Kuros Biosciences

Kuros Biosciences Announces Treatment of the First Patient in its Spinal Fusion Trial with Fibrin-PTH

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- **First investigational trial of a drug-biologic bone graft for spine fusion**
- **Phase 2 trial in the U.S. compares Fibrin-PTH (KUR-113) with local autograft**
- **Primary endpoint is radiographic interbody fusion at 12 months**
- **Potential to address a major commercial opportunity**

Schlieren (Zurich), Switzerland, September 1, 2020 – Kuros Biosciences, a leader in next generation bone graft technologies, today announced that the first patient has been treated in the STRUCTURE trial, investigating Fibrin-PTH (KUR-113) for transforaminal lumbar interbody fusion (TLIF) procedures in patients with degenerative disc disease. The first patient was treated by Dr Richard Todd Allen, investigator at University California San Diego. The STRUCTURE trial is conducted under an open Investigational New Drug (IND) for spinal fusion, which was recently filed with the U.S. Food and Drug Administration (FDA).

Kuros's STRUCTURE trial is a prospective, randomized, controlled, single-blind, dose-finding, multi-center study with the primary endpoint of radiographic interbody fusion, using CT-scans, at 12 months as determined by an independent radiology expert panel. This Phase 2 trial, conducted in the U.S., intends to demonstrate safety and efficacy of Fibrin-PTH in patients undergoing a single-level TLIF procedure.

In this first-of-its-kind investigational trial, a flowable drug-biologic bone graft will be delivered through a narrow-gauge delivery system to achieve interbody spine fusion. Not only is this the first time a drug-biologic bone graft is being tested for the treatment of Degenerative Disk Disease (DDD) in patients within a clinical trial, but it is also the first time such a technology is being evaluated for both open and minimally invasive surgical technique under clinical trial conditions.

STRUCTURE shall enroll 50 patients with DDD requiring single-level interbody fusion with concomitant posterolateral fusion (PLF). Patients treated with local autograft will serve as controls. KUR-113 or local autograft will be applied in and around FDA-cleared polyether-ether-ketone (PEEK) cages.

Joost de Bruijn, Chief Executive Officer of Kuros, said: "The treatment of the first patient in the STRUCTURE trial is an important milestone for Kuros`s Fibrin-PTH program. Fibrin-PTH targets a substantial clinical need and, if successful, addresses a huge commercial opportunity. We are happy that elective surgeries have resumed in the U.S., and expect recruiting the patients into the study without further delays."

The coordinating investigator of the STRUCTURE study, Dr. John Chi from Brigham and Women Hospital, commented: "It is exciting that the first patient has been included in this study which evaluates a completely novel investigational product that, if successful, has the potential to revolutionize the way we achieve spinal fusions."

Dr Todd Allen commented: "I am very pleased to be part of this unique study and to have enrolled the first patient. Given the strong pre-clinical data and ease of application of Fibrin-PTH, being particularly suitable for minimally invasive surgeries, I see great potential for this novel drug-biologic combination product".

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. The safety & efficacy of Fibrin-PTH (KUR-113) has not yet been evaluated for spinal fusion in humans.

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, MA, 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

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