Vivos Inc. Announces Launch of Groundbreaking RadioGel® Precision Radionuclide Therapy™ Human Clinical Trial

(Richland, WA – December 23, 2024) – **Vivos Inc.** (OTCQB: RDGL) proudly announces the initiation of its first human clinical trial for **RadioGel® Precision Radionuclide Therapy™** in India. This milestone trial, which has commenced with the successful treatment of five patients with cancerous lymph nodes, represents a transformative step in advancing innovative cancer therapies.

This clinical trial closely aligns with the protocol designed for Vivos' planned study at the Mayo Clinic in the United States. In the initial phase, five patients with cancerous nodes in the neck have been successfully treated, with a primary focus on demonstrating the therapy's safety. Imaging has confirmed precise placement of the RadioGel® treatment, and the patients are currently recovering well without complications.

The study has received regulatory approval to expand to 30 patients, targeting cancerous nodes throughout the body, enabling broader therapeutic applications.

Upon anticipated completion in Q2 2025, the trial's comprehensive data will be submitted for publication in a leading medical journal under the guidance of the lead investigator. These results will also be shared with the U.S. Food and Drug Administration (FDA) to reinforce RadioGel®'s safety profile, support Vivos' Investigational Device Exemption (IDE) submission, and advance expanded indications for use in the United States.

Meanwhile, Vivos continues active discussions with the FDA to initiate human clinical trials at the Mayo Clinic. The company's dual-track international strategy is accelerating the global introduction of this cutting-edge cancer therapy.

Key Milestones Enabling the Clinical Trial in India

The successful launch of this clinical trial reflects the dedication, expertise, and strategic planning of the Vivos team. Key achievements include:

- **Regulatory Approvals:** Secured clearances from the Scientific Committee, Ethics Committee, and the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, and was issued the Clinical Trial Registry-India (CTRI) number required for publishing results.

- **Logistical Coordination:** Acquired liability insurance, expanded the treatment institution's radioactive material license to include RadioGel®, and established robust international shipping protocols and an alternate contingency shipping path for the Yttrium-90 (Y-90)-based product.
- **Protocol Development:** Finalized the Clinical Trial Protocol, incorporating Mayo Clinic study designs and feedback from FDA pre-submission discussions.
- **Operational Readiness:** Re-validated RadioGel® manufacturing at IsoTherapeutics to ensure compliance with Quality Management System standards and FDA sterility and validation recommendations.
- **Administrative Preparations:** Signed agreements with the Ethics Committee and treatment institution while confirming trademark and patent protections in the region.
- **Training and Certification:** Conducted comprehensive certification training for the treatment team.

Statement from Vivos CEO, Dr. Michael Korenko

"At Vivos, our policy is to communicate results—not just promises. The initiation of this clinical trial marks an historic moment in the evolution of cancer treatment. It is the result of meticulous preparation, strategic execution, and our unwavering commitment to innovation.

We are making history by advancing RadioGel® Precision Radionuclide Therapy™ into its first human trials. This trial represents not just a milestone for Vivos, but a pivotal moment for the entire field of oncology. We eagerly anticipate sharing preliminary results soon and comprehensive findings upon trial completion"

For more information as it develops, please visit www.vivosinc.com or contact us at info@vivosinc.com

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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.