



## MediBeacon receives regulatory approval to sell the Transdermal GFR System in China

October 21, 2025

- **MediBeacon® Transdermal GFR System (TGFR) is a first-in-kind product for point of care assessment of kidney function in patients with normal or impaired renal function**
- **The TGFR will be available for sale in China before the end of the year**

NEW YORK, Oct. 21, 2025 (GLOBE NEWSWIRE) -- INNOVATE Corp. (NYSE: VATE) ("INNOVATE" or the "Company") announced today that MediBeacon Inc., a medical technology company specializing in the advancement of fluorescent tracer agents and their transdermal detection, and an equity method investment of INNOVATE, has received approval from the National Medical Products Administration (NMPA) for Lumitrace® (relmapirazin) injection, a non-radioactive, non-iodinated fluorescent GFR agent. Lumitrace will be sold as an integral component of the Transdermal GFR System in China.

Lumitrace injection, together with the MediBeacon® TGFR Monitor and MediBeacon® TGFR Sensor, allow 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).

A commercial and clinical development partnership between MediBeacon and Huadong Medicine was formed in July 2019. The TGFR will now be introduced into the clinic where it is designed to be an important tool for physicians who care for patients where kidney health is a concern. Chronic Kidney Disease (CKD) is estimated to affect 11% of the 1.4 billion people in China.<sup>1</sup>

In January, the U.S. Food and Drug Administration approved the MediBeacon TGFR including Lumitrace injection for the assessment of kidney function in patients with normal or impaired renal function. In February, the NMPA approved the MediBeacon TGFR Monitor and MediBeacon TGFR Sensor in China where Lumitrace® (relmapirazin) injection is categorized as a drug with a separate approval process.

"Full China approval is a major step forward in our commitment to expanding access to transdermal GFR globally," said Steven Hanley, CEO and Co-Founder of MediBeacon. "China represents a significant opportunity, and we look forward to providing access to our technology with the goal of improving patient management."

Estimation of kidney function in clinical practice has broad negative implications for certain patients.<sup>2</sup> An estimated Glomerular Filtration Rate (eGFR) is derived from a blood draw or urine sample. The test measures levels of serum creatinine or Cystatin C, which are waste products normally cleared by the kidneys. These values along with a person's age, weight, height and sex are used to estimate kidney function. These tests can be impacted by muscle mass, diet, hydration status, medication use and other non-renal inputs that may lead to misclassification of kidney function in patients.<sup>3</sup>

While measured GFR (mGFR) does exist it is not at the point of care. Its use remains limited since serial blood sampling and sophisticated laboratory analysis are required, driving an associated high cost.<sup>4</sup> Transdermal GFR (tGFR) has been designed to achieve the benefits of mGFR without the associated challenges of mGFR.

"Kidney function is often assessed reactively after abnormal labs given the limitations with tools today," said Dr. Richard Solomon, the Patrick Professor of Medicine and Director of the Division of Nephrology and Hypertension at University of Vermont Medical Center. "The benefit of Lumitrace is that it doesn't interact with medications, is cleared by GFR, and importantly, is agnostic to a patient's demographic information. Transdermal GFR can fundamentally impact kidney disease management through the assessment of a patient's GFR at the point of care without the use of estimating equations and has the potential to transform patient care and outcomes."

### 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](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 60 granted U.S. patents and over 245 granted patents worldwide that provide extensive coverage of the MediBeacon® TGFR, including Lumitrace® injection, the sensor and algorithms, as well as other strategic uses of its proprietary pyrazine platform and sensor technology. The TGFR 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.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>5</sup>

## About MediBeacon® Transdermal GFR System (TGFR)

The MediBeacon TGFR is comprised of the MediBeacon TGFR Sensor, MediBeacon TGFR Monitor, and Lumitrace® (relmapirazin), 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 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 TGFR (U.S. FDA) see [ifu.medibeacon.com](http://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 adoption of MediBeacon's TGFR in China or other markets. 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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1 International Society of Nephrology – Global Kidney Health Atlas (China page), <https://gkha.theisn.org/country/china/>

2 Quantifying Individual-Level Inaccuracy in Glomerular Filtration Rate Estimation: A Cross-Sectional Study. Ann Intern Med. 2022;175(8):1073-1082. doi: [10.7326/M22-0610](https://doi.org/10.7326/M22-0610)

3 How unmeasured muscle mass affects estimated GFR and diagnostic inaccuracy, EClinicalMedicine, 29-30 (2020), DOI: [10.1016/j.eclinm.2020.100662](https://doi.org/10.1016/j.eclinm.2020.100662)

4 GFR measurement in patients with CKD: Performance and feasibility of simplified iohexol plasma clearance techniques, PLOS ONE, July 17, 2024, DOI: [10.1371/journal.pone.0306935](https://doi.org/10.1371/journal.pone.0306935)

5 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](https://doi.org/10.1016/j.kint.2024.06.012)



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