Press Release Humedics

Humedics submits marketing authorization application for the diagnostic agent used with the LiMAx test

Application for marketing authorization of the diagnostic agent ^{13}C-Methacetin Solution for infusion used with the LiMAx test

Berlin, Germany, May 12, 2016 – Humedics GmbH, a specialist for real-time and mobile measurement of the individual liver function at the bedside of the patient, today announced that the company has submitted the marketing authorization application for the diagnostic agent necessary for the performance of the LiMAx test. The dossier was submitted in Germany, UK and Austria.

After the successful closing of the clinical phase III study with the LiMAx test in September 2015, Humedics submitted the application for marketing authorization of the diagnostic agent in April 2016. Submission was performed via the Decentralized Procedure in Germany, UK and Austria, with Germany being the reference member state.
The "*Fast-track LiveR*" Trial with the investigational diagnostic agent ^{13}C-Methacetin Solution for infusion was set up to demonstrate the positive impact of LiMAx test on patient management and diagnostic thinking related to postoperative management in patients undergoing partial liver resection.

Erwin de Buijzer, CEO of Humedics GmbH, stated: "After the successful closing of our phase III study we focused all of our efforts on preparing the marketing authorization dossier. This submission represents a breakthrough for the commercialization of our LiMAx test."

The recent submission for marketing authorization represents another milestone in the dynamic development of the company. After closing a series C financing round end of 2014 and the successful CE certification of the FLIP medical device in 2015, Humedics' team now focusses on the preparation of a successful European market entry of the diagnostic agent for the LiMAx test.

The LiMAx test, in combination with the corresponding FLIP device and the diagnostic drug offers a clinically proven significant added value for patients with liver diseases and liver surgery. The LiMAx test is already being used in 17 top-tier university clinics in Europe.

About Humedics
Humedics has developed a breath test based diagnostic system (LiMAx test), which comprises a CE-marked medical device, breath masks and a diagnostic drug. More than 100 million people world-wide suffer from liver diseases (i.e. cirrhosis, hepatitis, fatty liver, metabolic disorders and liver tumors). The LiMAx test enables the clinician to quantitatively determine the individual liver function capacity for a patient within minutes. This allows for selection of treatment strategies that are optimally adapted to the individual patients liver status. Current applications published in highly respected 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 liver failure) and assessment of diseases such as liver cirrhosis. The LiMAx test has been used about 15,000 times in clinical practice. The phase III multi-center clinical trial required for marketing authorization of the LiMAx test has been closed successfully.

LiMAx Test

The underlying principle of the LiMAx test involves the following steps: Firstly, the diagnostic drug solution is administered intravenously and the drug is metabolized in the liver to paracetamol and $^{13}CO_2$. The latter is exhaled in the breath. The exhaled air is collected via a respiratory mask. Subsequent continuous measurement of $^{13}CO_2$ in the patients' breath using laser detection in the FLIP device provides a quantitative determination of the liver capacity and thus reflects the liver function.

Fast-track LiveR Trial

Fast-track LiveR was a prospective, randomized, controlled, multi-centric, phase III study for the early identification of low-risk patients after partial liver resection with the LiMAx test. The LiMAx test determines the actual liver function in real-time. The test includes the application of the diagnostic investigational medicinal product, ^{13}C-Methacetin Solution for infusion and a breath test involving the use of Humedics' FLIP device for measurement and analysis. 148 patients with different types of liver tumors and designated for open liver surgery were included in the study. Two study arms had been set up; each enrolling more than 70 patients. The LiMAx group was subject to a perioperative patient management according to the fast-track procedure. This included a pre- and postsurgical analysis of the liver function with the LiMAx test. In the control group the perioperative patient management was performed according to current clinical standards. The trial was conducted at six study centers in Germany and was completed in September 2015.

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