TissueGen and Biomedical Structures Announce Availability of Breakthrough Drug Delivery Platform for Implantable Devices

The Associated Press

TissueGen® Inc., developer of a cutting-edge absorbable polymer technology for implantable drug delivery across a wide variety of therapeutic applications, today announced that its patented extrusion technology enables absorbable fibers to be loaded with a wider variety of drugs and biologically-based entities than ever previously possible. The company is partnering with Biomedical Structures LLC (BMS), a developer of biomedical textiles for medical devices and other advanced clinical applications, to develop a finished textile platform for drug-eluting medical device applications such as small diameter vascular grafts and stents, tissue and nerve regeneration, orthopedics, and sutures using TissueGen's patented drug delivery technology.

TissueGen's proven technology is purpose-built for advanced drug delivery and sustained therapeutic release. Its core technology includes fiber extrusion at room temperature, which preserves the biological activity of incorporated drugs and therapeutic agents. This enables drug delivery through biodegradable fibers -- a groundbreaking format that drastically expands the types of agents that can be directly incorporated into implantable medical devices. For the first time, device developers can take advantage of the sophisticated drug-delivery capabilities of fibers incorporating high levels of manufacturing tolerance to provide tailored release kinetics for in vivo support and regeneration applications. Designed for custom tunability of release profiles and capabilities, this unique biomaterial format is used across a wide variety of therapeutics and can be engineered for any biologic therapeutic from small pharmaceuticals to protein class drugs such as enzymes, and growth factors, even large viral particles. Drugs are incorporated into the fiber according to device performance requirements using a combination of commercially available polymer components, including PLLA and PDO.

BMS will utilize the TissueGen polymer extrusion platform to develop biomedical textile structures designed for drug delivery within the body. Because the TissueGen technology allows for the engineering of both chemical composition and mechanical properties such as size, shape, and porosity to each specific application, a single structure can satisfy both physical and pharmaceutical performance requirements without requiring additional material support for implantation. Ideal for tissue engineering and regenerative medicine applications, the polymer platform is bio-absorbable and can control therapeutic release over time in accordance with its designed degradation profile as device performance requires. As BMS continues to pursue new markets and expand the reach of biomedical textiles, it will utilize TissueGen's absorbable fiber technology to innovate on the possibilities for long-

term implant devices that provide repair and regrowth functions.

"TissueGen's polymer technology is exactly the drug delivery solution that can help to overcome many of the constraints of current polymer-based systems," said BMS CEO Dean Tulumaris. "As BMS works to provide our customers with an increasingly robust suite of solutions for every device design challenge, we believe the TissueGen absorbable delivery platform will provide a tremendous addition to our biomedical textile development capabilities for cardiovascular, tissue engineering, and other applications."

"We look forward to working with BMS and its customers to bring this important technology to market," said Christopher Knowles, CEO of TissueGen. "With its extensive expertise and leadership in the medical textiles market, Biomedical Structures is ideally suited to offer our proven drug delivery platform as a viable choice for medical device and pharma companies."

BMS offers expertise in knitting, braiding, weaving, nonwovens, and composites, and utilizes a broad offering of biocompatible absorbable and non-absorbable materials in devices, drug delivery and surgical systems for advanced applications such as bifurcated stent grafts, tapered tendon and ligament repair structures, heart valve solutions, and more.

The companies will be exhibiting their joint solution at BMS' booth, #1451, at the MD&M West event from February 12-14 in Anaheim, CA.

About TissueGen
TissueGen® Inc. has more than four decades of cumulative experience in extruding biodegradable polymer fibers with broad drug delivery capabilities. TissueGen offers the medical market a portfolio of issued patents on unique drug delivery technology with the capability to incorporate and elute a broad range of therapeutics and standard pharmaceuticals in hydrophobic polymeric fibers or tubes for sustained therapeutic release. For more information, visit www.tissuegen.com/.

About Biomedical Structures
Biomedical Structures LLC specializes in the advanced design, development and manufacturing of biomedical textiles for device manufacturers in the orthopedic, cardiovascular, general surgery, and tissue engineering and regenerative medicine markets. With specialized expertise in bio-polymer fabrication techniques, Biomedical Structures is enabling innovative implantable devices and other breakthrough medical applications. ISO 13485 registered, Biomedical Structures is a trusted outsourcing partner providing a full line of services from concept design to full-scale production, supply chain management, and post-manufacturing sterilization and packaging. For more information, visit www.bmsri.com.

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