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Polyganics achieves CE Mark certification for LIQOSEAL®

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Approval of the CE mark is based on outstanding data from Polyganics' ENCASE I clinical trial, evaluating thesafety and performance of LIQOSEAL® in reducing cerebrospinal fluid (CSF) leakage after elective cranial surgery

Polyganics, a medical technology company developing, manufacturing and commercializing bioresorbable medical devices, announced today that it has obtained CE marking for LIQOSEAL®, its easy-to-use and innovative dural sealant patch, and will launch the device in Europe with immediate effect.

Approval of the CE mark is based on outstanding data from Polyganics' ENCASE I clinical trial, evaluating the safety and performance of LIQOSEAL® in reducing cerebrospinal fluid (CSF) leakage after elective cranial surgery. 3-month follow-up results showed the absence of CSF leakage, as confirmed by MRI, no clinically significant swelling, and no device-related adverse events following surgery.

Initially, Polyganics will commercialize LIQOSEAL® in selected European countries with renowned distribution partners which have extensive experience in neurosurgical products. During 2020, the Company will then grow its network with the addition of multiple distributors throughout Europe.

Polyganics is also preparing to launch LIQOSEAL® in selected non-European countries. In addition, arrangements are well underway for the start of ENCASE II, a randomized controlled trial, which will enable the Company to submit the patch for pre-market approval to the US Food and Drug Administration.

Rudy Mareel, CEO of Polyganics, commented: “CSF leakage remains a devastating complication of neurosurgical procedures and represents a significant patient burden with high associated cost. The CE approval of this product is testament to the strength and quality of the clinical data from ENCASE I, showing that LIQOSEAL® establishes effective and enduring watertight dural closure. This is a key milestone in our journey to deliver our dural sealant patch to surgeons and patients in Europe and ultimately worldwide.”