HEPANOSTIC

A composite biomarker for diagnosing NASH based on a blood sample. The diagnostics build on patented individual NASH biomarkers that can be used to

- Non-invasive NASH biomarker

Value proposition and Field of application

diagnose NASH patients and monitor response to treatment. NASH BIOMARKER RESULTS AND VALUE PROPOSITION We have identified plasma TREM2 and SMOC2 as excellent biomarkers of NASH NASH (NAS>4) **NAFLD Activity score** ROC 1.00-400 1.0 (Im/gn) p<0.0001 0.75 300 ensitivity plasma TREM2 conc. Sensitivity 0.50 *p*<0.0001 200 0.5 TREM2 (AUROC 0.84; 95% CI 0.78-0.90) AST-score (AUROC 0.78; 95% CI 0.71-0.85) 0.25 FIB-4 (AUROC 0.58: 95% CI 0.49-0.67) 100 FORNS (AUROC 0.55; 95% CI 0.46-0.64) AUC = 0.83 NFS (AUROC 0.54; 95% CI 0.45-0.63) AST/ALT ratio (AUROC 0.56; 95% CI 0.46-0.64) p-value = <0.0001 0.0 0.00 NASY norMASH 0.5 10 0.50 0.75 1.00 0.0 0.25 0.00 1-specificity 1 - Specificity No NASH: NAS<4 (mild NAFLD) NAFLD Activity score NASH: NAS≥4 (servere NAFLD) Fibrosis (Kl. fibrosis > 2) в С 0.002 Plasma SMOC2 (ng/mL) 50 Plasma SMOC2 (ng/mL 0.0001 0.8 0.8 400 400 400 1.5 .0001 0.08 TREM2 (ng/ml) Sensitivity 0.4 0.6 Sensitivity 0.4 0.6 300 300 300 •. 1.0 200 200 200 0.5 lasma 0.2 0.2 AUROC 0.89 Sen. 0.89 Spe. 0.81 100 100 AUROC 0.80 Sen. 0.96 Spe. 0.42 0.0 0.0 B2 s3 NASH в1 s2 S1 0.2 0.4 0.6 0.8 0.0 1.0 0.0 0.2 0.4 0.6 0.8 1.0 eatosis sco Ballooning score 1-specificity 1-specificity

The HEPANOSTIC project seeks to develop a composite biomarker for easy and rapid NASH diagnosis based on blood sampling in the primary care

Ideally the composite biomarker will also be able to monitor regression in NASH as response to treatment. By combining several biomarkers a response will be more sensitive and also more specific to NASH since it will be less sensitive to one marker being involved in processes not related to NASH and reflect different aspects of NASH development.

The end goal is a composite biomarker combining 2-5 selected plasma proteins with standard biochemical parameters, ultimately enabling NASH diagnosis from a blood sample taken in the primary care. The introduction of this biomarker will substantially improve patient healthcare by timely diagnosis and intervention, and consequently also lower costs in the healthcare system, as well as serve as a valuable tool in drug development.

SDU

Current state of development

We have PoC for two novel NASH biomarkers and work on identification of combinations in good progress showing the ability to identify patients and monitor response to NASH regression. Proprietary assays for individual markers are in development.

Further identification of other relevant markers are also undertaken.

Team

Strong team bringing together basic research and clinical research skills – plus people with experience in university spin-outs and commercialization



Intellectual property rights

Two patent applications have so far been filed for priority and a third is under preparation.

J.H. Graversen, I. V. C., F.T. Larsen, L. Grøntved, K. Ravnskjær, M.M. Lauridsen, C.W. Wernberg A. Krag (Inventors); USE OF SPARC-RELATED MODULAR CALCIUM-BINDING PROTEIN 2 AS A NON-INVASIVE BIOMARKER EP2217751.

V. I. Chandran, C. W. W., M. M. Lauridsen, M. K. Skytthe, S. K. Moestrup, A. Krag, J. H. Graversen (Inventors); USE OF SOLUBLE TREM2 AS A NON-INVASIVE BIOMARKER FOR NASH

Business opportunity and Call to action

We are seeking partnering and investment to spin out from the university and/or funding and collaboration to continue development in academia.

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