Vivos Inc. Reports Encouraging Human Clinical Trial Results and Announces Expansion Plans

(Richland, WA – February 4, 2025) – Vivos Inc. (OTCQB: RDGL) is pleased to report that the first five patients demonstrated the safety of RadioGel Precision Radionuclide TherapyTM by satisfying the criteria in the Clinical Study Plan, including confirmation via PET imaging that the Y-90 remained at the point of injection and no adverse events reported by any of the initial five patients since the initial treatment date.

Additionally, 30-day PET/F-18 imaging of a local patient—a young teacher with a cancerous node near the trachea—revealed an over 80% reduction in both tumor size and metastatic activity. Other treatment options would have jeopardized her voice, making this outcome particularly meaningful. While the trial's primary objective is to establish safety, these early signs of efficacy are highly encouraging.

Expansion of Clinical Trial

After completing the detailed assessment of the available data from the patients, the results will be presented to the Ethics Committee. The lead investigator intends to request authority to increase the study from 30 patients to 50 patients. The expanded trial will provide valuable data on a variety of cancers and include the utilization of new deep injection technology being installed and tested in the treatment hospital in India.

This advanced deep-needle CT-guided precision injection device, designed for use with RadioGel®, will enable precise treatment of deeper-seated tumors, including lung and pancreatic cancer nodules.

Under the current timeline, we anticipate completing the initial 30-patient trial by June 30 and the expanded trial by year-end. Consistent with our previous disclosure, the trial's comprehensive data will be submitted under the guidance of the lead investigator for publication in leading medical journals. Additionally, as results emerge, they will be shared with the FDA to further support RadioGel®'s safety profile and reinforce our Investigational Device Exemption (IDE) submission and advance expanded indications for use in the United States.

Manufacturing and Global Expansion

Vivos continues to collaborate with its contract manufacturer, IsoTherapeutics, recently acquired by Telix (Nasdaq: TLX), to enhance production capacity for both Isopet™ and RadioGel®. Simultaneously, we are evaluating additional manufacturing partners in India and other regions to support global supply chain expansion.

Statement of CEO Mike Korenko:

“After years of dedicated effort, we are thrilled with these initial clinical trial results and optimistic about future findings. As the study progresses, we look forward to sharing additional updates. In parallel, we are advancing key growth initiatives to strengthen RadioGel®’s competitive position, and we will provide further updates on these technology and business developments in the coming weeks and months.”

– Michael K. Korenko, Sc.D.
President & CEO, Vivos Inc.

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About Vivos Inc. (OTCQB: RDGL)

Vivos Inc. has developed an Yttrium-90-based injectable Precision Radionuclide Therapy™ medical device to treat tumors in animals (IsoPet®) and humans (RadioGel®). Using the company's proprietary hydrogel technology, PRnT™ uses highly localized radiation to destroy cancerous tumors by placing a radioactive isotope directly inside the treatment area. The injection delivers therapeutic radiation from within the tumor without the entrance skin dose and associated side effects of treatment that characterize external-beam radiation therapy. This feature allows the safe delivery of higher doses needed for treating non-resectable and radiation-resistant cancers.

RadioGel® is a hydrogel liquid containing tiny yttrium-90 phosphate microparticles that may be administered directly into a tumor. The hydrogel is a yttrium-90 carrier at room temperature that gels within the tumor interstitial spaces after injection to keep the radiation sources safely in place. The short-range beta radiation from yttrium-90 localizes the dose within the treatment area so that normal organs and tissues are not adversely affected.

RadioGel® also has a short half-life – delivering more than 90% of its therapeutic radiation within 10 days. This compares favorably to other available treatment options requiring up to six weeks or more to deliver a full course of radiation therapy. Therapy can be safely administered as an outpatient procedure, and the patient may return home without subsequent concern for radiation dose to family members.

University veterinary hospitals use the IsoPet® Solutions division to demonstrate animal cancers' safety and therapeutic effectiveness. Testing on feline sarcoma at Washington State University was completed in 2018, and testing on canine soft tissue sarcomas at the University of Missouri was completed in 2019. The Company has obtained confirmation from the FDA Center for Veterinary Medicine that IsoPet® is classified as a medical device according to its intended use and means by which it achieves its intended purpose. The FDA also reviewed the product labeling, which included canine and feline sarcomas as the initial indications for use. The FDA does not require pre-market approval for veterinary devices, so no additional approval was required to generate revenue through the sale of IsoPet® to University animal hospitals and private veterinary clinics.

IsoPet® for treating animals uses the same technology as RadioGel® for treating humans. The Food and Drug Administration advised using different product names to avoid confusion and cross-use.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You can identify these statements by the use of the words "may," "will," "should," "plans," "expects," "anticipates," "continue," "estimates," "projects," "intends," and similar expressions. Forward-looking statements involve risks and uncertainties that could cause results to differ materially from those projected or anticipated. These risks and uncertainties include, but are not limited to, the Company's ability to successfully execute its expanded business strategy, including by entering into definitive agreements with suppliers, commercial partners, and customers; general economic and business conditions, effects of continued geopolitical unrest and regional conflicts, competition, changes in technology and methods of marketing, delays in completing various engineering and manufacturing programs, changes in customer order patterns, changes in product mix, continued success in technical advances and delivering technological innovations, shortages in components, production delays due to performance quality issues with outsourced components, regulatory requirements and the ability to meet them, government agency rules and changes, and various other factors beyond the Company's control.