



MediBeacon® Next Generation TGFR™ System Receives FDA Approval

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- **MediBeacon® TGFR™ System is a first-in-kind product for point of care kidney function assessment**
- **Centers of Excellence commercialization in select academic medical centers begins in early 2026**

NEW YORK, Dec. 16, 2025 (GLOBE NEWSWIRE) -- INNOVATE Corp. (NYSE: VATE) (“INNOVATE” or the “Company”) announced today that MediBeacon Inc. (“MediBeacon”), a medical technology company specializing in the advancement of fluorescent tracer agents and their transdermal detection, in which INNOVATE owns a 44.7% equity interest, has received approval from the U.S. Food and Drug Administration (FDA) for the next generation MediBeacon® TGFR™ System including the latest TGFR™ Reusable Sensor.

The TGFR System enables kidney function assessment at the point of care by measuring the clearance rate of Lumitrace® (relmapirazin), a non-radioactive, non-iodinated fluorescent GFR agent. The TGFR Reusable Sensor placed on the skin measures the change in Lumitrace fluorescence intensity as a function of time.

The latest TGFR Reusable Sensor has been designed for patient comfort, ease of application, and reusability. It also lowers the cost compared to the single use TGFR Sensor previously approved by the FDA.

The TGFR System was the subject of the lead peer-reviewed article featured on the cover of the Journal of the American Society of Nephrology (JASN) in August 2025.¹ The article reviewed the first use of the transdermal GFR (tGFR) methodology in patients of various levels of kidney function across a wide range of skin colors.

MediBeacon will offer early access for specific use cases at leading academic medical centers in the United States and China. Many of these medical centers have used MediBeacon’s transdermal GFR technology in preclinical research over the past 10 years. There are over 700 peer-reviewed publications and conference abstracts on preclinical use in which the tGFR methodology has been utilized.

“We look forward to including transdermal GFR in our ongoing heart failure study where renal function is a valuable consideration in patient monitoring,” said Dr. Melana Yuzefpolskaya, cardiologist at New York Presbyterian Hospital-Columbia. “Validating transdermal GFR in this patient population offers the opportunity to expose clinically meaningful inaccuracies in estimated GFR (eGFR).”

The TGFR Reusable Sensor is validated for reuse via connection to a disposable adhesive ring. Transdermal assessment of Glomerular Filtration Rate or kidney function (tGFR) has been designed to be effective across the adult population without input of age, weight, sex, gender, race, or ethnicity. MediBeacon received FDA approval of an earlier TGFR System version in January 2025.

“This approval is a major step for MediBeacon to achieve its goal to improve kidney health”, said Steven Hanley, CEO and Co-Founder of MediBeacon. “With this approval, we have a comprehensive, sustainable and economic technology solution to assess kidney function. We believe MediBeacon is well positioned to scale with discipline and unlock the significant market opportunity ahead in both inpatient and outpatient settings.”

MediBeacon expects to begin initial sales of the TGFR System to select academic medical centers in the first quarter of 2026 in the United States and China.

About INNOVATE

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 3,100 people across its subsidiaries. For more information, please visit: www.INNOVATECorp.com.

About MediBeacon Inc.

MediBeacon is a medical technology company specializing in the advancement of fluorescent tracer agents and their 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 owns over 60 granted U.S. patents and over 245 granted patents worldwide that provide extensive coverage of the MediBeacon® TGFR™ System, including Lumitrace® injection, the sensor and algorithms, as well as other strategic uses of its proprietary pyrazine platform and sensor technology. The TGFR System is approved for human use. Potential technology applications in gastroenterology, ophthalmology and surgery are in various stages of clinical development. MediBeacon is based in St. Louis, Missouri, with additional operations in Mannheim, Germany. For more information, please visit: www.medi beacon.com.

About Lumitrace® (relmapirazin) injection

Relmapirazin is a non-radioactive, non-iodinated 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 unique photophysical characteristics of Lumitrace 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 Lumitrace fluorescence over time and is converted into a transdermal GFR (tGFR) by proprietary algorithms. In a phase 2 investigational study mGFR deduced from Lumitrace matched that of mGFR deduced from iohexol over a range of GFR values. See the peer reviewed article published in the October 2024 issue of Kidney International by Dorshow et al.²

About MediBeacon® TGFR™ System

The MediBeacon® TGFR™ System is comprised of the TGFR™ Reusable Sensor, TGFR™ Monitor, TGFR™ Disposable Ring, and Lumitrace® (relmapirazin) injection, which together allow assessment of kidney function by measuring the clearance rate of the fluorescent agent as it leaves the

body. The system records Lumitrace fluorescence intensity transdermally as a function of time via a sensor placed on the skin. The TGFR Reusable Sensor records 2.5 fluorescent readings per second and the TGFR Monitor will display the average session tGFR reading at the patient's bedside or in the outpatient setting.

FOR IMPORTANT SAFETY INFORMATION FOR THE TGFR SYSTEM (U.S. FDA) see ifu.medibeacon.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws. Forward-looking statements generally relate to future events, including, but not limited to, statements regarding the timing of initial sales of the TGFR™ System and scaling of those sales. You are cautioned that such statements are not guarantees of future performance and that INNOVATE's actual results may differ materially from those set forth in the forward-looking statements. All of these forward-looking statements are subject to risks and uncertainties that may change at any time. Factors that could cause INNOVATE's actual expectations to differ materially from these forward-looking statements include risks associated with managing growth related to increased operational size, the misuse by customers, physicians and technicians of MediBeacon's products, and the ability of MediBeacon to effectively protect its intellectual property and the impact of a failure to do so and the other factors under the heading "Risk Factors" set forth in INNOVATE's Annual Report on Form 10-K, as supplemented by INNOVATE's quarterly reports on Form 10-Q. Such filings are available on our website or at www.sec.gov. You should not place undue reliance on these forward-looking statements, which are made only as of the date of this press release. INNOVATE undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent developments, events, or circumstances, except as may be required under applicable securities laws.

Investor Contact:

Solebury Strategic Communications
Anthony Rozmus
ir@innovatecorp.com
(212) 235-2691

¹ Glomerular Filtrate Rate Measurement Utilizing Transdermal Detection Methodology; Dorshow, Richard B., Debreczeny, Martin P.; Goldstein, Stuart L.; Journal of the American Society of Nephrology, 36(8):p 1592-1602, August 2025. DOI: 10.1681/ASN.0000000639

² Clinical validation of the novel fluorescent glomerular filtration rate tracer agent relmapirazin (MB-102), Kidney International, Volume 106, Issue 4, P679-687, October 2024, DOI: 10.1016/j.kint.2024.06.012



Source: INNOVATE Corp.