Vivos Inc. Submitted the Investigational Device Exemption (IDE) Application for Human Clinical Trials at Mayo Clinic

Kennewick, WA July 14, 2025 – Vivos Inc. (OTCQB: RDGL), a pioneer in Precision Radionuclide TherapyTM (PRnT) solutions, today announced the submission of its Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration (FDA) for RadioGel®, a novel hydrogel-based radioactive therapy designed to deliver targeted radiation to solid tumors. This comprehensive submission, supported by extensive animal and human data, marks a significant milestone in Vivos Inc.'s mission to provide innovative cancer treatments.

RadioGel® is a novel medical device that enables precise radiation delivery to tumors, while minimizing damage to surrounding healthy tissue. The IDE application, developed through months of close collaboration with the FDA under the Breakthrough Device sprint process, addresses regulatory concerns with robust evidence of RadioGel's safety and promising efficacy. The Breakthrough Device designation expedites development for devices that address life-threatening conditions with unmet medical needs.

"This is our most comprehensive IDE submission to date, backed by both animal and human data and months of productive dialogue with the FDA," said Dr. Michael Korenko, CEO of Vivos Inc. "The strong evidence of RadioGel's safety and efficacy brings us closer to delivering a transformative therapy to cancer patients in need."

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Follow Vivos Inc. on X (Twitter): @VivosIncUSA
Learn more about RadioGel® and IsoPet® atwww.VivosInc.com

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, identified by terms such as "will," "expects," "plans," "anticipates," and "intends." These statements involve risks and uncertainties that may cause actual results to differ materially, including challenges in executing business strategies, economic conditions, competition, regulatory changes, delays in clinic certifications, and other factors beyond Vivos Inc.'s control. For a detailed discussion of these risks, refer to the company's filings with the Securities and Exchange Commission