CONTACT:
Steve Hanley
MediBeacon Inc.
Office - 314-735-0971
hanley@medibeacon.com
www.medibeacon.com

MediBeacon Receives $10 Million in Amended Agreements with Huadong Medicine to Accelerate Development of Transdermal GFR Measurement System

MediBeacon approaching completion of Phase 3 study focused on kidney disease;
Has submitted three of five required PMA modules needed for FDA approval

ST. LOUIS, November 16, 2022 – MediBeacon Inc., a portfolio company within the Pansend Life Sciences segment of INNOVATE Corp. (NYSE: VATE), today announced amendments to its commercial partnership with Huadong Medicine Co., Ltd., which trades on the Shenzhen Stock Exchange. MediBeacon is a medical technology company specializing in the advances of fluorescent tracer agents and transdermal measurement.

Under terms of the amendments to existing agreements, which the companies originally entered into in July 2019, Huadong Medicine will provide approximately $10 million in funding through the end of Q2 2023. This includes $7.5 million or 50% of the remaining $15 million milestone investment due upon FDA approval of the MediBeacon® Transdermal GFR Measurement System (TGFR), at a pre-money valuation of approximately $400 million. This investment as well as additional non-dilutive funding enables accelerated development of future enhancements to the product globally. The amendments further strengthen the partnership towards approval of the MediBeacon TGFR in the U.S. and China.

The MediBeacon TGFR is designed to measure Glomerular Filtration Rate (GFR), an indicator of kidney function, at the point of care without the need for blood sampling or urine collection. MediBeacon is in the process of completing enrollment in the global TGFR Pivotal Study at U.S. and China-based clinical sites.

Earlier this month, at the annual meeting of the American Society of Nephrology, “Transdermal Glomerular Filtration Rate Measurement: Clinical Results from a Pilot Multi-Center Study Establishing Feasibility and Efficacy” was presented by MediBeacon Chief Scientific Officer Richard B. Dorshow, PhD.[1] The presentation provided an overview of the results of the MediBeacon TGFR clinical studies conducted in advance of the ongoing Phase 3 study.

Chronic Kidney Disease (CKD) is a progressive condition that affects over 800 million individuals worldwide, representing greater than 10% of the general population globally. In the U.S., more than one in seven people, or approximately 15% of American adults, are estimated to have CKD. As many as nine in ten adults with CKD and approximately two in five adults with severe CKD are unaware of their condition. CKD is extremely common and has emerged as one of the leading noncommunicable causes of death worldwide. Fortunately, however, people who are aware of their CKD or at risk for CKD can take steps to protect their kidneys with the help of their health care providers.[2,3]

MediBeacon has submitted three of the five PMA modules needed for full FDA review and approval. The Company has submitted PMA module 1 (Nonclinical Assays and Biocompatibility), PMA module 2 (Device Testing) and PMA module 3 (Device Manufacturing). The MediBeacon TGFR has been designated a Breakthrough Device by U.S. FDA and an Innovative Medical Device by China NMPA.

[1] https://www.asn-online.org/education/kidneyweek/2022/program-abstract.aspx?controlId=3766355
[2] https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html
[3] Csaba P. Kovesdy, “Epidemiology of chronic kidney disease: an update 2022”, Kidney International Supplements, (2022) 12, 7-11, https://doi.org/10.1016/j.kisu.2021.11.003.

MediBeacon TGFR Pivotal Study

MediBeacon TGFR Pivotal Study (NCT05425719) is a Phase 3 open label, multi-center, safety and pharmacokinetic study of relmapirazin (MB-102) and the use of the MediBeacon Transdermal GFR Measurement System (TGFR) in normal and renal compromised subjects for the evaluation of kidney function. The safety and effectiveness of the MediBeacon TGFR for point of care non-invasive transdermal fluorescence detection of relmapirazin is being evaluated in subjects with kidney function from normal to Stage 4 CKD. Patient enrollment covers the entire range of human skin colors spanning fair to black pigmentation. The study's primary outcome measure is the correlation of Transdermal Derived Glomerular Filtration Rate (tGFR) to the Measured GFR (mGFR) obtained from blood samples collected over time.[4]

About Relmapirazin (MB-102)

Relmapirazin (MB-102) is an investigational pyrazine-based compound which has been engineered to be inert, highly fluorescent and have the clearance properties of a GFR tracer agent in the body. The investigational relmapirazin solution for injection has been administered to over 400 subjects under Investigational Device Exemptions (IDE). The unique photophysical characteristics of relmapirazin have been designed to enable the collection of fluorescence data via a photodetector sensor placed on the skin. Data collected by the sensor measures the change in the intensity of relmapirazin fluorescence over time and is converted into a tGFR by proprietary algorithms.

About MediBeacon Inc.

MediBeacon is a medical technology company specializing in the advancement of fluorescent tracer agents and transdermal detection. MediBeacon's use of proprietary fluorescent tracer agents coupled with transdermal detection technology focuses on providing vital and actionable measurement of organ function. MediBeacon's 47 granted U.S. patents and 170+ granted patents worldwide provide extensive coverage of the MediBeacon TGFR, including relmapirazin, the sensor and algorithms, as well as other strategic uses of its proprietary pyrazine platform and sensor technology including potential applications in nephrology, gastroenterology, ophthalmology and surgery. For more information, please visit: www.medibeacon.com

About INNOVATE Corp.

INNOVATE Corp. is a portfolio of best-in-class assets in three key areas of the new economy – Infrastructure, Life Sciences and Spectrum. Dedicated to stakeholder capitalism, INNOVATE employs approximately 3,900 people across its subsidiaries. For more information, please visit: www.INNOVATECorp.com.

About Huadong Medicine Co., Ltd.

Huadong Medicine Co., Ltd. (SZ.000963) is a leading Chinese pharmaceutical company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immunology, nephrology and diabetes. The company has 11,000 employees and one of the most extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong Medicine's value. For additional information, please visit www.eastchinapharm.com/en

# # #

[4] ClinicalTrials.gov