Press Release Humedics

The LiMAx® liver capacity test is now commercially available in Germany, Austria and the UK

Following approval in the UK in 2017, Humedics has now also received Marketing Authorization for its diagnostic agent, LiMAxetin®, in Germany and Austria.

Berlin, Germany, and Paris, France, April 12, 2018 – Humedics GmbH, a specialist in real-time measurement of individual liver function, today announced that the company has received Marketing Authorization for its diagnostic agent LiMAxetin® in two additional countries: Germany and Austria. LiMAxetin® is the diagnostic agent used to perform the LiMAx® test.

The application for Marketing Authorization for the diagnostic agent LiMAxetin® *4mg/ml solution for injection* via the decentralized procedure in the UK, Austria and Germany, with Germany being the Reference Member State, was submitted in April 2016. The UK healthcare authority MHRA granted Marketing Authorization already in October 2017 and this was followed in January 2018 by the Austrian authority AGES. With the German Marketing Authorization by BfArM in March 2018 the first wave of marketing approvals has now been successfully achieved.

Karsten Damgaard-Iversen, CEO of Humedics GmbH, stated "We are very pleased to announce this good news here in Paris at the International Liver Congress as these approvals in the UK, Germany and Austria represent major milestones not only for Humedics, but also for the medical community of liver experts in these key markets in Europe. We are convinced that these approvals will further accelerate the process of our LiMAx® test becoming the new gold standard for liver function assessment and quantification."

Erwin de Buijzer, COO of Humedics, further commented: "We are currently focusing significant efforts on the further market introduction of the LiMAx® test and we are experiencing rapidly growing interest. During the past quarter, this has already resulted in multiple contracts being closed with university clinics that are now implementing our unique liver function capacity test into their clinical routines. The LiMAx® test offers important and clinically proven added value, providing hepatologists, oncologists, radiologists and liver surgeons with previously unavailable quantitative guidance for diagnostic and therapy decisions as well as delivering additional patient safety and improved care."

The LiMAx® test is already being used in over 30 top-tier university clinics across Europe and over 20 trials in new indications such as the diagnosis of chronic liver diseases like non-alcoholic steatohepatitis (NASH) and the improvement of treatment decisions in liver oncology are ongoing. These investigator initiated trials impressively demonstrate the further potential of the LiMAx® test.

Visit us at the International Liver Congress ILC in Paris, April 11-15, 2018
Paris Convention Centre

Booth No. 340
https://ilc-congress.eu/

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 non-alcoholic 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.

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