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PHARMAVIGILANT SUPPORTS TISSUEGENE'S PHASE II TRIAL WITH GROUNDBREAKING IMAGING CAPABILITIES

MRI Integration into I-Vault Provides Improved Access, Speed and Control Over Trial Data

WESTBOROUGH, Mass., February 2, 2010 – [PharmaVigilant](#), a clinical trial technology provider, was recently selected by TissueGene to support a three-year, Phase II study to test the efficacy and safety of a new drug aimed at treating patients with a degenerative joint disease of the knee. TissueGene, a privately-held biopharmaceutical company with a pipeline of promising regenerative medicine therapeutics in the field of cell-mediated therapy, chose PharmaVigilant as a result of its integrated imaging capability in I-Vault.

Too large to be opened in traditional EDC systems, MRIs are a vital imaging method to determine biomarkers for all phases of drug development. Embedded into one single system, this industry-leading capability from PharmaVigilant allows MRIs to be seamlessly integrated into the clinical trial process, streamlining the storage, access and readability of the images. By integrating this imaging capability into its I-Vault solution, PharmaVigilant provides TissueGene researchers and trial end users, such as radiologists, with a single login, significantly improving access and control of the trial's MRIs. This is a marked difference from other technology vendors who rely solely on their partnerships with other organizations to provide MRI imaging capabilities to sponsors and require additional steps and processes to manage and view images.

"I-Vault provides us with the opportunity to manage our trial participants' MRIs through one integrated solution with a single login, rather than relying on a separate organization to provide these capabilities," said Dr. Kwan Hee Lee, President and CEO of TissueGene. "Access and control over one's data is critical when conducting clinical trials, and we value the opportunity to retrieve our data through a streamlined and secure process. This has increased the efficiency of trial processes and improved the quality of the data while yielding significant cost savings. Combined, these factors will help us effectively determine the efficacy and safety of this new drug."

"On its own, I-Vault is a game-changing solution, providing considerable cost savings and decreasing the bottlenecks and delays that often hinder the clinical trial process," said James DeSanti, CEO and

Founder, PharmaVigilant. “After integrating this advanced imaging capability into I-Vault, we provide sponsors such as TissueGene the ability to consolidate its imaging needs within one solution and bring ground-breaking drugs to market quicker to help treat degenerative diseases.”

PharmaVigilant offers a full suite of clinical trial technology offerings including Electronic Data Capture (EDC), data warehousing, study building (I-Builder), Electronic Trial Master File system (eTMF), Remote Source Document Verification (rSDV), study administration and an automated site payment system. PharmaVigilant focuses on Phase I-IV clinical trials, registries and other post-marketing studies. The technology has supported more than 200,000 patients in 14 countries across North America, Europe, Asia and Australia and continues to expand rapidly.

About PharmaVigilant:

Based in Westborough, Mass., PharmaVigilant is a technology company founded in 2005 to demystify the clinical trial process for biopharmaceutical companies. Its full suite of patient-based technology automates the collection and management clinical trial data and most importantly puts that data in the sponsors' hands when and how they want it. Sponsors rely on PharmaVigilant to ease the regulatory and FDA submission and approval process and ultimately go-to-market more quickly with top quality drugs. For more information, visit www.pharmavigilant.com.