InVivo Therapeutics Receives FDA Approval for Pivotal, Randomized, Controlled Trial of the Neuro-Spinal Scaffold™ in Patients with Acute Spinal Cord Injury

March 8, 2018

Study Designed to Enhance Clinical Evidence from INSPIRE Study and Support Potential Humanitarian Device Exemption (HDE) Submission

CAMBRIDGE, Mass. (March 8, 2018) – InVivo Therapeutics Holdings Corp. (NVIV) today announced that the company has received supplemental Investigational Device Exemption (IDE) approval from the US Food and Drug Administration (FDA) for a second pivotal clinical study of the company's Neuro-Spinal Scaffold™ in patients with acute spinal cord injury (SCI). The 20-patient (10 subjects in each study arm), randomized, controlled trial is designed to enhance the existing clinical evidence for the Neuro-Spinal Scaffold™ from the company's single-arm INSPIRE study (**In**Vivo Study of Probable Benefit of the Neuro-**Spi**nal Scaffold™ for Safety and Neurologic**Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury). The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%.

InVivo recently reported that seven of 16 (43.8%) evaluable patients in the INSPIRE study experienced an improvement in AIS grade from baseline at six months compared to the Objective Performance Criterion (study success definition) of 25% of patients. Of these seven patients, three of five individuals who had converted from AIS A SCI (complete) to AIS B SCI (sensory incomplete) in the first six-month period of follow-up subsequently further improved to AIS C SCI (motor incomplete) within 12 to 24 months, including a recent patient who converted from AIS B to AIS C at the 12-month exam in January 2018.

Richard Toselli, M.D., President and Chief Executive Officer of InVivo, commented, "We are pleased to announce the FDA's approval of this randomized, controlled trial and appreciate the agency's collaboration with us on the development of a protocol to address the substantial unmet needs in this patient population. We believe this now sets us in a direction towards a clear and efficient path to approval under the HDE regulatory program, and we are focused on engaging with the investment community and exploring financing mechanisms to support this approved randomized study. We look forward to providing further updates as we obtain clarity on financing and the timing for our second pivotal trial."

"InVivo has achieved important milestones with the FDA over the past seven months under Dr. Toselli's leadership," stated Ann Merrifield, InVivo's Chair of the Board of Directors. "I wish to commend Rich and his team in their continuing interactions with the FDA and their strategy for advancing this important program in the clinic."

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. In January 2018, the company announced updated clinical evidence, including improvements in patients with acute spinal cord injury (SCI), from its INSPIRE study of the Neuro-Spinal Scaffold™. 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," "designed to," "potentially," and similar expressions, and include statements regarding the status of the company's clinical program. 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 discussions and engagement with the FDA; the company's ability to initiate, conduct and complete clinical trials; the expected benefits and potential efficacy of the company's products and technology in connection with the treatment of spinal cord injuries; the availability of substantial additional funding for the company to continue its operations and to conduct research and development, clinical trials and future product commercialization; and other risks associated with the company's business, research, product development, attainment of regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the company's Quarterly Report of the three months ended September 30, 2017 and its other filings with the SEC, including the company's most recent Form 10-K, its Form 10-Qs and its current reports on Form

8-K. The company does not undertake to update these forward-looking statements.