



First-In-Human Data Supporting the Safety of Glympse Bio's Biosensors are Presented at the AASLD 2020 Annual Meeting

Noninvasive biosensors are developed for the detection and monitoring of NASH

CAMBRIDGE, Mass., Nov. 13, 2020 – [Glympse Bio](#) (Glympse), a biotechnology company advancing the way diseases are understood, tracked, and treated, today announced first-in-human clinical data supporting the safety of Glympse's biosensors and data from a gene expression study of patients with advanced fibrosis demonstrating the important role of proteases in NASH pathophysiology. The data were presented during the American Association for the Study of Liver Disease (AASLD) 2020 Annual Meeting, taking place virtually from Nov. 13-16, 2020.

"The presentation of our first-in-human safety data represents a significant milestone for Glympse," said Wendy Winckler, Ph.D., Chief Scientific Officer at Glympse Bio. "Using our disruptive, noninvasive biosensors, we can directly query disease activity in the body. Glympse is able to specifically bioengineer our tunable sensors for different protease-mediated diseases, enabling us to address the absence of diagnostic tools in multiple disease states. The safety data we published today support the continued development of our biosensors in NASH, as well as other fibrotic, oncologic, and infectious diseases."

The results of the open-label Phase 1 clinical trial show that the novel injectable mixture of synthetic sensors, which measure the activity of proteases associated with Non-Alcoholic Steatohepatitis (NASH) via a urine test, are safe and well-tolerated in healthy volunteers. Three cohorts of 6 subjects were sequentially administered increasing doses of the biosensors developed for NASH. The sensors have shown preclinical safety in rodents and non-human primates and have also demonstrated both NASH progression/regression and drug response in preclinical models. This study provided clinical translational data to demonstrate safety in healthy volunteers, confirm urine signal detection, and identify optimum time points for urine collection in future trials.

"Our goal to transform the measurement of disease progression has been supported by our partner, Gilead Sciences, with whom we plan to conduct PMA-enabling clinical studies validating our biosensors in NASH," said Caroline Loew, Ph.D., Chief Executive Officer at Glympse Bio. "In addition to safely, noninvasively, and accurately predicting the specific stage of NASH in a patient, our clinical study will explore the potential of our technology to reliably measure a patient's response to therapy long before histopathology changes become visible."

The cross-validation gene expression study of advanced fibrosis demonstrated that hepatic transcript levels in a 13-protease signature were able to classify NASH patients with above stage 2 fibrosis with high accuracy across two independent data sets despite significant differences in clinical features including age, body mass, and liver enzyme levels. Examining 179 liver samples, the investigation



confirmed previous findings that dysregulated protease gene expression correlated with fibrosis severity in an intend-to-test population. The clinical efficacy of proteases for fibrosis staging in NASH supports Glympse Bio's ongoing clinical investigations in this disease.

About Glympse Bio

Glympse Bio is focused on better understanding diseases to transform disease detection and predict treatment response. Glympse is transforming the measurement of disease progression *in vivo* using bioengineered, tunable sensors that are designed for each protease-mediated disease. In October 2019, Glympse announced a strategic collaboration with Gilead Sciences to evaluate Glympse's technology as both a diagnostic and prognostic tool. Founded in 2015, Glympse Bio is an MIT spin-out from the laboratory of renowned bioengineer, Dr. Sangeeta Bhatia. Glympse is headquartered in Cambridge, Mass. For more information, please visit www.glympsebio.com.

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