Vivos Inc. Announces Significant Progress Toward FDA Investigational Device Exemption (IDE) Submission for RadioGel® Precision Radionuclide Therapy™

Kennewick, WA – February 10, 2026 – Vivos Inc. (OTCQB: RDGL), a medical device company pioneering Precision Radionuclide Therapy™ (PRnT™) with its innovative RadioGel® technology, today provided an update on its ongoing efforts to secure FDA Investigational Device Exemption (IDE) approval for human clinical trials of RadioGel® in advanced human therapy applications.

RadioGel® is a targeted radiation therapy designed to deliver precise, localized beta radiation to solid tumors via direct injection, minimizing exposure to surrounding healthy tissue and reducing systemic migration of the radiopharmaceutical agent.

Over the past several years, the Company has engaged extensively with the FDA, successfully addressing feedback from more than 40 individual reviewers—many comments stemming from frequent review team changes within the Agency. Vivos has provided comprehensive data and finalized the key technical parameters related to demonstrating precision delivery of RadioGel® to the treatment area and ensuring minimal exposure to non-target tissues.

In a key strategic move, Vivos has engaged one of the top regulatory experts in the field of brachytherapy and combination radiotherapy devices, with deep experience guiding such products through the FDA's Center for Devices and Radiological Health (CDRH). This expert's prior role at the FDA and proven track record of successful IDE approvals for Class III implantable radiation device, several reviewed by the same branch overseeing RadioGel®, have provided invaluable guidance.

With this expert's analysis of FDA feedback patterns, the Company is bolstering its IDE submission by:

1. Fully addressing all outstanding FDA concerns and adopting a submission format and structure proven effective by regulatory experts for similar devices.
2. Incorporating additional information from clinical human data that has become available since the Company's last IDE submission, further strengthening the evidence package.
3. Reformatting and summarizing pre-clinical data in a manner that more directly and effectively addresses the remaining FDA concerns.
4. Leveraging extensive veterinary clinical data from IsoPet®commercial use: Integrating comprehensive treatment outcomes from over 100 safely administered therapies across diverse tumor types and species, with zero reportable serious adverse events attributable to the product, to provide additional real-world safety and efficacy evidence supporting the Precision Radionuclide Therapy™ platform.
5. Highlighting specialized equine ocular applications:Including detailed case data on successful treatments of ocular squamous cell carcinoma in horses (with injections near or into the cornea),

showing no major side effects in adjacent critical structures, to further demonstrate the therapy's precision, minimal invasiveness, and favorable risk profile in challenging anatomical locations.

These enhancements maintain the intended use while maximizing the submission's clarity, completeness, and alignment with Agency expectations. These recommendations required substantial effort to incorporate into our next submission.

Vivos remains fully committed to advancing RadioGel® toward human clinical trials in the United States and continues its strong collaborations for future indications for use. The Company has plans to submit the IDE by the end of the first quarter or in April.

"We are encouraged by the constructive dialogue with the FDA and the substantial progress we have made in fortifying our submission," said Michael K. Korenko, CEO of Vivos Inc. "With guidance from one of the field's leading regulatory experts, combined with our incorporation of newly available human clinical data and a refined presentation of pre-clinical information, we are strongly positioned to achieve IDE approval and bring this innovative therapy to patients in need."

CONTACT:

Mike Korenko, ScD
CEO, Vivos Inc
mkorenko@radiogel.com

Brad Weeks
President, Vivos Inc
Brad.Weeks@vivosinc.com

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Learn more about RadioGel® and IsoPet® at www.VivosInc.com

About Vivos Inc.

Vivos Inc. is a clinical-stage medical device company developing RadioGel®, a precision radiotherapy hydrogel for human and veterinary oncology applications. IsoPet® is commercially available for veterinary use in certified clinics nationwide.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated. These risks are detailed in the Company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.