



## **Kuros Biosciences Receives US FDA 510K Clearance for MagnetOs Granules for Interbody Use and Regulatory Clearance of MagnetOs Granules and MagnetOs Putty in New Zealand**

January 31, 2024

- **MagnetOs™ Granules becomes the third product in the MagnetOs portfolio to receive FDA clearance to market for interbody use**
- **Kuros continues expansion of the MagnetOs franchise with launch of MagnetOs Granules and MagnetOs Putty in New Zealand via an exclusive distribution agreement with Vortek Spine Limited, a high-tech orthopedic and biologics company**

**Schlieren (Zurich), Switzerland, January 31, 2024** – Kuros Biosciences (“Kuros” or “the Company”), a leader in next generation bone graft technologies, today announced clearance of a 510(k) submission from the U.S. Food and Drug Administration (FDA) related to its MagnetOs™ Granules.

The Company also announced clearance to market in New Zealand for MagnetOs Granules and MagnetOs Putty. The products are now commercially available through Vortek Spine Limited (“Vortek”), a high-tech orthopedic and biologics company specializing in healthcare solutions for surgeons and patients. This further expands the MagnetOs portfolio in terms of application and accessibility.

Earlier in January, Kuros announced the FDA clearance of MagnetOs Easypack Putty for interbody use and MagnetOs Putty for standalone use in the posterolateral spine, meaning it can now be used without the need for autograft (patient’s own bone).

“We are very pleased that MagnetOs Granules has received marketing clearance for interbody use given the Granules technology is the foundation of the MagnetOs platform,” commented Chris Fair, Chief Executive Officer of Kuros Biosciences. “This clearance, coupled with the MagnetOs Flex Matrix and MagnetOs Easypack Putty formulations, provides our surgeons the widest variety of advanced biologic formulations available for use in the interbody space. We are also very excited to expand our international presence through a partnership with Vortek in New Zealand and to begin working with their team to introduce our clinically proven technology to this territory.”

The availability of MagnetOs in New Zealand marks a significant milestone for Kuros and the local medical community since patients can now benefit from an advanced bone graft that improves the overall quality of care in orthopedic and spinal procedures. This benefit was further demonstrated with recent level 1 clinical data in which MagnetOs outperformed the gold standard autograft by 73% in posterior spinal fusion in a difficult-to-treat real life patient population, of which 20% were current smokers.<sup>1</sup>

### **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).<sup>††2,3</sup> This in turn, unlocks previously untapped potential to stimulate stem cells – and form new bone throughout the graft.<sup>†§4-7</sup> 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>††6,7</sup>*

### **U.S. Indications Statement**

*MagnetOs Granules is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the extremities, pelvis, intervertebral disc space, and posterolateral spine. 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. When used in posterolateral spine, extremities and pelvis, MagnetOs Granules may be used standalone or mixed with autograft, blood, and/or bone marrow. When used in intervertebral body fusion procedures, MagnetOs Granules must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler and hydrated with blood. MagnetOs Granules may also be mixed with autograft. MagnetOs Granules 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 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 Flex Matrix 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 Flex Matrix must be hydrated with bone marrow aspirate (BMA) and used as an extender to autograft bone. When used in intervertebral body fusion procedures, MagnetOs Flex Matrix must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler. MagnetOs Flex Matrix resorbs and is replaced with bone during the healing process.*

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**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 25,000 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. Data on file. MaxA. Autograft in a Prospective, Multi-center, Randomized, Intra-patient Controlled Trial. P2016;117(7):1511–1521.
2. Duan, et al. eCM. 2019;37:60-73
3. Van Dijk, et al. eCM. 2021;41:756-73
4. Van Dijk, et al. JOR Spine. 2018;e1039
5. Van Dijk, et al. J Biomed Mater Res. Part B: Appl Biomater. 2019;107(6):2080-2090
6. Van Dijk, et al. Clin Spine Surg. 2020;33(6):E276–E287
7. 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](http://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.*