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CDG Therapeutics, Inc. Announces “First in Class, First in Human” Clinical Phase I Trial Results of Cell-Penetrating Peptide, p28

Azurin-derived peptide shows preferential cancer cell entry without serious safety effects

CHICAGO, IL – June 6, 2011 – CDG Therapeutics, Inc. (www.cdgti.com) today announced results from a [clinical Phase I](#) human trial of a novel platform technology utilizing p28, a synthetic, Azurin-derived peptide. Fifteen refractory (Stage IV) solid tumor patients with p53+ lesions were enrolled in an escalating, five-dose level (.83, 1.66, 2.5, 3.33, and 4.16 mg/kg) Phase I trial to evaluate the safety, tolerability, immunogenicity, pharmacokinetics and pharmacodynamics (PK/PD) of p28 as a single agent. [The data was presented](#) at this week’s American Society of Clinical Oncology (ASCO) annual meeting in Chicago.

Conducted in collaboration with the University of Illinois College of Medicine at Chicago and Oncology Specialists, S.C., p28 was administered three times (3x) per week for four weeks as an iv bolus with a two-week PK break before the next, higher dose. Serum was assessed for levels of p28.

To date, none of the 15 patients evaluated exhibited an immune (IgG) response of toxicity grade >1. The group consisted of 7 melanoma, 4 colon, 1 pancreatic, 1 prostate and 2 sarcoma patients with a median age of 62, age range of 50-80, and ECOG performance status of 0-2 including those receiving the highest dose

level. No dose limiting safety effects were observed. Consequently, the NAOEL and MTD appear to be above the highest dose studied. p28 distributes rapidly ($t_{1/2}$, 0.1 hr), has a prolonged terminal half-life ($t_{1/2}$ > 1.7 hr above 2.5 mg/kg) where velocity of distribution (V_{dss}) is maximal. Tumor levels mirrored serum concentrations. Objective responses were observed in target lesions of 8 of 15 patients evaluated to date – one complete regression (1 CR) and seven partial regressions (7 PR)). Patient survival paralleled objective response. The current range in overall survival for patients initially receiving dose levels 1-5 was 2-4, 5-13.5, 3.5-11, 1.5-6, and 2.5-4.5 months, respectively. Six of 12 patients receiving dose levels 2-5 remain alive; one with a CR.

“This was a ‘first in class, first in human’ trial of our novel platform technology utilizing p28, a synthetic, Azurin-derived peptide,” explained abstract co-author, Tapas K. Das Gupta, M.D., Ph.D., D.Sc. “Prior therapeutic testing of proteins and peptides has often shown an immune system response which can be difficult for the rest of the body to tolerate. In our Phase I trial, not a single patient evaluated exhibited an immune (IgG) response of toxicity grade > 1. We also believe preferential cancer cell entry of p28 and regression in a variety of refractory solid tumors suggest a novel therapeutic alternative to the treatments available today for cancer. Additionally, we believe some members in our patented portfolio of peptides may exhibit anti-infective potential in diseases such as HIV, and we are making considerable progress in understanding their potential as therapeutics,” said Dr. Das Gupta.

“When we first discovered anti-cancer activity in the redox protein, Azurin, and were then able to successfully isolate and synthesize a portion of Azurin protein that demonstrated such activity, we believed we were on to something unique,” said David R. Volk, President and CEO of CDG Therapeutics, Inc. “p28’s preferential cancer cell entry and apparent lack of serious safety effects may indicate that a new and important class of drug substances will one day be available for use in the treatment of cancer and, potentially, other diseases as well.”

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[The abstract](#), entitled “*A first in class, first in human, phase I trial of p28, a non-HDM2 mediated peptide inhibitor of p53 ubiquitination in patients with metastatic refractory solid tumors,*” can be viewed at www.cdgti.com, along with [the slide presentation](#) delivered to ASCO attendees.

About CDG

CDG Therapeutics, Inc. is a Chicago-based biotechnology firm engaged in the development and commercialization of proprietary synthetic peptides originally discovered in pathogenic and nonpathogenic bacteria and green plants. As a translational drug discovery company, CDG Therapeutics owns an exclusive, worldwide license to an extensive drug platform including a pipeline of novel, first in class peptides belonging to the “smart drug” or “biologics” class, a potential \$120 billion market.

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