

News Release

CytRx Initiates Phase 1b Clinical Trial with Combination of Aldoxorubicin and Ifosfamide/Mesna as First-Line Treatment in Patients with Advanced Sarcomas

LOS ANGELES--(BUSINESS WIRE)--Sep. 9, 2014-- CytRx Corporation (NASDAQ: CYTR), a biopharmaceutical research and development company specializing in oncology, today announced the initiation of enrollment in an open-label Phase 1b clinical trial designed to investigate the preliminary safety and activity of aldoxorubicin plus ifosfamide/mesna as a first-line treatment in subjects with various sarcomas. Aldoxorubicin is CytRx's modified version of the widely-used chemotherapeutic agent, doxorubicin.

The Phase 1b clinical trial will be conducted under the direction of Sant Chawla, M.D., Director of the Sarcoma Oncology Center, who is also the principal investigator of CytRx's global Phase 3 pivotal trial for patients with soft tissue sarcoma (STS) which is being conducted under a Special Protocol Assessment with the FDA. The Phase 1b trial is expected to enroll up to 30 male and female patients between the ages of 15 and 80 with locally advanced, unresectable, and/or metastatic STS, chondrosarcoma or certain osteosarcomas. The Company expects to complete enrollment by the third quarter of 2015.

"The timely initiation of this trial marks yet another important clinical milestone for CytRx, highlights the diligent execution of our clinical strategy by CytRx's research and development team, and if successful, will further expand the potential applications for the aldoxorubicin franchise," said CytRx CEO Steven A. Kriegsman. "We are pleased that Dr. Sant Chawla has agreed to serve as principal investigator for this study. His expertise and experience in treating cancer patients with aldoxorubicin will increase the likelihood for the success of this important treatment approach."

For this trial, aldoxorubicin will be administered at escalating doses by intravenous infusion (IVI) on Day 1 every 28 days, and 1 gm/m²/day of ifosfamide and an equivalent dose of mesna will be administered via continuous infusion with a portable at-home pump for up to 14 days every 28 days starting on Day 1 of each cycle, until disease progression, unacceptable toxicity or the patient withdraws consent. The primary objective of the trial is to determine the preliminary safety of administration of aldoxorubicin in combination with ifosfamide in subjects with metastatic, locally advanced, or unresectable STS as measured by the frequency and severity of adverse events (AEs), abnormal findings on physical examination, laboratory tests, vital signs, echocardiograms (ECHO) or multiple-gated acquisition (MUGA) scans, electrocardiogram (ECG) results, and weight. The secondary objective of the trial is to evaluate the activity of aldoxorubicin in combination with ifosfamide/mesna in this population, assessed by overall response rate (ORR), progression-free survival (PFS) and PFS at 4 and 6 months.

Aldoxorubicin is also currently being studied in a pivotal global Phase 3 clinical trial evaluating the efficacy and safety of aldoxorubicin as a second-line treatment for patients with STS under a Special Protocol Assessment with the FDA. CytRx is also evaluating aldoxorubicin in two Phase 2 clinical trials, one in patients with late-stage glioblastoma (GBM) and the other in HIV-related Kaposi's sarcoma. The Company expects to start a global phase 2b trial in patients with relapsed small cell lung cancer this month.

About Aldoxorubicin

The widely used chemotherapeutic agent doxorubicin is delivered systemically and is highly toxic, which limits its dose to a level below its maximum therapeutic benefit. Doxorubicin also is associated with many side effects, especially the potential for damage to heart muscle at cumulative doses greater than 450 mg/m². Aldoxorubicin combines doxorubicin with a novel single-molecule linker that binds directly and specifically to circulating albumin, the most plentiful protein in the bloodstream. Protein-hungry tumors concentrate albumin, thus increasing the delivery of the linker molecule with the attached doxorubicin to tumor sites. In the acidic environment of the tumor, but not the neutral environment of healthy tissues, doxorubicin is released. This allows for greater doses (3 ½ to 4 times) of doxorubicin to be administered while reducing its toxic side effects. In studies thus far there has been no evidence of clinically significant effects of aldoxorubicin on heart muscle, even at cumulative doses of drug well in excess of 2,000 mg/m².

About CytRx Corporation

CytRx Corporation is a biopharmaceutical research and development company specializing in oncology. CytRx currently is focused on the clinical development of aldoxorubicin (formerly known as INNO-206), its improved version of the widely used chemotherapeutic agent doxorubicin. CytRx has initiated under a special protocol assessment a pivotal Phase 3 global trial with aldoxorubicin as a therapy for patients with soft tissue sarcomas whose tumors have progressed following treatment with chemotherapy, and recently announced that it has received approval from the FDA to continue dosing patients with aldoxorubicin until disease progression in that clinical trial. CytRx has initiated a Phase 2 clinical trial in HIV-related Kaposi's sarcoma and a Phase 2 clinical trial with aldoxorubicin in patients with late-stage glioblastoma (brain cancer). CytRx has completed a global Phase 2b clinical trial with aldoxorubicin as a first-line therapy for soft tissue sarcomas, a Phase 1b/2 clinical trial primarily in the same indication, a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors and a Phase 1b pharmacokinetics clinical trial in patients with metastatic solid tumors. CytRx plans to expand its pipeline of oncology candidates at its laboratory facilities in Freiburg, Germany, based on novel linker technologies that can be utilized with multiple chemotherapeutic agents and may allow for greater concentration of drug at tumor sites. For more information about CytRx Corporation, visit www.cytrx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Such statements involve risks and uncertainties that could cause actual events or results to differ materially from the events or results described in the forward-looking statements, including the risk that any human testing of aldoxorubicin in combination with doxorubicin as a therapy for cancer, including the Phase 1b maximum tolerated dose trial described in this press release, might not produce positive results or results similar to those seen in preclinical studies, risks and uncertainties related to the outcome, timing and results of CytRx's other ongoing and planned clinical trials with aldoxorubicin, the risk that aldoxorubicin alone, or in combination with free doxorubicin, might not show greater efficacy than doxorubicin alone notwithstanding the administration of higher doses than the standard of care, the risk that additional longer-term dosing of aldoxorubicin might cause adverse events not seen to date, uncertainties regarding whether aldoxorubicin effectively targets doxorubicin to tumors, uncertainties regarding regulatory approvals for current and future clinical testing of aldoxorubicin and the scope of the clinical testing that may eventually be required by regulatory authorities for aldoxorubicin, the significant time and expense that will be incurred in developing any of the potential commercial applications for aldoxorubicin, including for soft tissue sarcomas, risks related to CytRx's ability to manufacture its drug candidates, including aldoxorubicin, in a timely fashion, cost-effectively or in commercial quantities in compliance with stringent regulatory requirements, risks related to CytRx's need for additional capital or strategic partnerships to fund its ongoing working capital needs and development efforts,

including any future clinical development of aldoxorubicin, and the risks and uncertainties described in the most recent annual and quarterly reports filed by CytRx with the Securities and Exchange Commission and current reports filed since the date of CytRx's most recent annual report. All forward-looking statements are based upon information available to CytRx on the date the statements are first published. CytRx undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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