



## **Kuros receives FDA 510(k) clearance for extending commercial indications of MagnetOs Putty in the United States**

December 10, 2018

- **US Food and Drug Administration (FDA) clearance granted for extending the use of MagnetOs Putty as a stand-alone bone graft in extremities and pelvis**
- **Paves way for commercial expansion into more clinical indications in orthopedic surgery**

**Schlieren (Zurich), Switzerland, December 10, 2018** – Kuros Biosciences (SIX: KURN) today announced that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for extending MagnetOs Putty indications to use as a stand-alone bone graft in extremities and pelvis. This is in addition to the existing clearance for use of MagnetOs Granules and MagnetOs Putty as an autograft extender in posterolateral spine.

Joost de Bruijn, Chief Executive Officer of Kuros, commented: “This FDA clearance is another major milestone for us as it allows Kuros to expand the commercial reach of MagnetOs into new orthopedic applications such as reconstructive surgery. It also consolidates Kuros’ strategy to expand into indications in which MagnetOs is utilized as a replacement for, rather than supplement to, autologous bone graft”.

Several studies have shown that MagnetOs leads to progressive bone formation comparable to the current gold standard autograft. The search for suitable alternatives to autograft could give the Company the opportunity to become a leading player in the area of total bone graft substitutes, with products that can compete in the majority of the markets growing to an estimated US \$3.4 billion by 2030.

### **About MagnetOs**

*The MagnetOs product family is based on a unique and proprietary synthetic surface science technology. These products are based on calcium phosphate and have an advanced submicron surface topography that aims to direct bone formation and greatly enhance their ability to promote local bone formation. The surface topography has been demonstrated to stimulate the body to form bone in a safe, localized and accelerated manner. A substantial number of clinically relevant and predictive preclinical studies in small and large animals have demonstrated that the MagnetOs bone graft substitute leads to progressive bone formation and implant resorption that is equivalent to the current gold standard autograft.*

*. MagnetOs is available as granules and as a putty formulation.*

### **Previous US FDA clearance**

*MagnetOs granules have also obtained US FDA 510k clearance as an autograft extender in posterolateral spine early 2017. MagnetOs putty obtained US FDA 510k clearance in August 2017 as an autograft extender in posterolateral spine.*

### **New US indications statement in FDA 510(k) clearance**

*MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system i.e., the extremities, pelvis and posterolateral spine. In the posterolateral spine, MagnetOs Putty must be used with autograft as bone graft extender. In extremities and pelvis, MagnetOs Putty is used alone. 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.*

### **About Kuros Biosciences AG**

*Kuros Biosciences (SIX: KURN) is focused on the development of innovative products for bone regeneration and is located in Schlieren (Zurich), Switzerland and Bilthoven, The Netherlands. Visit [www.kurosbio.com](http://www.kurosbio.com) for additional information on Kuros, its people, science and product pipeline.*

### **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.*

**For further information, please contact:**

Kuros Biosciences AG  
Michael Grau  
Chief Financial Officer  
Tel +41 44 733 47 47  
[michael.grau@kurosbio.com](mailto:michael.grau@kurosbio.com)

Media & Investors  
Hans Herklots  
LifeSci Advisors  
+41 79 598 7149  
[hherklots@lifesciadvisors.com](mailto:hherklots@lifesciadvisors.com)