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Cyclacel Pharmaceuticals Provides Update on Its Clinical Development Plan of Sapacitabine for Myelodysplastic Syndromes (MDS)

BERKELEY HEIGHTS, N.J., May 31, 2014 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (Nasdaq:CYCC) (Nasdaq:CYCCP) ("Cyclacel" or the "Company"), a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious disorders, announced plans for the clinical development of sapacitabine in a second potential indication for patients with myelodysplastic syndromes (MDS) after treatment failure of front-line hypomethylating agents.

Key points:

- Cyclacel will conduct a Phase 2b randomized, controlled clinical trial (RCT) of a regimen of sapacitabine alternating with low dose chemotherapy versus an active control of low dose chemotherapy.
- Eligible patients will be aged 60 years or older with intermediate-2 or high-risk MDS who have failed prior hypomethylating agent therapy.
- Approximately 250 patients will be enrolled in the RCT.
- The primary endpoint will be overall survival.
- The RCT will be preceded by a feasibility survey and a lead-in stage.
- The MDS program was the subject of a recent Cyclacel fundraising.
- Sapacitabine, an oral nucleoside analogue, is being evaluated in the SEAMLESS Phase 3 clinical trial, as its first potential indication, in elderly patients with acute myeloid leukemia (AML). SEAMLESS is funded beyond data readout which is expected around the second half of 2015.

Spiro Rombotis, president and chief executive officer of Cyclacel, said, "Sapacitabine has shown promising overall survival in an ongoing Phase 2 clinical trial in MDS patients who have failed prior hypomethylating agent therapy. As we continue to enroll patients in the SEAMLESS pivotal trial of sapacitabine as first-line therapy in elderly patients with acute myeloid leukemia, with the goal of completing enrollment around the end of 2014, we are planning a controlled trial of sapacitabine in MDS after front-line failure. We are very much aware of the urgent, unmet medical need of patients with MDS and look forward to providing more details on our MDS program in coming months."

An archived webcast of an event discussing the clinical plan for MDS is available for six months as of May 31, 2014 at www.cyclacel.com under the Investors & Media section.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a biopharmaceutical company developing oral therapies that target the various phases of cell cycle control for the treatment of cancer and other serious diseases. Sapacitabine, Cyclacel's most advanced product candidate, is the subject of SEAMLESS, a Phase 3 trial being conducted under an SPA with the FDA as front-line treatment for acute myeloid leukemia (AML) in the elderly, and other studies for myelodysplastic syndromes (MDS), chronic lymphocytic leukemia (CLL) and solid tumors including breast, lung, ovarian and pancreatic cancer and in particular those carrying gBRCA mutations. Cyclacel's strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a development pipeline of novel drug candidates. Please visit www.cyclacel.com for additional information.

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