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MediBeacon® Transdermal GFR System receives device approval in China

Peer-reviewed articles on MediBeacon technology published

- **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 Clinical Kidney Journal in February published MediBeacon study results on measured GFR (mGFR) using relmapirazin versus estimated GFR (eGFR) for the purpose of classifying patient Chronic Kidney Disease (CKD) stages.**
- **MediBeacon TGFR study results have been posted online in the February ahead of print section in the Journal of the American Society of Nephrology (JASN).**

ST. LOUIS, February 25, 2025 - MediBeacon Inc. today announced the National Medical Products Administration (NMPA) in China has approved the MediBeacon® TGFR Monitor and TGFR Sensor for the assessment of kidney function in patients with normal or impaired renal function. Lumitrace® (relmapirazin) injection, categorized as a drug in China, is under review and is targeted for approval in late 2025. The transdermal GFR technology includes Lumitrace (relmapirazin) injection, a non-radioactive, non-iodinated fluorescent GFR tracer agent, which together with the TGFR Monitor and TGFR Sensor allow assessment of kidney function by measuring the clearance rate of the fluorescent agent as it leaves the body.

In 2021, the NMPA granted the TGFR Innovative Medical Device Designation. Only 10% of applications are granted this designation. Benefits of this registration route including early product promotion are considerable.

In February, the Clinical Kidney Journal published MediBeacon data in an article on Chronic Kidney Disease (CKD) stage misclassification via estimated GFR (eGFR) compared to measured GFR (mGFR) using relmapirazin. In a stable CKD population, more than one-third of

the subjects had an actual mGFR (relmapirazin) that differed by at least one CKD stage from their estimated GFR (eGFR).[1] Relmapirazin is indicated for use with the TGFR.

"The *Clinical Kidney Journal* study raises serious concerns about how chronic kidney disease is diagnosed today," said Dr. Ira Kurtz, Chief of the Division of Nephrology at UCLA Medical Center. "Researchers found that current eGFR methods misclassified 35% of patients, leading to potentially incorrect treatments and delayed interventions."

In the February ahead of print section in the Journal of the American Society of Nephrology (JASN), MediBeacon clinical study data from the use of transdermal detection of relmapirazin in patients with normal to impaired kidney function across a range of skin color types was posted online.[2] JASN publishes high-impact research to advance the understanding and treatment of kidney diseases.[3]

In addition to his leadership role at UCLA Medical Center, Dr. Kurtz is active in the development of an artificial kidney and artificial intelligence in the training and practice of nephrology.

Dr. Kurtz commented that: "The study in the *Journal of the American Society of Nephrology* introduces a wearable, transdermal device that assesses GFR without the need for blood samples. The fluorescence-based test, developed by MediBeacon, demonstrated an exceptional correlation ($r^2 = 0.90$) with plasma mGFR across all skin types, paving the way for more equitable and accurate kidney function assessment. These two new studies have reshaped the landscape of kidney disease diagnostics, offering both a cutting-edge innovation and a stark warning about current practices. The findings underscore the urgent need for improved kidney function assessment tools, with non-invasive, point of care GFR measurement emerging as a game-changing solution."

"Awareness of kidney disease is relatively low despite the fact that it is the 7th leading risk factor for mortality worldwide.[4] MediBeacon is pleased to have the opportunity to aid in the

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[1] CKD stage misclassification between estimated GFR and measured GFR in a clinical study of chronic kidney patients, Clinical Kidney Journal, Dorshow, Richard B. et al., 2025 Jan 9;18(2):sfaf006. DOI: 10.1093/ckj/sfaf006

[2] Glomerular Filtration Rate Measurement Utilizing Transdermal Detection Methodology, Journal of the American Society of Nephrology (JASN), Dorshow, Richard B. et al., February 7, 2025, DOI: 10.1681/ASN.0000000639

[3] https://www.asn-online.org/publications/

[4] Chronic kidney disease and the global public health agenda: an international consensus, Nature Reviews Nephrology, 20, 473-485 (2024), doi.org/10.1038/s41581-024-00820-6

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assessment of kidney function in China," said Steve Hanley CEO of MediBeacon. "NMPA approval is the culmination of a rigorous device application process that required close collaboration of the MediBeacon and Huadong Medicine teams. We look forward to the next phase of our partnership with Huadong Medicine and eagerly anticipate Lumitrace approval in China later this year."

The TGFR, which includes Lumitrace (relmapirazin), was approved on January 17th by the U.S. Food and Drug Administration (FDA). MediBeacon continues development of future TGFR products including a next-generation TGFR Sensor with updated software and algorithms.

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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 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.[5]

About MediBeacon® Transdermal GFR System (TGFR)
The TGFR is comprised of the TGFR Sensor, 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.

[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

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IMPORTANT SAFETY INFORMATION FOR TGFR (U.S. FDA)

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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