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Brahm Goldstein, Director of Clinical Research - Biopharmaceuticals at Novo Nordisk will present at GTCbio's Global Clinical Trial Operations Conference on September 25-26, 2008 in San Diego, CA

Brahm Goldstein, Director of Clinical Research - Biopharmaceuticals at Novo Nordisk to present a rational approach towards global pediatric drug development in the pharmaceutical industry at GTCbio's Global Clinical Trial Operations conference on Sept 25-26, 2008 in San Diego, CA.

/24-7PressRelease/ - MONROVIA, CA, June 20, 2008 - Both the FDA and EMEA have passed regulations intended to ensure that healthcare professionals can make treatment decisions for pediatric patients using medicines that have been properly evaluated. Logically this requires that product development programs should include pediatric studies when pediatric use could be anticipated based on the product's mechanism and properties. While these new regulations are not intended to delay adult studies nor granting marketing authorizations for adult use, each pharmaceutical company filing a new marketing authorization application nonetheless now needs to develop a strategy for a complete and balanced scientific, medical, regulatory, business, and ethical evaluation of new drugs and biopharmaceuticals including data for all pediatric age groups. The scope of these regulations also affects already approved products. Based on compliance with these regulations, the final responsibility to improve children's health will be shared by pharmaceutical companies, regulatory authorities, health professionals, and society as a whole. Dr. Goldstein will provide a brief overview of FDA and EMEA pediatric regulations and presents a rationale for a sequential multi-disciplinary approach to pediatric drug development. He will discuss three main points including the establishment of a global, multi-disciplinary team approach for pediatric drug development, continuous review of pediatric drug development throughout the lifetime of a drug and across all drugs to ensure within project continuity and cross-project synergies and joint development of the pediatric investigational plan (PIP) for EMEA and the pediatric assessment (PA) for the FDA.

The Global Clinical Trial Operations conference brings together leaders, directors, vice presidents, heads, managers, supervisors, and CROs from all over the world to collaborate and discuss the latest developments in clinical trial operations and logistics and covers clinical trials in emerging markets, first-in-man clinical trials, pediatric clinical trials, material storage, distribution, site selection, patient recruitment and retention, technology in clinical trials and case studies of running global clinical trials.

For more information including a detailed agenda, exhibitor opportunities and registration information visit <http://gtcbio.com/conferenceDetails.aspx?id=127>.

ABOUT GTCbio

GTCbio organizes conferences specifically for the biomedical and biopharmaceutical industries. Our goal is to facilitate the exchange of biopharmaceutical and biomedical intelligence between industry leaders, academic and government organizations, and the financial community.

GTCbio is a subsidiary of Global Technology Community, LLC, a privately held company founded in 2002.

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