Press Release Humedics

Humedics receives UK Marketing Authorization for its diagnostic agent, LiMAxetin®, and thus achieves full market clearance for the LiMAx® maximum liver capacity test in the UK, - the company's first in Europe!

The LiMAx® test is now commercially available in the UK

Berlin, Germany, November 21, 2017 – Humedics GmbH, a specialist in real-time measurement of individual liver function at bedside, today announced that the company has received the first Marketing Authorization for its diagnostic agent LiMAxetin®, which is needed to perform the LiMAx® test.

CE Mark for the LiMAx system was obtained in 2015, and application for Marketing Authorization for the diagnostic agent via the Decentralized Procedure in the UK, Austria and Germany, with Germany being the Reference Member State, was submitted in April 2016.

Marketing Authorization for the diagnostic agent LiMAxetin® *4mg/ml solution for injection* has now been granted by the UK healthcare authority, MHRA (Medicines and Healthcare Products Regulatory Agency), and additional marketing authorizations in Germany and Austria are expected to follow in short order.

Karsten Damgaard-Iversen, CEO of Humedics GmbH, stated: "This approval is a major milestone not only for Humedics, but also for the medical community of liver experts. In the UK, we will now focus our efforts on achieving a successful commercial launch of the LiMAx® test, while concurrently continuing our work to introduce the LiMAx® test and establish it as the new standard of care for liver function assessment."

Erwin de Buijzer, COO of Humedics, further commented: "Our company has been pursuing pre-marketing activities for more than two years, and from numerous conversations with medical experts all over the world, we know that the healthcare providers are eagerly awaiting the opportunity to start using the LiMAx® test. Everyone we have spoken to appreciates the profound benefits of this new diagnostic method which enables precise determination of the individual liver function capacity of patients. As an example, when used prior to liver tumor resection and liver transplantation surgery, the LiMAx® test offers important and clinically proven added value, providing physicians with essential guidance and patients with additional safety. The LiMAx® test is already being used and evaluated in 25 top-tier university clinics across Europe and multiple trials in new indications such as the diagnosis of nonalcoholic steatohepatitis (NASH) and measuring the impact of chemotherapy on liver function are ongoing."

About Humedics

Humedics has developed a breath test based *in vivo* diagnostic system (the LiMAx® test), which comprises a CE-marked medical device, breath masks and a diagnostic drug, LiMAxetin®. More than 600 million people world-wide suffer from liver diseases and liver tumors. The LiMAx® test enables the clinician to quantitatively determine the individual liver function capacity of a patient within minutes. This allows for selection of treatment strategies that are optimally adapted to the individual patients' liver status. Current clinical applications, studies of which have already been published in highly respected peer-reviewed scientific journals, include diagnosis of the liver function before and after liver transplantation, liver surgery planning (e.g. assessment of the amount of liver to be resected without potentially increasing the risk of acute liver failure) and assessment of diseases such as liver fibrosis and cirrhosis. Studies focusing on new indications in oncology and chronic liver diseases such as nonalcoholic steatohepatitis (NASH) are ongoing. More than 20.000 LiMAx® tests have already been performed.

LiMAx® Test

Based on the specific metabolic action of the liver enzyme CYP1A2, which is expressed in all functioning hepatocytes, performing the LiMAx® test is a simple procedure. The diagnostic drug solution is administered intravenously, and the liver immediately starts to metabolize the drug into low dose paracetamol and $^{13}CO_2$ (non-radioactive). The latter is exhaled in the breath, collected via a respiratory mask and guided to the LiMAx® system where, within 1-2 minutes following the injection, the LiMAx® IR laser spectroscopy system allows real-time and very precise quantification of the increase in $^{13}CO_2$ content. The resulting LiMAx® value, measured in micrograms per kilo body weight per hour, is a reliable and repeatable measure of the maximum functional capacity of the liver.

Humedics Contact:
Humedics GmbH
Erwin de Buijzer MD MBA
Marie-Elisabeth-Lüders Str. 1
10625 Berlin
Phone: +49 30 590083240
E-Mail: info@humedics.de
Homepage: www.limaxtest.com

PR Contact:
Almut Gebhard
Strategische Kommunikation
Hasenheide 56
10967 Berlin
Phone: +49 (0)30 - 6120 1081
Mobile +49 (0)174 3017754
E-Mail: ag@almutgebhard.de