What partners of the **Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) project** are saying about the NIMBLE Letter of Intent (LOI) acceptance by the U.S. Food and Drug Administration (FDA)

Boehringer Ingelheim

"Boehringer Ingelheim congratulates FNIH NIMBLE for achieving this important milestone and is looking forward to future results in identification and validation of biomarkers replacing biopsies in NASH. Biopsies remain a major hurdle, preventing patients from being diagnosed and treated for NASH. Non-invasive biomarkers have the potential to improve the care of patients with NASH, and we are proud to be part of this collaboration."

Florian Gantner, Ph.D., Vice President / Global Head of Translational Medicine and Clinical Pharmacology, Boehringer Ingelheim

Bristol Myers Squibb

"Currently, a formal diagnosis of NASH requires a liver biopsy, an invasive technique that limits the ability to identify and monitor NASH patients. As the prevalence of NASH increases worldwide, non-invasive biomarkers for diagnosis of at-risk patients will be required to effectively treat the condition. We are excited to hear that NIMBLE's LOI for four circulating biomarkers was accepted by the FDA's CDER Biomarker Qualification Program. This is an important first step, and we are proud to partner with the FNIH Biomarkers Consortium on this critical initiative."

Melissa Harris, PharmD., Vice President and Head of Fibrosis Development, Bristol Myers Squibb

Echosens SA

"The acceptance of the Letter of Intent by the FDA is an important successful milestone of the NIMBLE initiative. Active in the field of non-invasive liver diagnosis since 2001, Echosens is convinced that the combination of imaging and circulating biomarkers will play a key role in the management of patients with NASH. It is our mission to support the standardization and validation of these new tools."

Laurent Sandrin, Ph.D., Chief Technology Officer and Founder, Echosens SA

Foundation for the National Institutes of Health (FNIH)

“The acceptance by the FDA of the NIMBLE project’s Letter of Intent for four circulating biomarkers represents a key milestone for the project. This early accomplishment, resulting from the collective work by the members of this diverse and talented team, signals crucial regulatory support for a proposed path to developing much-needed non-invasive biomarkers to better diagnose patients with NASH.”

Joseph Menetski, Ph.D., Associate Vice President of Research Partnerships, FNIH

Global Liver Institute

“The need to validate and integrate non-invasive technologies for the identification, staging and treatment response of patients with non-alcoholic fatty liver disease and non-alcoholic steatohepatitis could not be more urgent or essential for advancement of the field and appropriate patient care. The FNIH's NIMBLE consortium and the NIMBLE study are important pillars of the global movement to address the epidemic of NAFLD and NASH."

Donna Cryer, J.D., Founder and Chief Executive Officer, Global Liver Institute

Intercept Pharmaceuticals, Inc.

“It is inspiring to see how quickly the hepatology community has mobilized around efforts to identify, validate and implement non-invasive strategies to monitor and manage liver health in patients with NASH.”

Kay Bhothinard, M.B.A., Executive Director, NASH Diagnostic Strategy, Intercept Pharmaceuticals, Inc.

“We are proud to be participating in NIMBLE and joining with other stakeholders to facilitate data generation and share insights that will help shape future clinical and regulatory pathways in NASH.”

Mary Erickson, Executive Director, Clinical Research, Intercept Pharmaceuticals, Inc.

Massachusetts General Hospital

“The Center for Ultrasound Research & Translation at the Massachusetts General Hospital Department of Radiology is honored to work with the FNIH and other leading NAFLD experts in the NIMBLE consortium. Efficient drug development is dependent on validated fit-for-purpose biomarkers. Our collective work in this domain is likely to have a lasting impact on one of the most common and important diseases in the USA.”

Anthony E. Samir M.D., MPH, Director, Center for Ultrasound Research & Translation, Service Chief, Body Ultrasound Imaging, Massachusetts General Hospital

Pfizer Inc.

"The acceptance of NIMBLE's first LOI by the FDA is a significant milestone. We are excited about the progress made by the NIMBLE consortium, of which Pfizer is a proud member, in its mission to qualify non-invasive biomarkers for non-alcoholic steatohepatitis. These tools are sorely needed to accelerate and fully realize the potential of the drugs being developed to treat this serious disease, for which there is currently no approved therapy."

Morris J. Birnbaum, M.D., Ph.D., Senior Vice President and Chief Scientific Officer, Internal Medicine Research Unit, Pfizer Inc.

Virginia Commonwealth University (VCU)

"This pioneering work addresses the major public health problem of early detection of non-alcoholic fatty acid liver disease and the use of biomarkers to guide assessment and inform treatment. We are fortunate and grateful at VCU to have Dr. Sanyal's stellar leadership of this national consortium."

Peter F. Buckley, M.D., Interim Senior Vice President, VCU Health Sciences and Interim Chief Executive Officer, VCU Health System Dean, VCU School of Medicine Executive Vice President for Medical Affairs, VCU Health System

"This is an important milestone for NIMBLE and represents the successful completion of the first step of the biomarker qualification process. We are making progress even in the times of the Covid-19 pandemic and look forward to successfully completing the next milestone."

Arun J. Sanyal, M.B.B.S., M.D., Z. Reno Vlahcevic Professor of Medicine, Division of Gastroenterology, Hepatology and Nutrition, Executive Director, Education Core, C. Kenneth and Diane Wright Center for Clinical and Translational Research, VCU Medical Center