



Kuros Biosciences Announces FDA 510(k) Clearance for MagnetOs Easypack Putty

September 9, 2021

Schlieren (Zurich), Switzerland, 9 September, 2021 – Kuros Biosciences (“Kuros” or the “Company”), a leader in next generation bone graft technologies, announced today that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for MagnetOs Easypack Putty, a soft and moldable formulation ideal for packing into voids of the skeletal system, particularly the posterolateral spine during spinal fusion surgery.

The clearance of MagnetOs Easypack Putty follows existing clearances by the FDA for the use of MagnetOs Granules and MagnetOs Putty in the spine.

Joost de Bruijn, Chief Executive Officer of Kuros, said: “The new formulation in the MagnetOs product family offers surgeons a broader set of options for perioperative properties. This latest successful regulatory milestone continues our track record of market clearances with the FDA and strengthens our position on the market. “

Human-derived products, such as cell-based allografts, and recombinant protein products, such as bone morphogenetic proteins, need to be stored in freezers and then carefully thawed under strict protocol prior to or during surgery.

To the benefit of surgeons and their patients, MagnetOs Easypack Putty is provided in an open-ended dispenser and is ready to use with no need for thawing or mixing with blood or bone marrow aspirate. It can be stored at room temperature and used immediately from the packaging, which can save Operating Room staff vital time during procedures.

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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. Results from in vitro or in vivo laboratory testing may not be predictive of clinical experience in humans. MagnetOs is not cleared by TGA or FDA as an osteoinductive bone graft.

US indications statement

MagnetOs Easypack Putty is intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. In the posterolateral spine, MagnetOs Easypack Putty must be used with autograft as a bone graft extender. 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. MagnetOs Easypack Putty resorbs and is replaced with bone during the healing process.

About Kuros Biosciences AG

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 some 4,000 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.