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TISSIUM Advances Clinical Pipeline in Hernia Repair Following First FDA Authorization

Paris, France, Cambridge, USA, September 4 2025 - TISSIUM, a MedTech company pioneering biomorphic programmable polymers for tissue reconstruction, today announced further progress in its clinical pipeline of atraumatic solutions following the recent U.S. Food and Drug Administration (FDA) De Novo authorization of its first product, COAPTIUM Connect.

The company has received an Investigational Device Exemption (IDE) from the FDA for ECLIPSIUM, its innovative solution for ventral hernia repair. TISSIUM will initiate a Clinical Trial in the United States in the coming weeks under this approval.

In parallel, TISSIUM has successfully completed the enrollment in its European clinical study (ALPHA) for ECLIPSIUM and has engaged with its notified body, TÜV SÜD, as part of the CE-Mark submission.

"The ALPHA study provides encouraging evidence that atraumatic fixation not only improves patient outcomes but also enhances surgical workflow and safety. These benefits hold promise not only in ventral hernia repair, but also in expanding the scope of atraumatic fixation" said Pr. Morales-Conde, Head of the Department of General and Digestive Surgery of the University Hospital Virgen Macarena (Sevilla) and investigator of the ALPHA study.

"*We are building strong momentum on both sides of the Atlantic*" said Christophe Bancel, Chief Executive Officer of TISSIUM. "*The De Novo authorization of COAPTIUM Connect marked a transformative milestone for TISSIUM, and we are rapidly advancing our broader product pipeline to bring new solutions to patients.*"

Clinical progress in the U.S. and Europe supports TISSIUM's global strategy of developing a platform of products leveraging its proprietary polymer technology to meet diverse therapeutic needs.

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About TISSIUM

TISSIUM is a clinical and commercial stage MedTech company based in Paris, France, Cambridge, USA, and with a manufacturing site in Roncq, France. The company is pioneering a proprietary platform of fully biosynthetic, biomorphic, programmable, elastomeric polymers designed to address critical unmet needs in atraumatic tissue repair and tissue reconstruction.

TISSIUM's diversified pipeline includes one commercial product and six products in development across three core verticals: sutureless nerve repair, atraumatic hernia repair, and cardiovascular sealants. Each solution is designed to optimize tissue repair through controlled and consistent procedures with specialized delivery and activation devices to maximize the performance and usability of its products.

Founded in 2013, TISSIUM is built on breakthrough research and intellectual property originating from the laboratories of Professor Robert Langer (MIT) and Professor Jeffrey M. Karp (Brigham and Women's Hospital).

For more information, please visit www.TISSIUM.com and follow us on LinkedIn: TISSIUM.

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