## **THERAPEUTICS**

InVivo Therapeutics Announces Presentation of Complete Six-Month Primary Endpoint Results from the INSPIRE Study of the Investigational Neuro-Spinal Scaffold™ in Acute Thoracic Complete Spinal Cord Injury

May 2, 2018

- Findings Presented at the 2018 American Association of Neurological Surgeons (AANS) Annual Scientific Meeting -

CAMBRIDGE, Mass. (May 2, 2018) – InVivo Therapeutics Holdings Corp. (Nasdaq: NVIV) today announced the presentation of the complete six-month primary endpoint results from the company's single-arm The INSPIRE Study (InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and NeurologicRecovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury) at a medical meeting. The presentation was given by Stuart Lee, M.D., Division of Neurosurgery, Vidant Health, at the 2018 AANS Meeting during the Plenary Session II on Tuesday, May 1, 2018. The presentation was titled, "Complete 6-Month Primary Endpoint Results from the Prospective INSPIRE Study of the Investigational Neuro-Spinal Scaffold™ in Acute Thoracic Complete Spinal Cord Injury", co-authored by Dr. Lee, Domagoj Coric, M.D., Carolina Neurosurgery and Spine, Charlotte, NC, Nicholas Theodore M.D., Department of Neurosurgery, Johns Hopkins Hospital, Baltimore, MD, and Kee Kim, M.D., Department of Neurosurgery, UC-Davis, Sacramento, CA. This is the first presentation at a medical meeting of the complete six-month data from the INSPIRE study.

As reported by Dr. Lee and previously announced by InVivo, 7 of 16 (44%) patients who reached the six-month primary endpoint visit in the INSPIRE study had an ASIA Impairment Scale (AIS) conversion at 6 months, which is the primary endpoint of the trial (defined as improvement in AIS grade from baseline for all evaluable patients at the six-month visit). Altogether, 19 patients have been implanted with the Neuro-Spinal Scaffold. Three patients died within two weeks of implantation. The Objective Performance Criterion (OPC) (study success definition) for the study was a 25% AIS conversion rate based on the published conversion rates for thoracic spinal cord injury (SCI) reported in the literature. The AANS presentation further reported these data in light of the company's recently announced CONTEMPO study results. The CONTEMPO study was designed to provide comprehensive natural history benchmarks for Neuro-Spinal Scaffold<sup>TM</sup> clinical study results. The CONTEMPO study included neurological recovery data from 170 patients across three registries of SCI patients with similar baseline characteristics to those in the INSPIRE study and validated the company's previously established OPC with AIS conversion rates at approximately six months post-injury of 16.7% – 23.4% across the three registries.

InVivo has officially closed the INSPIRE study and 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 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.

"I was honored to present these clinical findings at the AANS Annual Scientific Meeting, and I believe the complete six-month INSPIRE findings encourage future clinical investigation of the Neuro-Spinal Scaffold," said Dr. Lee.

## **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" and similar expressions, and include statements regarding future clinical investigation of the Company's Neuro-Spinal Scaffold. 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: successfully identify financing alternatives and raise the capital necessary to undertake the second pivotal trial, successfully decreasing costs and spending and

successfully opening additional clinical sites for enrollment and enrolling additional patients if such trial is initiated; 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 other risks associated with the company's business, research, product development, regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the company's Annual Report on Form 10-K for the year ended December 31, 2017 and its other filings with the SEC, including the company's quarterly reports on Form 10-Q and current reports on Form 8-K. The company does not undertake to update these forward-looking statements.