Regentis Receives IDE Approval for Pivotal GelrinC Clinical Trial

Key step to gaining FDA approval for the US market

Princeton, NJ and Or Akiva, Israel, September 26 — Regentis Biomaterials, a developer of hydrogels for tissue regeneration, announced it has received U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval to initiate a pivotal Phase III clinical study of GelrinC, a novel treatment for focal cartilage defects in the knee. This clinical study will be used to support a Premarket Approval Application (PMA) which will allow Regentis to market GelrinC in the U.S.

The cartilage repair market is the largest unmet need in orthopedic sports medicine today, and represents an estimated market opportunity of more than US $1 billion. Articular cartilage is the smooth, white tissue covering the ends of bones where they come together to form joints. Cartilage has limited ability to repair itself, which means that surgical intervention is often required. Focal defects typically occur as a result of trauma and are extremely painful to the patient. Microfracture, the standard of care procedure, provides only short-term relief to patients and often requires additional surgical intervention.

“Gaining IDE approval is a significant step forward for Regentis and brings us that much closer to helping US patients recover from damaged articular knee cartilage,” said Regentis President and CEO Alastair Clemow. “GelrinC has been shown to effectively regenerate high quality cartilage, a key challenge in treating these kinds of knee injuries. GelrinC has already demonstrated excellent clinical outcomes in our European study, and we look forward to substantiating these results in the U.S."

The GelrinC procedure is easy and quick for surgeons to perform and can be carried out using a minimally invasive approach. It is administered as a liquid allowing it to fill any size and shape of defect, making it suitable for all lesion types. After a short exposure to ultra-violet light, GelrinC is converted into a solid implant completely filling in the lesion. The implant naturally degrades within 6-12 months and is gradually replaced with functional and durable cartilage.

“GelrinC is a potential game changer in the cartilage repair space, and can be an attractive and viable option for patients,” said Dr. Brian J. Cole, Associate Chairman and Professor within the Department of Orthopedics at Rush University Medical Center in Chicago. “GelrinC has promising clinical outcomes to date and the pre-clinical work is very supportive."

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

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 a biodegradable hydrogel called Gelrin™. It is based on polyethylene glycol diacrylate and denatured 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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