

Gecko Biomedical Achieves Significant Milestone with ISO 13485:2003 Certification

A critical step towards bringing Gecko Biomedical's innovative polymers to patients.

Paris, France, September 14th 2015 - Gecko Biomedical, a French medical device company developing innovative polymers in the form of sealants and adhesives for wound closure, announced today that it has received the ISO 13485:2003 certification for the design and development of its state-of-the-art technologies.

Christophe Bancel, Chief Executive Officer and co-founder of Gecko Biomedical, said: *"We are thrilled that the standards and reliability of our quality management system have met the requirements of a leading reference organization. Achieving the ISO 13485 certification sets Gecko Biomedical on a strong dynamic path towards the full development of our technologies, and paves the way for receiving CE mark for our innovative sealants."*

The international notified body Lloyd's Register recorded and approved the company's compliance with the quality system regulatory requirements, its control of special processes and the risk analysis along the products value chain.

About ISO Standards

ISO 13485 is a standard for measuring the quality of instruments and medical equipment as well as that of medical technologies. This standard defines the requirements linked to quality management systems and quality assurance systems related to the design, development, production, installation and maintenance of medical devices. This standard may be used internally or by third parties, particularly certification bodies, to assess an organization's ability to answer both regulatory and customer requirements.

About Gecko Biomedical

Gecko Biomedical is a privately owned medical device company based in Paris, France that is dedicated to the rapid development and the commercialization of innovative polymers in the form of sealants and adhesives for surgical wound closure. Gecko Biomedical's polymers are non-toxic, bind strongly to tissues and deliver 'on-demand' wound closure within the 'wet' and dynamic environments in the body. The company is expected to start clinical trials for its first product "GB02" in vascular reconstruction, towards the end of 2015. Gecko Biomedical is also working on expanding its versatile polymer platform to various tissues and to other applications, while leveraging the significant regulatory milestones achieved with GB02. The Company's technologies are based on world-class research and intellectual property from the laboratories of Robert Langer (MIT) and Jeff Karp

(Brigham and Women's Hospital). Gecko Biomedical was founded in 2013 and is backed by leading healthcare investors Omnes Capital, CM-CIC and CapDecisif Management.

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