

Kuros Biosciences receives US marketing clearance for intervertebral body fusion device

- 510(k) clearance of the TLIF cage is an important step towards progression of Fibrin-PTH product candidate KUR-113 into clinical development
- Kuro's TLIF cage will be used in combination with its Fibrin-PTH product candidate in the upcoming interbody spinal fusion clinical trial

Schlieren (Zurich), Switzerland, March 13, 2019 – Kuros Biosciences (SIX: KURN) today announced that its Dutch subsidiary, Kuros Biosciences BV, has received clearance for the Kuros TLIF cage from the U.S. Food and Drug Administration (FDA).

The TLIF cage has been developed for the use with KUR-113, Kuros's advanced Fibrin-PTH product candidate for spinal fusion. The combination of KUR-113 with the TLIF cage will be investigated in upcoming clinical trials.

The Kuros TLIF cage is intended for use in intervertebral body fusion of the spine. The cage comes in a range of sizes and includes instruments to prepare the disc space and implant the device. The cage is cleared for use in the lumbar spine (L1 to S1) in combination with autograft and/or allograft, under 510(k) number K183092

Joost de Bruijn, Chief Executive Officer of Kuros, said "This regulatory clearance is an important corporate milestone that allows progression towards initiation of a spinal fusion study with our lead KUR-113 product candidate in the U.S. We look forward to the next step in the development of KUR-113, a submission for approval to initiate a U.S. clinical study."

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About the Kuros TLIF Cage

The Kuros TLIF Cage is intended for use in intervertebral body fusion of the spine. The Kuros TLIF cage is inserted via a posterior approach and can be used in one level or two contiguous levels of the lumbar spine (L1 to S1). The Kuros TLIF cage is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion, and is to be used with supplemental posterior spinal fixation systems for use in the lumbar spine that are cleared by the FDA.

About KUR-113

KUR-113 consists of a natural fibrin-based healing matrix with an immobilized targeted bone growth factor (truncated human parathyroid hormone (PTH) analog). KUR-113 is designed to be applied directly into and around an intervertebral body fusion device as a gel, where it polymerizes in situ. KUR-113 will be combined with the Kuros TLIF Cage in the upcoming clinical trial for interbody spinal fusion.



About Kuros Biosciences AG

Kuros Biosciences is focused on the development of innovative products for tissue repair and regeneration and is located in Schlieren (Zurich), Switzerland and Bilthoven, The Netherlands. The Company is listed according to the International Financial Reporting Standard on the SIX Swiss Exchange under the symbol KURN. Visit www.kurosbio.com for additional information on Kuros, its 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.