



## MediBeacon® Transdermal GFR Monitor and Reusable Sensor Receive CE Mark Under European Medical Device Regulation

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NEW YORK, March 31, 2026 (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, and an equity method investment of INNOVATE, announced receipt of European Union (EU) CE Mark certification under the EU Medical Device Regulation (MDR) for its TGFR™ Monitor and TGFR™ Reusable Sensor. The certification confirms that the Monitor and Sensor have met the robust safety, quality, and performance standards required under the EU MDR 2017/745.

"Obtaining the EU CE Mark is a significant milestone for MediBeacon," said Steven Hanley, CEO and Co-Founder of MediBeacon. "As the TGFR™ System enters the clinic in the U.S. and China, the CE Mark allows for the potential use of the transdermal technology in clinical trials that include European sites. The achievement also underscores our commitment to meeting the highest quality and safety standards."

MediBeacon received certification across two Class IIa devices, the TGFR Monitor and TGFR Reusable Sensor. The two, coupled with the Lumitrace® (relmapirazin) injection and the CE marked TGFR™ Disposable Ring, comprise the TGFR System, which enables the assessment of kidney function by measuring the clearance rate of the fluorescent agent as it leaves the body. The result is a transdermal assessment of Glomerular Filtration Rate or kidney function (tGFR). Lumitrace (relmapirazin) injection is approved in the U.S. and China. Submission of Lumitrace (relmapirazin) injection to the EU regulatory authorities is pending.

"An accurate, clinically practical, point of care method to assess kidney function could be revolutionary in the development and implementation of future strategies designed to help patients who are at risk of renal complications," said Dr. Lui Forni, a lead intensive care medicine physician at the Royal Surrey County Hospital NHS Foundation Trust and a global leader in critical care nephrology. "I look forward to including transdermal GFR in my clinical research in Europe later this year."

### About INNOVATE

INNOVATE 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 3,700 people across its subsidiaries. For more information, please visit: [www.INNOVATECorp.com](http://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 55 granted U.S. patents and over 250 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 including Lumitrace is approved for human use by the U.S. FDA and the China NMPA. In addition, the TGFR Monitor and TGFR Reusable Sensor have received the EU MDR CE Mark. 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.medibeacon.com](http://www.medibeacon.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.<sup>1</sup>

### 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 displays the average session tGFR reading at the point of care.

FOR IMPORTANT SAFETY INFORMATION FOR THE TGFR SYSTEM (U.S. FDA) see [fu.medibeacon.com](http://fu.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 market for the TGFR™. 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](http://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.

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<sup>1</sup> 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.