Kuros Biosciences

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Kuros Biosciences's MagnetOs Granules cleared by FDA for expanded spinal indications

- **Rare clearance for bone graft for standalone use in spine based on human clinical data**
- **Clearance attained with evidence from Level 1 randomized controlled trial**
- **Positions MagnetOs above most other 510(k)-cleared bone grafts on the market**

Schlieren (Zurich), Switzerland, February 3rd, 2022 – Kuros Biosciences ("Kuros" or the "Company"), a leader in next generation bone graft technologies, announced today that its MagnetOs Granules has been cleared by the U.S. Food and Drug Administration (FDA) for expanded indications in the spine, making it only the second-ever bone graft to achieve clearance for standalone use in the spine based on human clinical data.

The FDA clearance was attained using radiographic data, clinical outcomes and safety data from 50 patients who were enrolled in a Level 1 randomized controlled multicenter trial in which MagnetOs Granules were compared head-to-head against autograft, the gold standard for posterolateral fusion. The clearance for standalone use proves MagnetOs to be an augmented graft that can be used in place of, as well as in combination with, autograft bone.

Joost de Bruijn, Chief Executive Officer of Kuros, said: "Almost all of the more than four hundred bone grafts cleared by the FDA via 510(k) were done so based on preclinical evidence alone. In an environment in which there is increasing focus on value-based medicine, our clearance for standalone use based on human clinical data positions MagnetOs above most other 510(k)-cleared bone grafts being offered to providers and surgeons. There is a clear need for bone grafts that are supported by Level 1 evidence and cleared for multiple uses, including the most challenging such as standalone use."

Standalone use requires the body to rely on the implanted bone graft product and not on combined autograft from the patient, which means the bar for proving standalone efficacy is higher than for bone graft extender efficacy.

Contrary to MagnetOs Granules, very few bone grafts are supported by Level 1 evidence from a randomized controlled trial. For instance, the current market-leading synthetic is supported by only one Level 1 pilot study, in which 20 patients were treated as opposed to the 50 patients treated in Kuros's multicenter trial. Across all published studies for the market-leading synthetic, 90% of patients were from studies by a single investigator, and conducted at a single clinical site,

and 96% of all patients were from non-randomized Level III/IV studies which provide a lower evidence base for clinical decision-making than Level I studies. The data package used in the FDA submission is the first Level 1 data to emerge from the Company's Project Fusion (https://kurosbio.com/project-fusion/).

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About MagnetOs

MagnetOs isn't like other bone grafts. It grows bone even in soft tissue thanks to its unique NeedleGrip surface technology which 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 efficient and predictable fusion.

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 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 Project Fusion

Today, nearly 1 in 5 spinal fusions fail. So, what can we do to change this situation – for the benefit of patients, surgeons and our wider society? This is the question that drives us at Kuros Biosciences. Every day our team works across three continents to unlock the hidden secrets of bone healing through our research, development & technology program: ***Project Fusion****. To deliver the ideal bone graft, we believe you need the highest quality & quantity of scientific evidence behind it. Which is why Project Fusion brings together an unprecedented blend of scientific, preclinical and clinical studies – all aimed at making the unpredictable…predictable. For more information on Project Fusion, visit kurosbio.com/project-fusion.*

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 5,000 spinal fusion surgeries. The next candidate in the Kuros pipeline is Fibrin-PTH – the first drug-biologic combination for interbody spinal fusions, currently undergoing a Phase 2 clinical trial in the US. 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.