MediBeacon® Next Generation TGFR™ System Receives FDA Approval

- **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**

ST. LOUIS, December 16, 2025 (GLOBE NEWSWIRE) - MediBeacon Inc., a medical technology company specializing in the advancement of fluorescent tracer agents and their transdermal detection, today announced the U.S. Food and Drug Administration (FDA) has approved 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.

The Company 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)."

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[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

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. The Company 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.

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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.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.[2]

[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

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.