# REGENTIS BIOMATERIALS PERFORMS THE FIRST CASES IN GELRIN*C* PIVOTAL STUDY

*Procedures were completed in the USA and Europe*

Princeton, NJ and Or Akiva, Israel, November 28 — Regentis Biomaterials announced today the start of its Phase III pivotal clinical trial of GelrinC for the treatment of focal knee cartilage defects with successful surgery on three patients in the U.S. and Denmark. These procedures are part of a Food and Drug Adminstration (FDA) approved Investigational Device Exemption (IDE) clinical study to compare GelrinC to microfracture, the current standard of care treatment. The clinical study will be used to support a Pre-market Approval Application (PMA) which will allow Regentis to market GelrinC in the U.S.

The US procedures were performed by Dr. Jason Scopp at the Peninsula Orthopaedic Clinic in Salisbury, Maryland and by Dr. Bryan Huber at Mansfield Orthopaedics at Copley Hospital in Morrisville, Vermont while the Denmark procedure was completed by Dr. Martin Lind in Aarhus University Hospital in Aarhus.

“We are entering our next evolution in the field of joint preservation. While many current techniques involve transplanting cartilage from a donor, the GelrinC implant allows us to harness the benefits of our patient’s own mesenchymal stem cells," said Dr. Jason Scopp from Peninsula Orthopaedic Clinic. “The technique was extremely quick, adding a mere 10 minutes to a standard practice procedure. Product application to the lesion was easy with the assistance of Regentis’s proprietery delivery device. It completely filled the defect and after a short exposure to UV light, an optimal implant was formed."

“The success of these three clinical procedures is a significant milestone for Regentis and represents a big step to helping US and European patients recover from damaged articular knee cartilage,” said Regentis President and CEO Alastair Clemow, Ph.D. “In our previous study in Europe, GelrinC demonstrated outstanding clinical outcomes, and we look forward to continue demonstrating the effectiveness of this novel treatment for US patients.”

The FDA trial will appraise the safety and efficacy of GelrinC compared to the raw level data of a historical microfracture control arm. This study design overcomes the limitation of randomized control studies in this field, and is expected to generate faster patient enrollment and significantly reduce the time for product approval.

With an estimated market opportunity in excess of $1 billion, cartilage repair is the largest unmet need in orthopedic sports medicine today. Articular cartilage is the smooth, white tissue covering the ends of bones where they come together to form joints. Focal defects of the cartilage layer are extremely painful for patients and usually occur due to sudden trauma. Surgical intervention is often required because of the limited capacity for cartilage to repair itself. The current standard of care treatment is microfracture but this only provides short term relief and often requires surgical re-intervention.

**About Regentis Biomaterials**

With offices in Or Akiva, Israel and Princeton, NJ, Regentis Biomaterials is a privately held company focused on developing and commercializing proprietary hydrogels for tissue regeneration. The company’s core technology is Gelrin™, a biodegradable hydrogel based on polyethylene glycol diacrylate and denatured human fibrinogen originally developed at the Technion - Israel Institute of Technology by Dr. Dror Seliktar. The Gelrin hydrogel platform combines the stability and versatility of a synthetic material with the bio-functionality of a natural substance for a range of clinical applications. For more information, please visit www.regentis.co.il.

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