GRÜNENTHAL GROUP
Press Release

Grünenthal Group receives FDA's Expedited Access Pathway designation for VIVO

Aachen, Germany, February 01, 2018 – Grünenthal announced today that Adhesys Medical Inc., a wholly-owned subsidiary of Grünenthal, has been granted Expedited Access Pathway (EAP) designation by the U.S. Food and Drug Administration (FDA) for VIVO. VIVO is a surgical sealant proposed for being an adjunct to standard closure techniques in gastrointestinal procedures to reduce intestinal leakage. VIVO is a candidate from Grünenthal's innovative development-pipeline of surgical sealants. Flix®, the first product from this portfolio, already obtained CE-Certification in Europe.

"We are delighted about the FDA's positive recognition of VIVO. We still face a high unmet medical need in preventing intestinal leakages after gastrointestinal surgeries – life-threatening postoperative complications that affect up to 20% of patients[1]," Gabriel Baertschi, Chief Executive Officer Grünenthal, explains. "We believe VIVO may become a valuable adjunct to current closure techniques and in combination with these provide a much higher safety standard for patients," he adds.

"Obtaining EAP designation brings further momentum to the development of our surgical sealants, for which we have a unique technology platform at hand. Its combination of features is unparalleled and comprises bonding strength, fast sealing and flexibility", Klaus-Dieter Langner, Chief Scientific Officer Grünenthal, adds. "Moreover, the faster, more predictive and cost-conscious development of devices and technologies improves the risk profile of our portfolio."

Grünenthal acquired Adhesys Medical GmbH and its US affiliate, a medical device start-up, in April 2017 and holds the worldwide development and commercialization rights for an innovative pipeline of surgical sealants and the underlying technology platform.

The FDA grants EAP designation helping patients to have more timely access to devices and breakthrough technologies that provide for more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases, for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared therapies. Development candidates that receive EAP designation may benefit from shorter review timelines for pre-market approval applications (PMA) and a faster implementation of clinical trials by the FDA.

About Grünenthal

The Grünenthal Group is an entrepreneurial, science-based pharmaceutical company specialized in pain, gout and inflammation. Our ambition is to deliver four to five new products to patients in diseases with high unmet medical need by 2022 and become a €2 billion company. By sustainably investing in research and development above the industrial average, we are committing to innovation in order to bring value-adding products to patients.

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[1] Alberts, et al. Predicting risk and diminishing the consequences of anastomotic dehiscence following rectal resection. Colorectal Dissection, September 2003.

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Grünenthal is an independent, family-owned pharmaceutical company headquartered in Aachen, Germany. We are a fully integrated research & development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. Grünenthal is present in 32 countries with affiliates in Europe, Latin America and the US. Our products are sold in more than 155 countries and approx. 5,500 employees are working for the Grünenthal Group worldwide. In 2016, Grünenthal achieved revenues of approximately € 1.4 bn.

More information: www.grunenthal.com.

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