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## **InVivo Therapeutics Receives Approval from FDA for First Human Trial Using Biomaterials for Traumatic Spinal Cord Injury**

**CAMBRIDGE, Mass. (April 5, 2013) - 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 U.S. Food and Drug Administration (FDA) has approved the Company's Investigational Device Exemption (IDE) to begin human studies to test its biopolymer scaffold product, a technology developed to treat patients with acute, traumatic SCI.

With this approval, InVivo intends to commence a first-in-man clinical study in the next few months that will test safety and performance of its biopolymer scaffold in five patients. The Company expects the study to occur over approximately 15 months. There are currently no treatment options approved by the FDA, or in clinical trials, to intervene directly in the spinal cord following SCI. The trial will be conducted at multiple U.S. hospitals, and work to gain Institutional Review Board (IRB) approval at Massachusetts General Hospital in Boston is already underway.

"It's heartbreaking for all of us for it to take even a minute longer than necessary to begin human studies, and we've all heard of, or experienced, treatments that have proven to be unsafe, but when conducting a first-in-man study, it is imperative to take the time to get it right, because any mistakes can lead to years of lost time for the scientists and patients that follow," said Frank Reynolds, InVivo Chief Executive Officer.

"I want to thank my team for their years of dedication and hard work, and the FDA for its diligence, careful consideration and engagement during the stringent review of our technology, a true platform that we believe is capable of being leveraged into new treatments for a wide range of acute and chronic neurological conditions. Many of these neurological problems have limited options for care, and for the patients and families of those with lower incidence conditions, often called 'orphan' conditions, every day life can feel like there is no way out. We expect a successful safety study to provide not only the first treatment for acute SCI, but also a safe platform for next generation treatment options for conditions such as ALS, MS and Parkinson's Disease. At InVivo we live by the mantra 'What a drug or cell can do... We can optimize,' and we believe that these treatments will include combination therapies that will be optimized with long-term release and localized delivery of agents or cells."

Continued Reynolds, "Everyone knows my obsession with safe FDA studies. Over the next month or so, we plan to finalize the details of our study, and we expect to have all data to the FDA by the end of 2014. We will be conducting an open label study, and so we look forward to keeping the public aware of its progress. As a historical first-in-man study, this trial marks the next phase in our corporate growth and begins our mission to maintain a collaborative relationship with the FDA. We've built a framework to optimize speed-to-market for our pipeline



of technologies, and we'll be working to commercialize over fifteen products in the next five years while remaining focused on mitigating patient risk and maximizing patient safety and benefit."

The Company was also recently granted approval from the FDA on its Humanitarian Use Device (HUD) designation request. HUD designation is reserved for devices designed to treat rare diseases or conditions. InVivo has received this designation for the treatment of recent complete spinal cord injury (no motor or sensory function) that does not involve penetrating injury or complete severing of the spinal cord. The HUD designation and clinical trial data are required to support a Humanitarian Device Exemption (HDE) application to the FDA with the goal of commercializing the scaffold in the United States sooner than a Pre-Market (PMA) approval would allow.

### **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 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](http://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, 2012 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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