



For Immediate Release
July 22, 2008

Contact: Alicia Moran
703-739-2424 x110

CytImmune Sciences CEO Presents to FDA Drug Evaluation Committee on Nanotechnology

Rockville, Maryland – Dr. Lawrence Tamarkin, CEO of CytImmune Sciences was a featured speaker this morning at the Food and Drug Administration’s Center for Drug Evaluation Research Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP). The Advisory Committee provides the FDA with independent advice from outside experts on issues related to human and veterinary drugs, biological products, medical devices, and food. Such input is a vital contribution to assist in general policy and decision making by the Agency, as it often provides information on cutting-edge techniques. The focus of Dr. Tamarkin’s presentation was nanotechnology.

CytImmune Sciences is a clinical stage nanomedicine company with a core focus on the discovery, development and commercialization of multifunctional, tumor-targeted therapies. Based on a research and development strategy which harnesses the unique properties of gold nanoparticles, cytotoxic agents, and biology of tumors, CytImmune is developing a pipeline of proprietary drug candidates binding potent anti-cancer agents -- whose toxicity profiles currently prevent or severely limit clinical use -- to its patented colloidal gold tumor-targeting nanotechnology. CytImmune’s nano-scale development strategy, to engineer new drug formulations that harness the therapeutic potential of well-characterized cytotoxic agents and limit their biodistribution primarily to tumor sites, is the key to realizing improved patient outcomes. This therapeutic approach offers the potential to enable or expand the clinical modality of a variety of toxic agents whose clinical and commercial value has been limited (such as TNF- α , interleukins/interferons, monoclonal antibodies, chemotherapeutic agents, etc.) as CytImmune’s tumor-targeting technology is highly versatile and may be used for the safe and systemic administration of drugs directly to the site of disease -- thereby avoiding uptake by or accumulation in healthy organs and surrounding tissues. The goal is to build from this common core technology a family of therapeutics with accelerated development times, new commercialization value, and ultimately greater patient benefits.

Dr. Tamarkin addressed a number of items related to drug delivery systems using nanotechnology, including: promising applications, advantages of these systems, challenges in developing these systems, comments as to preclinical assessment and quality assurance of nanotechnology-based drugs. He also addressed a number of items related to manufacturing nanoparticle-containing drugs, including: minimal characterization needs for nanotechnology drug product applications; the characteristics/parameters/features of nanomaterials that need to be evaluated during drug development; the relevant tools that should be used to adequately characterize the most important features of nanomaterial containing drugs; and considerations for the

assessment of quality assurance, batch-to-batch variability, stability and purity of nanomaterial containing drugs.

In addition to these questions, Dr. Tamarkin identified the key elements that he believed should be addressed regarding nanomaterial-containing products, their safety, and their manufacturing. At the conclusion of today's meeting, the advisory committee may provide advice on policy matters and regulatory positions to the FDA. However, committee advice is not binding and the final decisions are made by FDA.

"The purpose of my presentation today was to provide an update on the science with respect to my area of expertise, specifically nanotechnology, and how our experiences offer insights into drug delivery, drug development and manufacturing of nanomaterial-containing drugs," said Dr. Tamarkin after his presentation.

###

ABOUT CYTIMMUNE

CytImmune Sciences is a clinical stage nanomedicine company focused on the development and commercialization of multifunctional, tumor-targeted therapies harnessing the unique properties of gold nanoparticles, known anti-cancer agents and biology of tumors. The platform technology allows for the targeted delivery of anti-cancer therapies. CytImmune hopes to build from this common core technology a family of therapeutics with faster development timelines, efficient regulatory approvals, new commercialization value, and greater patient benefits. www.CytImmune.com

**To obtain a copy of Dr. Tamarkin's powerpoint presentation to this committee, call 410-991-7027.