RadioGel®
Precision Radionuclide Therapy™

Vivos Inc. Reports Continued Progress in India Human Clinical Trial for RadioGel® Precision Radionuclide Therapy™

Kennewick, WA - April 15, 2025 Vivos Inc. (OTCQB: RDGL) is pleased to share new developments in its ongoing human clinical trial in India for RadioGel® Precision Radionuclide Therapy™, an FDA-designated Breakthrough Device for the treatment of solid tumors. The latest results highlight both technical progress and growing clinical validation.

This update builds upon the initial results released in February 2025, which confirmed the safety of RadioGel® in the first five patients. As of this report, ten patients with cancerous nodes have now been successfully treated, further establishing a strong safety profile while generating promising early evidence of efficacy.

Clinical Milestones: Safety, Precision, and Innovation

Every patient in the trial has met the primary safety endpoint, confirmed through PET imaging showing precise retention of the therapeutic Yttrium-90 isotope at the injection site—with no observed adverse events. Patients continue to recover well with no complications, monitored under disciplined clinical follow-up protocols.

Importantly, two of the ten patients presented with tumors in direct contact with the trachea and carotid artery, anatomical regions often considered inoperable or high-risk for radiation damage. Yet, RadioGel® achieved successful treatment without injuring adjacent critical tissues, underscoring the therapy's high Therapeutic Ratio and the core rationale behind the FDA's Breakthrough Device designation.

These outcomes affirm the unique advantage of RadioGel®: internal, highly localized beta radiation delivered directly within the tumor, sparing healthy tissue and enabling outpatient treatment with minimal post-procedure restrictions.

Ongoing Innovation and Technical Exchange with U.S. Investigators

Led by a highly experienced principal investigator in India, the clinical team has introduced new technical refinements to the treatment methodology, including deep-needle injection techniques, precision image guidance, and the use of saline spacers to enhance dose control and organ protection. These protocol advancements are being actively reviewed in discussions with Mayo Clinic investigators who are preparing for a parallel clinical study in the United States.

The study in India, has been approved to treat 30 patients. A formal request is being prepared for the Ethics Committee to approve up to 50 patients, enabling evaluation of RadioGel® in a broader range of tumor types, including those located deeper in the body such as lung and pancreatic cancers.

Strategic Presence in India and Global Pathway

Vivos is concurrently laying the groundwork for a permanent operational footprint in India, including plans to open a corporate office and to establish a regional manufacturing facility for yttrium phosphate microparticles. This infrastructure will support the clinical rollout and eventual commercial availability of RadioGel® in India—serving as a strategic hub for future global expansion.

The results of the India trial, including comprehensive clinical and imaging data, will be submitted for peer-reviewed publication later this year. This milestone is expected to significantly enhance the therapy's visibility among physicians and oncologists and support regulatory submissions globally.

Regulatory Engagement and Market Entry Strategy

Building on the FDA "Breakthrough Device" status of Radiogel® Precision Radionuclide Therapy™, Vivos is sharing preliminary India trial data directly with the FDA to support the company's goal to submit an Investigational Device Exemption (IDE) within the next 90 days

While the company is encouraged by its regulatory progress, it also acknowledges the inherent unpredictability of the U.S. regulatory environment, particularly amid shifting priorities and evolving review protocols under the new FDA administration. As such, Vivos continues to pursue a multi-track global strategy to ensure momentum regardless of domestic regulatory timing.Importantly, the clinical and commercial potential for RadioGel® outside the U.S. is significant, particularly in regions with streamlined regulatory pathways and increasing demand for innovative, minimally invasive cancer therapies. Vivos views its expanding presence in India not only as a foundation for local commercialization, but also as a strategic hub for broader international adoption—especially in markets where the burden of solid tumors remains high and treatment innovation is urgently needed.

The Indian cancer treatment market presents a significant and growing opportunity for innovative therapies like RadioGel®. In 2023, the market was valued at approximately USD 4.21 billion and is projected to reach USD 5.89 billion by 2030. Given the substantial size and growth of the Indian cancer treatment market, progress and adoption of RadioGel® in international markets like India present a substantial opportunity to enhance long-term shareholder value. By establishing a presence in these expanding markets, Vivos can diversify its revenue streams and accelerate the global recognition of Radiogel® as a globally relevant oncology solution.

CEO Statement

Dr. Michael Korenko, President and CEO of Vivos Inc., stated:

"With every patient treated, the value of RadioGel® becomes more evident. We are witnessing precise, safe, and promising therapy outcomes in tumors that traditionally pose high treatment risk. These results not only reinforce our confidence in the technology, but also validates the FDA's designation of RadioGel® as a Breakthrough Device. We are optimistic about what lies ahead in India and globally—as we move toward making this therapy accessible to patients in urgent need of new cancer treatment options." Additionally, our companion IsoPet® animal data has been generating impressive results which complement the human therapy data. We will share the exciting developments from our Isopet® animal health division in the near future.

About Vivos Inc. (OTCQB: RDGL)

Vivos Inc. is a radiotherapeutic oncology company pioneering the use of Yttrium-90-based injectable hydrogel technology to treat tumors in both animals (IsoPet®) and humans (RadioGel®). The company's Precision Radionuclide Therapy™ (PRnT™) platform delivers targeted internal radiation from within the tumor, minimizing damage to healthy tissue and reducing patient recovery time.

RadioGel®, designated as a Breakthrough Device by the U.S. FDA, uses a hydrogel matrix to confine beta radiation within the tumor, delivering more than 90% of its therapeutic effect within 10 days. Treatment can be administered in an outpatient setting with no post-procedure radiation risk to family or caregivers. RadioGel® is currently not approved for human commercial use.

For more information, please visit: www.vivosinc.com

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