

## CONTACT:

Steve Hanley MediBeacon Inc. Office - 314-269-5808 Email - Hanley@medibeacon.com www.medibeacon.com

## FDA Grants Breakthrough Device Status for MediBeacon's Transdermal GFR Measurement System

MediBeacon's Breakthrough Device is Intended to Measure GFR in Patients with Impaired or Normal Kidney Function

**ST. LOUIS, October 22, 2018** – MediBeacon Inc., whose largest shareholder is Pansend Life Sciences of HC2 Holdings, Inc. (NYSE MKT: HCHC), announced today the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation to the company's Transdermal GFR Measurement System (TGFR). The device is intended to measure Glomerular Filtration Rate (GFR) in patients with impaired or normal renal function.<sup>1</sup>

MediBeacon's TGFR, which is designated by the FDA to be a combination product, includes an optical skin sensor, monitor and MB-102, which is a proprietary fluorescent tracer agent that glows in the presence of light. The TGFR is designed to provide clinicians continuous real-time measurement of GFR at the point of care with no need for blood sampling or urine collection.

The ability to measure GFR is of high clinical interest especially in patients with or at risk of kidney disease. Kidney disease is a hidden epidemic, affecting more than 850 million people worldwide. This is twice the number of people who have diabetes and more than 20 times the number of people with cancer.<sup>2</sup>

Under the Breakthrough Devices program, a provision of the 21st Century Cures Act, the FDA works with companies to expedite regulatory review in order to give patients more timely access to diagnostic and therapeutic technologies. According to the FDA, a "Breakthrough Device" like the TGFR is a product that has the potential to be more effective at diagnosing a life-threatening or irreversibly debilitating disease or condition compared to the current standard of care.<sup>3</sup>

"We are delighted that the FDA has recognized the Transdermal GFR Measurement System meets the requirements for this designation," said Steve Hanley, MediBeacon CEO. "We look forward to continued close collaboration with the FDA as we begin our pivotal multicenter clinical study in the United States and Europe."

"We are extremely excited about MediBeacon's breakthrough real-time kidney function measurement system," said Philip Falcone, HC2's Chairman, Chief Executive Officer and President. "HC2 is committed to continued support of this remarkable innovation which has the potential to help millions of people around the world."

MediBeacon tracer agents and devices, including the TGFR, are not approved or cleared for human use by any regulatory agency.

About MediBeacon Inc.

MediBeacon's mission is to commercialize biocompatible optical diagnostic agents for physiological monitoring, surgical guidance, and imaging of pathological disease in the human population. Several product concepts in these arenas are contained in the MediBeacon Intellectual Property estate. MediBeacon's portfolio includes a renal function system that uses an optical skin sensor combined with a proprietary fluorescent tracer agent that glows in the presence of light. This system, currently in human trials, is designed to enable clinically practical point of care measurement of a patient's kidney function.

Learn more about MediBeacon at <u>www.medibeacon.com</u>

About HC2 Holdings, Inc.

HC2 Holdings, Inc. is a publicly traded (NYSE:HCHC) diversified holding company, which seeks opportunities to acquire and grow businesses that can generate long-term sustainable free cash flow and attractive returns in order to maximize value for all stakeholders. HC2 has a diverse array of operating subsidiaries across eight reportable segments, including Construction, Marine Services, Energy, Telecommunications, Life Sciences, Broadcasting, Insurance and Other. HC2's largest operating subsidiaries include DBM Global Inc., a family of companies providing fully integrated structural and steel construction services, and Global Marine Systems Limited, a leading provider of engineering and underwater services on submarine cables. Founded in 1994, HC2 is headquartered in New York, New York. Learn more about HC2 and its portfolio companies at <u>www.hc2.com</u>

For information on HC2 Holdings, Inc., please contact: Andrew G. Backman Managing Director - Investor Relations & Public Relations abackman@hc2.com 212-339-5836

<sup>3</sup> U.S. Food and Drug Administration.

###

<sup>&</sup>lt;sup>1</sup> Data on file. MediBeacon Inc., St. Louis, MO.

<sup>&</sup>lt;sup>2</sup> Joint Press Release, June 27, 2018 "The hidden epidemic: Worldwide, over 850 million people suffer from kidney diseases", American Society of Nephrology – ASN (https://www.asn-online.org), ERA-EDTA (http://web.era-edta.org) and ISN (https://www.theisn.org).

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf