InVivo Therapeutics Announces FDA Acceptance of Preclinical Module in Support of Company's Complete HDE Submission

July 13, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 13, 2021-- InVivo Therapeutics Holdings Corp. (Nasdaq: NVIV), a research and clinical-stage biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries, today announced the acceptance by the U.S. Food and Drug Administration (FDA) of its preclinical module, which is one of three individual modules required for the Company's humanitarian device exemption (HDE) application. Acceptance of the module indicates that FDA has completed its review of this module of the HDE and has no outstanding questions. Review of the remaining two HDE modules, when complete, will be required prior to a final approval decision.

The FDA previously approved the Company's proposed HDE modular shell submission and review process for the Neuro-Spinal Scaffold™ implant. The HDE modular shell is comprised of three modules: the preclinical studies module, a manufacturing module and a clinical data module. The Company believes that the modular shell submission could allow for potentially more efficient review processes and timelines with the FDA. As part of the process, the FDA reviews each module on a rolling basis.

The preclinical module is the first module that the Company has submitted for review to the FDA. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

InVivo is actively enrolling patients with acute spinal cord injury into its INSPIRE 2.0 study, a pivotal trial of the Neuro-Spinal Scaffold™. INSPIRE 2.0 is a 20-patient, randomized, controlled trial that is designed to expand upon the existing clinical evidence for the Neuro-Spinal Scaffold™ from the Company's INSPIRE 1.0 study.

Richard Toselli, M.D., InVivo's President and Chief Executive Officer, said, "It is rewarding to see our continued progress in advancing the Neuro-Spinal Scaffold™ towards our complete HDE submission, and we value the FDA's continued collaboration with us to help achieve this goal."

About InVivo Therapeutics

InVivo Therapeutics Holdings Corp. is a research and clinical-stage biomaterials and biotechnology Company with a focus on treatment of spinal cord injuries. The Company was founded in 2005 with proprietary technology co-invented by Robert Langer, Sc.D., Professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, M.D., who then was at Boston Children's Hospital and who now is affiliated with Massachusetts General Hospital. The publicly traded company is headquartered in Cambridge, MA. For more details, visit www.invivotherapeutics.com.

Safe Harbor Statement

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as "believe," "anticipate," "intend," "estimate," "will," "may," "should," "expect" and similar expressions, and include statements about the future modular submissions for the Company's Neuro-Spinal Scaffold implant and the timing and processes involved for review of such submissions. Any forward-looking statements contained herein are based on current expectations and are subject to a number of risks and uncertainties. Factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to successfully enroll additional patients; the impact of the COVID-19 pandemic on the Company's operations, including its clinical trials; the timing of the Institutional Review Board process; the Company's ability to obtain FDA approval to commercialize its products; the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology in connection with spinal cord injuries; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and general economic and market conditions and other factors discussed in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and its other filings with the SEC, including the Company's Form 10-Qs and current reports on Form 8-K. The Company does not undertake to update these forward-looking statements.

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