Vivos Inc. Provides IDE Submission Status Update – Conversion to Pre-Sub Filing Accepted by the FDA

(Richland WA July 28, 2024) Vivos Inc. (OTCQB: RDGL) Provides IDE Submission Status Update

The FDA has been working diligently to review the extensive amount of material that we provided in our IDE submission within the 30-day statutory time limit. We have been in regular communication with the FDA and provided responses to five sets of Interactive Review Requests. Based on our communication with the FDA on Friday, we concluded that there was not sufficient time for completion of the IDE review process within the 30-day statutory period. Therefore, with the consent of the FDA, Vivos has elected to convert the IDE submission (G240159) to a Pre-Sub filing (Q241925). This strategic decision allows us to address the FDA's feedback comprehensively and effectively, while maintaining open communication through quick review sessions made available to Vivos with the FDA.

Based on our current discussions with the FDA, this week we should receive follow-up questions to fully analyze the risk/benefit device assessment of RadioGel ®. We are confident that thus far our submissions have provided 90-95% percent of the information they require and that Vivos will be able to resubmit the refined IDE application with high quality responses demonstrating a compelling risk/benefit analysis to the FDA within the next 45 days.

We have been in regular contact with our collaboration partners at the Mayo Clinic and are well positioned to promptly submit, following receipt of the IDE from the FDA, our treatment plan to Mayo Clinic's Independent Review Board (IRB). As previously discussed, the initial treatment target with Mayo for RadioGel® will be treating solid metastatic tumors in lymph nodes associated with papillary thyroid cancer. We remain dedicated to achieving full compliance and are confident that we will demonstrate a compelling risk/benefit profile to the FDA.

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About Vivos Inc. (OTCQB: RDGL)

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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® 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.

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