InVivo Therapeutics Requests Humanitarian Use Device Designation with FDA

The Associated Press

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec 14, 2012--InVivo Therapeutics Holdings Corp. (NVIV), a developer of groundbreaking technologies for the treatment of spinal cord injuries (SCI) and other neurotrauma conditions, today announced that the Company has filed a request with the U.S. Food and Drug Administration (FDA) for Humanitarian Use Device (HUD) designation for its biopolymer scaffolding product. InVivo is currently working with the FDA on the final steps to seek approval to begin a clinical trial of the scaffolding in acute SCI in early 2013.

Devices eligible for HUD designation are developed to treat rare diseases or conditions. InVivo has requested designation for the use of its biopolymer scaffolding in the treatment of complete functional spinal cord injuries that do not involve penetrating injury or the complete severing of the spinal cord.

The request comes after an April 2012 meeting in which InVivo and the FDA discussed the requirements for the HUD designation and the potential for the device to be regulated and distributed under a Humanitarian Device Exemption (HDE). An HUD designation and a subsequent approved Humanitarian Device Exemption (HDE) would enable InVivo to commercialize the devices in the United States faster than the Pre-Market (PMA) approval process.

Said InVivo Director of Regulatory Affairs Jack Bonasera, “The HUD/HDE provision provides a pathway for obtaining market approval from FDA for medical devices that may help people with rare diseases or conditions that otherwise would be remain unmet. InVivo is confident that the results of well designed pre-clinical studies will satisfy the primary HDE requirements in this type of devastating injury where no motor or sensory function is present below the level of neurological injury.” “HUD designation is not only important for speed-to-market but also represents a benchmark in InVivo’s commitment to patients with spinal cord injuries and other neurotrauma conditions. Our GMP team is ready to go, and our clean room is humming. We expect 2013 to be a breakout year for InVivo stakeholders as we advance additional products into the FDA process,” said Frank Reynolds, InVivo Chief Executive Officer.

The Company expects to receive feedback from the FDA on the HUD request in January 2013.

About InVivo Therapeutics InVivo Therapeutics Holdings Corp. is utilizing polymers as a platform technology to develop treatments to improve function in individuals paralyzed from traumatic spinal cord injuries. The company was founded in 2005 based on proprietary technology co-invented by Robert S. Langer, ScD. Professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, M.D., who is affiliated

with Massachusetts General Hospital. In 2011, the company earned the prestigious 2011 David F. Apple Award from the American Spinal Injury Association for its outstanding contribution to spinal cord injury medicine. The publicly traded company is headquartered in Cambridge, MA. For more details, visit www.invivotherapeutics.com.

Safe Harbor Statement Certain statements contained in this press release that are not historical facts may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities and Exchange Act of 1934, and the Company intends that such statements are subject to the safe harbor created thereby. These statements include, but are not limited to, those relating to the expected approval of the FDA to conduct human clinical trials for the Company's products, the expected commencement date of any approved human clinical trials, the expected size of the pilot study, the expectation that the scaffold product will be regulated under a HDE pathway, and the expected acceleration of commercialization of the Company's products resulting therefrom. These forward-looking statements are based on current expectations, but are subject to a number of risks and uncertainties. The 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 obtain FDA approval to conduct human clinical trials; whether the human clinical trials produce acceptable results; 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, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our Annual Report on Form 10-K for the year ended December 31, 2011 and subsequent filings with the SEC.

Forward-looking statements contained in this press release speak only as of the date of this release. Subsequent events or circumstances occurring after such date may render these statements incomplete or out of date. The Company undertakes no obligation and expressly disclaims any duty to update such statements.

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