



Project & Data Management + Clinical & Medical Monitoring + Site Selection + Trial Rescue + Safety + Regulatory + Biostatistics + Medical Writing + IVR-IWR

Press Release

Available for Immediate Release

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CRITERIUM, Inc. CRO supplier of services and support for important trial

(April 23rd, 2014 - Saratoga Springs NY) Criterium, Inc., a full-service CRO is proud to be the CRO of record as the supplier of services and support for this important trial: A Novel Drug for Treatment of Necrotizing Soft-Tissue Infections. Further study details are provided by the pharmaceutical development sponsor, AtoxBio Ltd. on ClinicalTrials.gov

A complete article detailing the trial and its current progress was highlighted in JAMA's April 2014 issue in print and online (http://archsurg.jamanetwork.com/article.aspx?articleid=1859986). This is a study to evaluate the safety and pharmacokinetics profile of different doses of AB-103 administered to patients diagnosed with Necrotizing Soft Tissue Infections that are scheduled for an urgent surgical intervention as part of their standard of care. The primary study hypothesis is that AB-103 can be administered safely to the patients presenting with Necrotizing Soft Tissue Infections. Secondary endpoints are efficacy by exploratory descriptive analyses of specific efficacy endpoints from three outcome domains to demonstrate treatment benefit of AB-103 in comparison to placebo in patients with Necrotizing Soft Tissue Infections. The efficacy domains are:

- 1. Clinical status domain
- 2. Pharmacoeconomics domain
- 3. Systemic and local inflammatory biomarker domain

Criterium, with extensive experience in dermatology and infectious disease indications, particularly with wound and burn treatments, provided services for data and project management, clinical and medical monitoring, biostatistics, safety, regulatory support, and medical writing.

About Criterium

Criterium, Inc. is a full-service, global CRO (contract research organization) that offers a unique mix of high-quality clinical research services and communication processes for the biopharmaceutical, pharmaceutical, and medical device industries to manage trials from initial planning to approval. Founded in 1991, Criterium's services are customized to fit each client's specific needs, providing a seamless flow of data and information from the investigative site through Criterium and back to the sponsor — 24/7, in real-time.Criterium's experienced team manages and implements clinical trials using technology-based solutions. Dedicated clinical professionals are committed to providing personal service and to forming strong and productive relationships with clients. Criterium's well-established staff are trained according to ICH GCP guidelines.

The Oncology Consortia of Criterium Global CRO are a collaboration of outstanding Cancer Research Consortia that deliver innovative research and unparalleled expertise: The Academic GI Cancer Consortium (AGICC) is presently represented by Key Opinion Leaders (KOLs) and top Investigators at 11 of the most prestigious institutions in the USA. The Academic Myeloma Cancer Consortium (AMyC) is represented by Key Opinion Leaders (KOLs) and top Investigators at 9 of the most prestigious institutions in the USA. The Academic Thoracic Oncology Medical Investigators Consortium (ATOMIC) is represented by Key Opinion Leaders (KOLs) and top Investigators at 7 of the most prestigious institutions in the USA. The Academic Breast Cancer Consortium (ABRCC) is represented by Key Opinion Leaders (KOLs) and top Investigators at 9 of the most prestigious institutions in the USA.

Corporate headquarters are located in Saratoga Springs, New York with offices in Florida, California, South Africa, India, and Canada, and representatives in-country in The EU, Israel, and Russia. This multi-national approach enables Criterium to provide time- and cost-efficient study management and monitoring to all our clients. To learn more about Criterium, visit the website www.criteriuminc.com.

