

Media Coverage

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Ground Zero Pharmaceuticals Announces Expansion of Global Consulting in Somatic Cell Therapies

IRVINE, Calif., Oct. 5 /PRNewswire/ -- GZP is pleased to announce that it has expanded its capabilities for strategic regulatory and product development support of gene therapy and somatic cell therapies, including treatment vaccines for cancer and other serious or life-threatening diseases.

New senior associates with expertise in manufacturing and clinical development in these expanding areas allow GZP to provide its clients with hands-on guidance through the FDA regulatory review process. Firms in the US and Australia have already taken advantage of this expertise and are preparing to launch programs in Phase 1, 2 and 3 clinical trials for their "new concept" products. Two of our staff, Dr. Chaline Brown and Ms. Tisha Templeton, will be attending and presenting this month at the TRX10 and AusBiotech conferences in Brisbane and Melbourne Australia, respectively, and will be available to discuss these added capabilities. They will be available for partnering meetings as well.

Specifics of these Australian speaking engagements are:

12 October 2010 – Brisbane – TRX10 – *"Regulations Pertinent to Pharmacogenomics and Biomarkers in Europe and USA"*

20 October 2010 – Melbourne – AusBiotech 2010 - *"Dealing with the FDA – What's Hot?"*

GZP continues to believe that early, frequent, and creative communication with the FDA (including informal targeted review of specific issues that can slow down development programs at both early and mid-stages) can lead to more successful medical product development, attracting more funding in today's difficult financial climate.

In 2010, GZP increased its global client base at all phases of development across therapeutic areas such as oncology and neurological disease, and created and submitted several INDs.

Pre-pre-IND, pre-IND and mid-phase meetings with the FDA led to acceleration of drug and biologic development programs for our clients. Our medical device practice also expanded and included consultation with California's Food and Drug Branch as well as the FDA.

According to Evan Siegel, "We are pleased to see that the need for continued review and approval of key medical products and the determination of our clients to be successful has contributed to the recovery from the global financial crisis across industry. Our client's dedication, loyalty, their referrals, and the excellence of our staff and associates in maintaining an integrated, cohesive and client-specific approach furthers the commitment of GZP to provide the highest quality ethical and knowledgeable consulting."

Based in Irvine, a major biotechnology center in Southern California, Ground Zero Pharmaceuticals, Inc. is a regulatory affairs and product development consulting firm providing strategic and tactical services to the pharmaceutical, biotechnology and medical device industries. These include regulatory representation and submissions (paper and electronic), strategic medical consulting, preclinical/nonclinical planning, auditing and review of clinical, nonclinical and CMO sites, medical writing, chemistry, manufacturing and controls consulting, clinical assessment, data management, biostatistics, and project management. GZP has resources throughout the US, Canada, Australia and Europe, and a wholly owned subsidiary in Brisbane and Melbourne, Australia.