

**SafeHeal closes €40 million financing co-led by Sofinnova Partners and Genesis MedTech to finance its Colovac device through a pivotal clinical trial in the United States**

**Paris, France, Jan. 31, 2022**

SafeHeal, a leading innovator in the field of digestive surgery and developer of the Colovac device, announced today a successful 40M€ financing, co-led by Sofinnova Partners and Genesis MedTech Group. Sofinnova Partners is a leading venture capital firm based in Paris, London and Milan and an historic shareholder in the company. Genesis MedTech is a medical device company headquartered in Singapore.

SafeHeal's Colovac device is a temporary flexible endoluminal bypass sheath used for patients undergoing colectomies. It is designed to eliminate the need for diverting ostomies, the current standard of care. The Colovac solution addresses the most serious complication of colorectal surgery - anastomotic leakage, the leaking of fecal content in the abdominal cavity, which can lead to sepsis or even death. Leakage is typically managed by placing a diverting ostomy to protect the surgical anastomosis during healing and is surgically closed 3 to 6 months after the initial surgery. Colovac is a temporary endoluminal anastomosis protection device, placed in lieu of the ostomy, and removed endoscopically after 10 days. If the patient is leak-free at that time, he or she can resume a normal life, without the need for a diverting ostomy, representing a significant improvement to the recovery process and quality of life.

Following the positive outcomes of its first clinical studies, SafeHeal will use the proceeds from this financing to accelerate the company's investigational device exemption (IDE) pivotal clinical trial, SAFE-2, for which initiation has already been approved by the United States Food and Drug Administration (FDA). SAFE-2 is a prospective, randomized pivotal study, that will be conducted at leading medical centers in the U.S. and Europe and aims to evaluate the safety and efficacy of Colovac to support future regulatory approval in the U.S.

"This financing operation enables SafeHeal to bring Colovac one step closer to becoming a standard of care for patients," said Karl-Heinz Blohm, Chief Executive Officer of SafeHeal. "The initiation of the SAFE-2 trial represents a significant milestone for the company. We are grateful for the continuing support from Sofinnova Partners and delighted to welcome Genesis MedTech as a new investor and board member."

"This collaboration will accelerate the development of this world-class endoluminal bypass sheath, benefiting both patients and practitioners," said Warren Wang, Chairman and Chief Executive Officer of Genesis MedTech Group.

"This round of financing marks the beginning of a new phase in SafeHeal's strategic development. The company has come a long way since it was founded by the MD Start II team, which now leads Sofinnova's in-house medtech accelerator, and I look forward to its continued growth," said Antoine Papiernik, Chairman and Managing Partner of Sofinnova Partners.

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#### **ABOUT SAFEHEAL**

SafeHeal is an early-stage medical device company in Paris and created in 2015. The company develops Colovac, a device invented by a French digestive surgeon, Dr. Charam Khosrovani, to obviate the need for a digestive ostomy in patients undergoing colorectal surgery. The device is a flexible bypass sheath, intended to reduce any contact of fecal content at the anastomotic level, following colorectal surgery. Colovac is seamless, minimally invasive and fully reversible. The device remains in place for 10 days, after which it is removed during an endoscopic procedure, without the need for a second surgical intervention. This enables patients to resume



their normal life without having to bear an artificial anus or stoma for several months. SafeHeal was founded by MD Start II.

#### **ABOUT GENESIS MEDTECH**

Genesis MedTech Group is a medical device company headquartered in Singapore. Founded by a group of professionals and entrepreneurs with MedTech experience globally and in Asia, the company's product portfolio focuses on value segment multi-therapy medical device products for emerging markets with sales and distribution through its established commercial network. Genesis MedTech Group covers the entire industry value chain of research and development, production, quality management, supply chain, marketing, and sales.

#### **ABOUT SOFINNOVA PARTNERS**

Sofinnova Partners is a leading European venture capital firm in life sciences, specializing in healthcare and sustainability. Based in Paris, London and Milan, the firm brings together a team of professionals from all over the world with strong scientific, medical and business expertise. Sofinnova Partners is a hands-on company builder across the entire value chain of life sciences investments, from seed to later-stage. The firm actively partners with ambitious entrepreneurs as a lead or cornerstone investor to develop transformative innovations that have the potential to positively impact our collective future.

Founded in 1972, Sofinnova Partners is a deeply-established venture capital firm in Europe, with 50 years of experience backing over 500 companies and creating market leaders around the globe. Today, Sofinnova Partners has over €2.5 billion under management. For more information, please visit: [www.sofinnovapartners.com](http://www.sofinnovapartners.com)

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