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## **CELATOR® PHARMACEUTICALS PRESENTS DATA ON THE ACTIVITY OF CPX-351 AGAINST LEUKEMIA AT THE EUROPEAN HEMATOLOGY ASSOCIATION CONGRESS**

**Princeton, NJ (June 8, 2009)** – Celator Pharmaceuticals today announced that new clinical and preclinical data demonstrating the extended therapeutic bioavailability and tumor cell selectivity of CPX-351 (Cytarabine:Daunorubicin) Liposome Injection in leukemia were presented at the 14<sup>th</sup> Congress of the European Hematology Association (EHA) in Berlin, Germany, June 4-7, 2009 (Abstracts 1398 and 383).

“These findings underscore the potential pharmacological and pharmacokinetic advantages of CPX-351 in the treatment of advanced leukemias,” said Scott Jackson, chief executive officer, Celator Pharmaceuticals. “Our nano-scale liposomal encapsulation maintains the desired 5:1 molar ratio of cytarabine:daunorubicin in CPX-351, extends bioavailability beyond that seen with conventional administration of the combination, and, based on this evidence, facilitates selectivity for and uptake by leukemia cells. As a result, CPX-351 may lengthen or enhance the anti-tumor activity of cytarabine:daunorubicin, even in patients with relapsed and refractory disease.”

The first poster presented data on the pharmacokinetics and pharmacology of CPX-351 from a Phase I study of patients with relapsed or refractory acute leukemias.<sup>1</sup> Evidence of antitumor effect, details of which were presented at the American Society of Hematology (ASH) meeting in late 2008, included complete remissions (CRs) in 1 of 3 patients with ALL and 10 of 44 patients with AML (9 CRs and 1 CRp - complete remission without full platelet recovery). Some of these remissions occurred at dose levels as low as one-third to one-half of the maximum tolerated dose (MTD; established in this study as 101 u/m<sup>2</sup>). Treatment with CPX-351 was generally well tolerated, with cytopenia-related adverse events consistent with standard cytarabine:daunorubicin regimens. Alopecia and grade ≥3 gastrointestinal adverse events were uncommon.

The current analysis confirmed that CPX-351 maintained the fixed 5:1 molar ratio of cytarabine:daunorubicin for prolonged periods of time (24 hours and longer) after administration. It also showed that while the bioavailability of the encapsulated drugs was similar to that expected with conventional administration, CPX-351 produced prolonged half-lives for both agents and accumulation of the drugs over the three dose induction course (infusions on Days 1, 3, 5). These results suggest that effective drug exposure could be extended beyond that produced by conventional administration of this drug combination. The further observation that circulating liposomal drug could be detected in the plasma up to Day 12, while remaining bioavailable, led the investigators to conclude that leukemia cells could be exposed to cytotoxic drug levels throughout the first two weeks of induction treatment.

In a separate poster presentation, researchers described the results of a preclinical study comparing the sensitivity of various blood cell types to CPX-351 and evaluating the uptake of CPX-351 by human leukemia cells both *in vitro* and *in vivo* (mouse xenograft models).<sup>2</sup> They reported that CPX-351 ablated leukemic cells but permitted the regrowth of normal bone marrow cells within 42 days of treatment in a Rag2-M mouse xenograft model. These mice remained leukemia-free for up to 70 days (saline-treated controls all died by Day 42). In several additional experiments, investigators confirmed the presence of intact CPX-351 liposomes inside the leukemia cells, allowing the release of the synergistic 5:1 molar ratio of the active agents

intracellularly, and demonstrated that CPX-351 is taken up in higher levels by leukemic cells in the bone marrow than by normal bone marrow cells. They concluded that the preferential uptake of CPX-351 by leukemia cells may contribute to its enhanced efficacy and improved therapeutic index.

#### **About Celator Pharmaceuticals, Inc.**

Celator Pharmaceuticals, Inc., with locations in Princeton, NJ, and Vancouver, BC, is a privately held pharmaceutical company developing new and more effective therapies to treat cancer. CombiPlex<sup>®</sup>, the company's proprietary drug ratio technology platform, represents a novel approach that identifies molar ratios of drugs that will deliver a synergistic benefit, and locks the desired ratio in a nano-scale drug delivery vehicle that maintains the ratio in patients with the goal of improving clinical outcomes. The company pipeline includes: CPX-351 (a liposomal formulation of cytarabine:daunorubicin), currently in Phase 2 in patients with acute myeloid leukemia; CPX-1 (a liposomal formulation of irinotecan:floxuridine), currently in Phase 2 in patients with colorectal cancer; CPX-571 (a liposomal formulation of irinotecan:cisplatin), a preclinical stage compound; and multiple research programs. Based on the applications of CombiPlex, Celator is positioned to advance a broad pipeline of combination therapies involving both previously approved and novel drug agents. For more information, please visit the company's website at [www.celatorpharma.com](http://www.celatorpharma.com). Information about ongoing trials is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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List of abstracts:

1. Feldman E, Lancet J, Koltz JE, et al. Pharmacology of CPX-351: a nano-scale liposomal fixed molar ratio cytarabine-daunorubicin for patients with advanced leukemia. EHA Abstract #1398.
2. Harasym T, Lim W, Tardi P, et al. Leukemia cell-selective uptake of cytarabine (Cyt) and daunorubicin (Daun) mediated by CPX-351 liposome injection in the bone marrow compartment. EHA Abstract #383