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MediBeacon® Transdermal GFR System Receives FDA Approval to Assess Kidney Function

- **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 transdermal GFR (tGFR) methodology has been designed to be effective across the adult population without input of age, weight, sex, gender, race, or ethnicity.**
- **More than 800 million people have Chronic Kidney Disease (CKD), one of the world's leading causes of mortality worldwide, with associated deaths increasing over the past two decades.**[1]

ST. LOUIS, January 17, 2025 - MediBeacon Inc. today announced the U.S. Food and Drug Administration (FDA) has approved the MediBeacon® TGFR for the assessment of kidney function in patients with normal or impaired renal function.

The TGFR is comprised of the TGFR Sensor, TGFR Monitor, and Lumitrace® (relmapirazin) injection, a non-radioactive, non-iodinated fluorescent GFR tracer agent, 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.

The TGFR is validated for use in the assessment of Glomerular Filtration Rate (GFR) in patients with stable kidney function at the point of care. The TGFR utilizes an intravenous Lumitrace injection but does not require blood draws or urine analysis, unlike current methodologies requiring multiple blood draws or urine samples. In addition, current clinical

[1] Epidemiology of chronic kidney disease: an update 2022, Kidney International Supplement, 2022 Apr;12(1):7-11. doi: 10.1016/j.kisu.2021.11.003., Csaba P Kovesdy

practice measured GFR (mGFR) assessment requires sophisticated clinical laboratory analysis away from the patient's point of care.

"The development of a system such as the TGFR that assesses a patient's kidney function without the need to use estimating equations is an important milestone for the nephrology community," said Dr. Mitchell Rosner, chair of the Department of Medicine at University of Virginia and a highly regarded expert who has authored numerous articles on the challenges of assessing kidney function. "We are excited to explore applications of the transdermal GFR methodology in patients where current clinical practice is understood to be suboptimal."

Dr. Pierre Galichon, an active kidney researcher at the Sorbonne Université and an attending physician in kidney transplantation at Pitié-Salpêtrière Hospital in Paris, said: "It has long been a challenge to understand kidney function in the context of its interaction with other vital organs, such as the heart and lungs. My experience with MediBeacon products in preclinical use, as relayed in Scientific Reports,[2] has been exciting, and I look forward to evaluating how transdermal GFR can be applied in clinical practice."

"The approval of the TGFR by the FDA demonstrates our proprietary system can provide an effective option for assessing kidney function," said Steve Hanley, CEO of MediBeacon. "According to the National Kidney Foundation, CKD causes more deaths each year than breast cancer or prostate cancer. It is the under-recognized public health crisis.[3] The potential applications for the TGFR are numerous, and we look forward to exploring them with clinicians both in the hospital and outpatient settings."

The timing of FDA approval aligns well with the Q4 2024 publication by MediBeacon's Chief Scientific Officer, Dr. Richard Dorshow, et al. in Kidney International[4] with data that supports the utility of MediBeacon's patented agent Lumitrace®.

The TGFR met its primary efficacy endpoint as per agreement with the FDA by demonstrating a P30 value of 94% while recruiting patients with a range of GFR values and skin tones. P30 is

[2] Pulmonary hypertension without heart failure causes cardiorenal syndrome in a porcine model, Scientific Reports (2023) 13:9130, Orieux et al, doi.org/10.1038/s41598-023-36124-1

[3] National Kidney Foundation, Fast Facts (2024 Update), Updated as of 8/6/2024

[4] 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

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defined as the percentage of GFR estimation falling within +/- 30% of measured GFR (mGFR) values.

P30 Value	Upper 95% Confidence Bounds	Lower 95% Confidence Bounds
94.0%	96.9%	89.4%

In clinical studies no serious or severe adverse events have been observed. For more information, including the FDA Summary of Safety and Effectiveness Data, please refer to www.fda.gov.

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 215 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.**

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.

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IMPORTANT SAFETY INFORMATION FOR TGFR

Indication for Use:
The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73 m^2, GFR >120 ml/min/1.73m^2, patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Sensor and exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Sensor is a single use device intended to attach to the patient's skin and excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

Contraindications:
There are no known contraindications.

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MediBeacon®

Warnings and Precautions:

- See ifu.medibeacon.com for full instructions, warnings, and cautions.
- In clinical studies no serious or severe adverse events have been observed.
- Lumitrace® injection has light absorbance at 266nm and 435nm, and broad fluorescent emission at ~560nm when excited at ~440nm. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.
- Lumitrace injection may interfere with clinical laboratory tests. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally-impaired patients). The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited testing.
- Bolus infusions may impact the GFR assessment temporarily while the vasculature-tissue equilibrium is re-established.
- During a TGFR session, the patient should be as still as possible, especially during the “Establishing Baseline” stage. The current system is designed to compensate for light activity such as reading or eating after the Baseline stage.

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