CTI CLINICAL TRIAL & CONSULTING

October Newsletter

Where Life-changing Therapies Turn First™

Volume 11, Issue 10

We are recruiting for CRAs in the US, Australia, UK, France, Belgium, Sweden, Germany, Poland, Italy and the Netherlands!

If you are interested in scheduling a meeting with CTI, please contact Nick Schatzman at 513-598-9290 or via email at nschatzman@ctifacts.com

Upcoming Meetings CTI will be Attending …

American Association for the Study of Liver Diseases Annual Meeting
Washington, DC – November 1-5

American Society of Nephrology Kidney Week 2013
Atlanta, GA – November 5-10

World Stem Cell Summit
San Diego, CA – December 4- 6

American Society of Hematology Annual Meeting
New Orleans, LA – December 7-10

FDA Breakthrough Designation

CTI's regulatory experts can evaluate your drug in development to determine whether breakthrough therapy designation and other expedited approval pathways such as fast track, accelerated approval, and orphan drug designation would be appropriate. Our regulatory team has over 20 years of global drug development experience, long-term relationships with key regulatory officials, and regularly present to international regulatory authorities. CTI currently works on over 20 different programs with expedited pathways, including nearly 10% of the total breakthrough therapy designation approvals. In 2013, CTI has a 100% success rate with orphan drug designation approvals.

The new Food and Drug Administration (FDA) designation of "breakthrough therapy" was created just last year, but has taken off quickly. Breakthrough designation is available when drugs "treat a serious or life-threatening disease or condition and preliminary evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints." Some preliminary clinical evidence is required; nonclinical evidence or theoretical rationales are not sufficient.

Drugs designated as breakthrough therapies receive a suite of benefits to expedite drug development and FDA review. These benefits include timely advice and interactive communications with the FDA and the potential for a compressed drug development program, with smaller, faster clinical trials. These are basically the same benefits that come with fast track designation, but breakthrough designation is available for additional therapeutic categories. The FDA pledges to assign a cross-disciplinary project lead for each review team evaluating a breakthrough therapy product, and to intensively involve senior managers and experienced reviewers in a collaborative, cross-disciplinary review to help these products reach approval as efficiently as possible.

As of September 23, 2013, 24 breakthrough therapy designations have been

Congratulations to these recently promoted CTI employees:

Brad Spiers – Senior Accounting Manager

Welcome the newest CTI employees:

Kelly Kelso – Study Manager

Louis Minham – Senior Director, Information Technology

Elba Alonso, PhD – Clinical Research Associate, Spain

Sara Nicolas, PhD – Senior Clinical Research Associate, France

Fatima Boumares – Senior Clinical Research Associate, France

Kimlan Noriega – Senior Clinical Research Associate, UK

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publicly announced by sponsors. The FDA does not disclose these designations, considering them to be confidential, but they do disclose data on the number of applications received and granted. The most recent information released by the FDA indicates that, as of September 30, 2013, CDER had received 94 requests for breakthrough therapy designation. Of these, 28 were granted, 42 were denied, and 24 were still under review. As of August 31, 2013 CBER had received 10 requests, with 8 denials and 2 still pending. The FDA reports that virtually all of the applications received responses within 60 days.

For more information please contact:

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About CTI

CTI Clinical Trial and Consulting Services is an innovative, international drug and device development organization that delivers a full spectrum of clinical trial and consulting services from bench to commercialization with a focus on immunology and a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. CTI's focused therapeutic approach provides pharmaceutical, biotechnology and startup firms with clinical and disease area expertise from a unique mix of academic, medical and industry specialists; rich intellectual capital in transplantation, immunology, infectious diseases, hematology, cardiology, nephrology, hepatology, regenerative medicine and rare diseases; flexible study designs that accelerate development programs and deliver high approval ratings that are among the best in the industry; and exceptional global project management and gold standard safety and data management systems that strengthen their program's success potential. Established in 1999 and headquartered in Cincinnati, OH; CTI has offices in North America, Europe and South America.