLF);
- Nearly double the fusion rate as compared to autograft in PLF, showing a 79% overall fusion rate with MagnetOs as independently measured with fine-cut CT, compared to 47% for autograft, which included difficult-to-treat patients of current and former smokers (n=19 and 35 respectively); and
- Noninferiority of MagnetOs versus autograft per study design, with primary outcome analysis even indicating MagnetOs superiority.

“We are extremely pleased to share the results of the MAXA study with the medical community,” said Moyo C. Kruyt, MD, PhD, lead researcher in the MAXA study. “The MAXA study demonstrates for the first time that an advanced synthetic bone substitute likely performs better than the current gold standard autograft in a challenging posterolateral fusion location.”

Chris Fair, Chief Executive Officer of Kuros, said, “Kuros is committed to supporting clinical research and providing evidence-based solutions for next generation bone healing technologies. This study’s acceptance and publication in Spine is proof of that commitment.” Fair continued, “We commend Professor Kruyt and his team for their independent efforts and their desire to provide the spine community and their patients with a robust level 1 study that supports the use of MagnetOs for difficult to treat patients and highlights a viable alternative to autograft.”

The publication, which includes additional details such as study design, patient demographics, inclusion/exclusion criteria, and complications reported in the study, can be accessed on the [Spine](#) website and is also available on the [Kuros Biosciences](#) website.

1. Stempels, H. et al., “Efficacy of biphasic calcium phosphate ceramic with a needle-shaped surface topography versus autograft in instrumented posterolateral spinal fusion: A randomized trial.” *Spine*. June 17, 2024. <https://doi.org/10.1097/BRS.0000000000005075>

2. Van Dijk, et al. *eCM*. 2021; 41:756-73.

3. Duan, et al. *eCM*. 2019; 37:60-73.

4. Van Dijk, et al. *Clin Spine Surg*. 2020;33(6): E276-E287.

5. Van Dijk, et al. *JOR Spine*. 2018 ; e1039

6. Van Dijk, et al. *J Biomed Mater Res. Part B: Appl Biomater*.

\*MagnetOs was mixed with venous blood

†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](http://kurosbio.com).

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

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

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### **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 fine-cut 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 (consisting of at least 50% bone harvested from the iliac crest mixed with local bone) was implanted on the other side of the spine. The investigators were blinded to the side assigned to the grafts until just prior to graft application. Thereby, each patient serves as its own control. More details can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03625544). Fusion performance of MagnetOs was tested with a noninferiority margin of 15%.

The MAXA clinical trial was funded via an unrestricted research grant from Kuros Biosciences. Unrestricted research grants provide funding to clinical investigators with an interest in advancing the knowledge and understanding of certain technologies. These grants are donations in the form of flexible funding that can be directed toward whatever program, project, or expense the investigator chooses.

#### **About 'Spine'**

As the leading international journal in spine surgery, Spine publishes high-impact, peer-reviewed original research manuscripts. Spine is one of the top referenced journals in the field and is recognized for featuring new technology and innovative procedures and techniques.

#### **About MagnetOs**

MagnetOs is a bone graft like no other: thanks to its NeedleGrip™ surface technology, it enables bone formation without added cells or growth factors. This surface technology provides traction for our body's vitally important 'pro-healing' immune cells (M2 macrophages). This in turn, unlocks previously untapped potential to stimulate stem cells – and form new bone throughout the graft. The growing body of science behind NeedleGrip is called osteoimmunology. But for surgeons and their patients it means one thing: a more predictable fusion. <sup>2-6†‡§</sup>

#### **Indications statement**

Please refer to the instructions for use for your local region for a full list of indications, contraindications, warnings, and precautions.

#### **About Kuros Biosciences**

Kuros Biosciences is on a mission to discover, develop and deliver innovative biologic fusion technologies. 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 advanced bone graft that has already been used across three continents in 25,000 fusion surgeries. For more information on the company and its products, 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.