BiBBInstruments AB
Press release, 2023-03-30

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BIBB receives market clearance for EndoDrill GI in the US

The cancer diagnostics company BiBBInstruments AB ("BiBB" or the "Company"), which develops and manufactures a new type of electric-driven endoscopic biopsy instrument, EndoDrill®, announces that the Company has now received a 510(k) market clearance from the US Food and Drug Administration (FDA) for EndoDrill® GI. The clearance means that BiBB can now market and sell EndoDrill® GI in the US, which is by far the largest market in the world for tissue sampling with endoscopic ultrasound (EUS). EndoDrill® GI is BiBB's most important product variant, with the widest indication range, that improves tissue sampling and the possibilities for faster diagnosis of a variety of tumors in the upper gastrointestinal tract, such as stomach, esophagus, pancreas, lymph nodes and liver. Initially, the 510(k) clearance will be used to begin market studies in the United States.

"With the 510(k) clearance, the *world's largest market is opened up to our most important instrument in the product portfolio. This is of course very good news for BiBB, but more importantly, American patients and doctors get access to a groundbreaking biopsy instrument that can improve the prospects for many patients through earlier diagnosis and treatment start. This milestone is the result of an extensive and purposeful regulatory work that has engaged the BiBB team for over a year. This means that EndoDrill® will now be* the *first electric-driven EUS biopsy instrument to be cleared in the US. The next step will be to conduct clinical market studies in the US and in parallel discussions are ongoing with potential global distribution partners. Together with previously achieved milestones, we have created a fantastic starting point for future commercialization in the US", says Fredrik Lindblad, CEO of BiBB.*

The FDA 510(k) clearance means that BiBB can now plan and initiate clinical activities in the US. The journey to bring EndoDrill® to users and patients thus takes a big step forward.

About EndoDrill®

EndoDrill® gives endoscopists increased opportunities to take high-quality coherent core biopsies in suspected tumors. An intact tissue sample contains more information, which can be crucial for accurate and complete diagnosis as well as the earliest possible start of treatment. The completed clinical pilot study with EndoDrill® GI (EDMX01) showed one hundred percent diagnostic accuracy in the analysis of the samples.

EndoDrill® utilizes a patent-pending electric-driven rotating needle cylinder that provides high-precision tissue samples of higher diagnostic quality than existing manually handled biopsy instruments. In addition to the mentioned indications in the upper gastrointestinal tract for EndoDrill® GI, the EndoDrill® product family also includes biopsy instruments for lung cancer (EndoDrill® EBUS) and muscle invasive bladder cancer (EndoDrill® URO).

This is a translation of the Swedish press release. If there should be any discrepancies, the Swedish language version prevails.

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This disclosure contains information that BiBBInstruments AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on March 30, 2023.

About BiBBInstruments AB
BiBBInstruments AB is a medical device company that develops and markets diagnostic instruments under the brand name EndoDrill® for early detection of cancerous tumors. EndoDrill® is the world's first CE-marked and FDA 510(k) cleared electric-driven endoscopic biopsy instrument. The product is designed to provide larger and more high-quality tissue samples (core biopsies) of suspected tumors than existing products. The product family will include biopsy instruments for many of the most serious cancers, such as stomach, pancreas, liver, lung and bladder cancer. EndoDrill® targets the global market for endoscopic biopsy instruments with a focus on the ultrasound-guided biopsy instruments (EUS-FNA/FNB, EBUS-TBNA) segment, which is the fastest growing area in endoscopy. The company was founded in 2013 by Dr Charles Walther, cancer researcher at Lund University and chief physician in clinical pathology at Skåne University Hospital in Lund.