Kuros Biosciences

Kuros Biosciences Announces U.S. FDA approval of IND Application to Initiate Fibrin-PTH Phase 2a Clinical Trial in Spinal Fusion

- **Kuros to conduct Phase 2a trial in spinal fusion, comparing Fibrin-PTH to autograft**
- **Primary endpoint is radiographic interbody fusion at 12 months**

Schlieren (Zurich), Switzerland, September 3, 2019 – Kuros Biosciences, a leader in next generation bone graft technologies, today announces that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application to initiate a Phase 2a clinical trial to evaluate the use of Fibrin-PTH (KUR-113) in single level transforaminal lumbar interbody fusion (TLIF) procedures in patients with degenerative disc disease, with autograft (patient's own bone) as comparator.

This IND application is considered the first ever approval by the FDA to evaluate a drug/biologic combination product candidate for lumbar interbody fusion of the spine.

Joost de Bruijn, Chief Executive Officer of Kuros, said: "The IND approval is an important milestone for Kuros allowing us to advance the clinical program for Fibrin-PTH in spinal fusion into Phase 2a. Fibrin-PTH targets a substantial clinical need, and, if successful, opens up a huge commercial opportunity."

The planned clinical study is a prospective, randomized, controlled, open-label, multi-center, parallel group study with the primary endpoint of radiographic interbody fusion, using CT-scans at 12 months, determined by an independent radiology expert panel.

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Investigational Product Candidates

Fibrin PTH (KUR-113) is an investigational drug/biologic combination product candidate. Fibrin PTH (KUR-113) has been evaluated in animals for use in lumbar interbody fusion. The safety & efficacy of Fibrin PTH (KUR-113) has not yet been evaluated for spinal fusion in humans.

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About Fibrin-PTH (KUR-113)

Fibrin-PTH (KUR-113) consists of a natural fibrin-based healing matrix with an immobilized targeted bone growth factor (truncated human parathyroid hormone (PTH) analog). Fibrin-PTH (KUR-113) is designed to be applied directly into and around an intervertebral body fusion device as a gel, where it polymerizes in situ. Fibrin-PTH (KUR-113) functions via the well-established mechanism of action of parathyroid hormone; has been demonstrated in animal models of spinal fusion to be comparable to rhBMP-2; and has been shown in preclinical studies to be easy to use and ideal for open or minimally invasive techniques.

About Spine Fusion

Lumbar fusion surgery is designed to create solid bone between adjoining vertebrae of the spine, eliminating any movement between the bones. Spinal fusion may be recommended for conditions such as spondylolisthesis, degenerative disc disease or recurrent disc herniations. The goal of fusion surgery is to reduce pain and nerve irritation. Surgeons perform lumbar fusion using several techniques. One such technique – Transforaminal lumbar interbody fusion (TLIF) - is used to stabilize the spinal vertebrae. This definition is adapted from www.spine-health.com. It is estimated that the orthobiology market for spinal fusion is growing to $2.2 billion in 2030, while currently over 800,000 spinal fusion procedures are performed annually in the US & EU.

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, Bilthoven, The Netherlands and Burlington, U.S. 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.