

REGENTIS BIOMATERIALS EXPANDS SAGE CLINICAL TRIAL OF GELRINC™ FOR KNEE PAIN

Eleven U.S. Sites Now Enrolling People with Knee Pain Caused by Damaged Articular Cartilage

PRINCETON, NJ and OR AKIVA, Israel – October 23, 2018 – [Regentis Biomaterials](#) today announced it has expanded the SAGE clinical trial of [GelrinC™](#) for the treatment of articular cartilage damage in the knee to 11 U.S. sites. GelrinC is an investigational device being evaluated as a treatment to help the body regrow cartilage in the knee.

Articular cartilage is the smooth, white tissue covering the ends of bones where they come together to form joints. Damage to the cartilage layer can be extremely painful for patients and is generally associated with sudden trauma. Surgical intervention is often required because of the limited capacity for cartilage to repair itself. The current standard of care is called microfracture, which involves drilling small holes in the underlying bone to allow a blood clot to form within the defect. However, microfracture often provides only short-term relief and may require repeat surgeries.

“Cartilage repair is the largest unmet need in orthopedic sports medicine today,” said Alastair Clemow, Ph.D., president and CEO, Regentis Biomaterials. “GelrinC enables patients to harness the benefits of their own stem cells to promote cartilage regeneration in a single, minimally invasive procedure.”

People with knee pain caused by damaged articular cartilage who would like to be considered for the study can inquire by visiting www.MyKneeStudy.com or by calling (833) 430-8686.

The following orthopedic centers are currently or will soon be recruiting patients, with additional sites to be added soon in Denver, Colorado; San Francisco, California; Orlando, Florida; and Portland, Oregon.

- RUSH University Medical Center (Chicago, Illinois)
- Fort Lauderdale Orthopaedic Surgery & Sports Medicine (Fort Lauderdale, Florida)
- Grossmont Orthopaedic Medical Group (San Diego, California)
- Peninsula Orthopaedic Associates (Salisbury, Maryland)
- Andrews Research & Education Foundation (Gulf Breeze, Florida)
- Mansfield Orthopaedics (Morrisville, Vermont)
- University Orthopedics Center (Altoona and State College, Pennsylvania)
- TRIA Orthopaedic Center (Minneapolis, Minnesota)
- The San Antonio Orthopaedics Group (San Antonio, Texas)
- Optim Orthopedics (Savannah, Georgia)
- Alpine Orthopedics (Bozeman, Montana)

About the SAGE Clinical Trial

The SAGE study is a Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical study comparing GelrinC to microfracture, the current standard of care treatment for damaged knee cartilage. The multi-center Phase III pivotal study will enroll 120 patients. All patients who meet study requirements and agree to enter the trial are provided GelrinC as treatment, and their results will be compared to raw level historical data of a microfracture control arm. To be eligible for the study, participants must be between the ages of 18 and 50

and have pain caused by cartilage damage in only one knee. To learn more about the SAGE study, please visit www.GelrinC.com or call (833) 430-8686.

About GelrinC™

In the U.S., GelrinC™ from Regentis Biomaterials is an investigational device for patients with articular cartilage damage in their knee. GelrinC is composed of a synthetic material called polyethylene glycol (PEG) and a structurally modified form of human fibrinogen, a protein which in its native form assists healing processes. PEG and native human fibrinogen have been used individually in medical products for many years with excellent results. GelrinC's unique mode of action relies upon its ability to be implanted as a liquid so that it completely fills the defect, and then be cured into a gel that enables the body's own stem cells to settle on its surface. Over a period of six to 12 months, the GelrinC is gradually resorbed by the body and replaced by new cartilage tissue. Preliminary clinical trials in Europe have indicated that this regenerated tissue provides excellent improvement in pain and function. To learn more about GelrinC, please visit www.GelrinC.com.

About Regentis Biomaterials

With offices in Princeton, New Jersey, and Or Akiva, Israel, Regentis Biomaterials is a privately held company focused on developing and commercializing proprietary hydrogels for tissue regeneration. The technology was originally developed at the Technion-Israel Institute of Technology by Dr. Dror Seliktar. For more information, please visit www.regentis.co.il.

CAUTION Investigational device. Limited by United States law to investigational use,

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For media inquiries, please contact:

Joni Ramirez
Merryman Communications
323.532.0746
joni@merrymancommunications.com