



Gecko Biomedical receives CE Mark Approval for SETALUM™ Sealant

Approval of CE Mark paves the way for application expansion and the exploration of new therapeutic areas for ground-breaking surgical solutions.

Paris, France, September 11, 2017 – [Gecko Biomedical](#) (“Gecko”), a medical device company developing innovative polymers to support tissue reconstruction, announced today that it has received CE Mark approval for its SETALUM™ Sealant allowing the company to market its technology in Europe.

The SETALUM™ Sealant is a biocompatible, bioresorbable and on-demand activated sealant usable in wet and dynamic environments as an add-on to sutures during vascular surgery. The polymer is applied to tissue *in-situ* and activated using a proprietary light activation pen.

The technology at the foundation of the SETALUM™ Sealant was developed at The Massachusetts Institute of Technology, Harvard Medical School, and Brigham and Women’s Hospital. SETALUM™ Sealant is the most recent successful example of bio-inspired technology in medicine, and is based on the adhesive mechanisms found in nature that work in wet and dynamic environments.

The grant of the CE Mark for the vascular sealant is the first regulatory validation of the safety and performance of Gecko Biomedical’s scalable and innovative polymer platform.

“The SETALUM™ sealant can be precisely and easily applied thanks to its viscosity and hydrophobicity and then activated at will to provide an instant hermetic barrier and effective hemostasis. The key features of this polymer technology were selected with physicians and patients in mind, and significantly improves upon the latest generation of hemostatic agents to become a gold standard in vascular surgery,” said Jean-Marc Alsac, MD, PhD, vascular surgeon at the Hôpital Européen Georges Pompidou in Paris, France and the principal investigator of Gecko Biomedical’s BlueSeal clinical study.

The BlueSeal clinical study was a prospective, single-arm and multi-center clinical investigation performed at four French university hospitals and undertaken in patients necessitating a carotid endarterectomy. Performance of the sealant was evaluated by the percentage of immediate hemostasis following clamp removal. Based on a sequential Bayesian design, the recruitment was stopped at 22 enrolled patients given the fulfilled performance criteria and the optimal safety profile of the sealant. Immediate hemostasis was achieved in 85% of patients and all recorded adverse events were found to be representative of those commonly occurring in patients necessitating vascular reconstruction with none considered as related to the sealant.



Christophe Bancel, Gecko's CEO, said: "We are delighted to receive the CE Mark for our first product, SETALUM™ Sealant, as this will allow us to bring new and innovative solutions to the market to improve patient care. As a result, we are now ramping up our manufacturing capabilities and selection of strategic partners to bring this innovation to patients."

The company is swiftly expanding its applications, targeting new functionalities and tissue types to develop solutions for new clinical indications and geographic markets.

"Our ability to bring an entire new family of innovative polymers from the bench to the bedside in less than two and a half years, is a testimony of the versatility and scalability of our platform. We are now ready to fully expand, internally and through partnerships, into new therapeutic areas to design disruptive, surgical solutions for patients," Bancel added.

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About Gecko Biomedical

Gecko Biomedical is a privately owned medical device company based in Paris, France that is dedicated to the rapid development and commercialization of a unique biopolymer platform to address various unmet clinical needs.

The company's platform is based on a proprietary polymer family with unique properties including superior biocompatibility, tunable bioresorbability, and adjustable tissue adherence. Furthermore, the polymer hydrophobicity, high viscosity and controlled "on demand" curing enables a unique and controlled delivery to targeted tissues or the creation of scaffolds.

Gecko Biomedical's first product, SETALUM™ Sealant, is an innovative polymer dedicated for tissue reconstruction. It is targeted to vascular reconstruction as an initial indication. Its structure is tunable, allowing customization for various applications and tissue types. The polymer is part of a biopolymer platform family that is fully industrialized and highly versatile, with potential novel applications in other fields of tissue reconstruction such as guided tissue repair, and the field of localized drug delivery.

The Company's technology is based on world-class research and intellectual property from the laboratories of Professor Robert Langer (MIT) and Professor Jeffrey M. Karp (Brigham and Women's Hospital), who co-founded the company in 2013, alongside Christophe Bancel and Bernard Gilly from the [iBionext](#) Network. For more information, please visit: www.geckobiomedical.com

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