

Kuros Biosciences Announces Three Advancements Related to its MagnetOs™ Portfolio Including Impressive Fusion Data from MAXA Prospective Randomized Clinical Trial and Two 510(k) Clearances from FDA

- **New level 1 data from the MAXA Clinical Trial comparing standalone MagnetOs to the gold standard autograft in the challenging posterior spinal fusion approach, demonstrates a fusion rate of 78% versus 45% after one year**
- **In the difficult-to-treat patient population of smokers, MagnetOs demonstrates impressive 80% fusion rate compared to 32% fusion rate with autograft (inpatient control)**
- **MagnetOs Easypack Putty becomes the second product in the MagnetOs portfolio to receive FDA clearance to market for interbody use**
- **MagnetOs Putty receives FDA clearance for standalone use and can now be used without the need for autograft**

Schlieren (Zurich), Switzerland, January 4, 2024 – Kuros Biosciences, a leader in next generation bone graft technologies, announced today three advancements related to its MagnetOs portfolio of products: specifically positive results from the MAXA level 1 clinical trial comparing standalone MagnetOs to autograft in a real world patient population in the challenging posterolateral fusion procedure, and two 510(k) clearances from the U.S. Food and Drug Administration (FDA) related to its MagnetOs family of products.

New Data from MAXA Study

Kuros announced additional data from the MAXA level 1 clinical trial evaluating MagnetOs in a challenging posterior spinal fusion model compared to the gold standard autograft (containing at least 50% iliac bone crest), following initial data that was [announced on December 27, 2023](#). In this trial, MagnetOs was evaluated as a standalone alternative to autograft in an instrumented posterolateral fusion (PLF) model in 91 patients and a total of 130 segments. Notably, 20% of the patients in this study were smokers – an extremely challenging patient population when it comes to achieving fusion. In the 91 subjects that were analyzed after one year, a fusion rate of 78% was observed with MagnetOs compared to a 45% fusion rate with autograft (the inpatient control), as evaluated by independent reviewers using fine-cut computed tomography (CT) scans.

In the patients who were smokers, a fusion rate of 80% was observed with MagnetOs compared to just 32% with autograft, further demonstrating that MagnetOs should be the preferred choice for predictable fusions.

Professor Moyo Kruijt, Orthopedic Spine Surgeon at the University Medical Centre Utrecht, Netherlands, and Principal Investigator of the study, commented, “The first results from this level 1 study indicate excellent fusion rates for MagnetOs when used standalone. These fusion rates appear to exceed those of other bone graft substitutes we have previously studied in this indication. We look forward to sharing the definitive numbers after full statistical analysis and peer review.”

Chris Fair, Chief Executive Officer of Kuros, commented, “This additional data from smokers in the MAXA clinical trial, showing more than twice the fusion rate when compared to autograft, provides even further support for MagnetOs as a standalone alternative to autograft in instrumented PLF procedures. This difficult study design was chosen to give surgeons greater confidence in our product and its ability to enable predictable fusions, even in a difficult-to-treat population of patients.”

The MAXA study is designed as a multi-center, observer-blinded, randomized, controlled, non-inferiority trial with inpatient comparisons. This study compared MagnetOs standalone to autograft for posterolateral fusion. A challenging real-world population of 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 MagnetOs placed on one side of the spine and the gold standard autograft (at least 50% bone harvested from the iliac crest of the greater pelvis) on the other side of the spine, allowing each patient to act as its own control.

510(k) Clearances for MagnetOs Easypack Putty and MagnetOs Putty

MagnetOs Easypack Putty has become the second product in the MagnetOs portfolio to be cleared for use in the interbody space by FDA. As a result, MagnetOs Easypack Putty can now be used in any interbody space (cervical, thoracolumbar); and packed into any cage approved for use with a bone void filler.

Additionally, MagnetOs Putty has been cleared for use either standalone or mixed with autograft. This 510(k) clearance expands the device’s indications to also allow use of the device on a standalone basis in the posterolateral spine, pelvis and extremities.

Chris Fair, Chief Executive Officer of Kuros, said: “We are delighted to have two MagnetOs products now cleared for interbody use, increasing the opportunity to serve our surgeon customers and the patients they treat.” Fair continued, “The commercial advancements to our MagnetOs portfolio along with the impressive level 1 clinical trial results, will continue to fuel our growth ambitions through 2024 and beyond.”

All products within the MagnetOs portfolio promote bone growth by optimizing the effect of Kuros’ established NeedleGrip™ surface technology. MagnetOs has been used in over 15,000

fusion procedures and is now cleared for more indications than any other synthetic bone graft substitute in the market today.

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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).^{†‡3,4} This in turn, unlocks previously untapped potential to stimulate stem cells - and form new bone throughout the graft.^{†§5-8} The growing body of science behind NeedleGrip™ is called osteoimmunology. But for surgeons and their patients it means one thing: a more predictable fusion.^{†¶7,8}*

U.S. Indications Statement

MagnetOs Easypack Putty is intended to fill bony voids or gaps of the skeletal system, i.e., the intervertebral disc space, and posterolateral spine. The osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the intervertebral disc space and posterolateral spine, MagnetOs Easypack Putty must be used with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs Easypack Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler. MagnetOs Easypack Putty resorbs and is replaced with bone during the healing process.

MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system i.e., the extremities, pelvis and posterolateral spine. MagnetOs Putty may be used standalone or mixed with autograft. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. MagnetOs Putty resorbs and is replaced with bone during the healing process.

MagnetOs Granules is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the extremities, pelvis and posterolateral spine. MagnetOs Granules may be used standalone or mixed with autograft, blood, and/or bone marrow. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. MagnetOs Granules resorbs and is replaced with bone during the healing process.

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 advanced bone graft that has already been used successfully across three continents and in over 15,000 fusion surgeries.

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. iData Research, How Many Spinal Fusions are Performed Each Year in the United States? <https://idataresearch.com/how-many-instrumented-spinal-fusions-are-performed-each-year-in-the-united-states/>, accessed November 2023*
- 2. AcuityMD, procedure numbers estimated by CPT code Q4 2022-Q3 2023*
- 3. Duan, et al. eCM. 2019;37:60-73*
- 4. Van Dijk, et al. eCM. 2021;41:756-73*
- 5. Van Dijk, et al. JOR Spine. 2018;e1039*
- 6. Van Dijk, et al. J Biomed Mater Res. Part B: Appl Biomater. 2019;107(6):2080-2090*
- 7. Van Dijk, et al. Clin Spine Surg. 2020;33(6):E276–E287*
- 8. 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.