



MissionIR Blog

CytRx Corp.'s (CYTR) Aldoxorubicin Demonstrates Blockbuster Potential, Says Motley Fool Contributor

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CytRx is a biopharmaceutical R&D company particularly focused on the clinical development of aldoxorubicin, the company's improved version of widely used chemotherapeutic agent doxorubicin. In a recent article entitled, "Aldoxorubicin: The Drug CytRx Investors Should Be Watching," the author describes supporting reasons aldoxorubicin has the potential to replace doxorubicin, the current standard of care in cancer treatment, and the value this could provide for shareholders.

Key points in the article, as discussed by author James Johnson, are:

- Superior efficacy in phase 2b trial
- Addressable Market for aldoxorubicin in STS
- Aldoxorubicin's capability to treat GBM
- Opportunity for aldoxorubicin in treating other medical conditions

To read the full article visit: <http://www.fool.com/investing/general/2014/02/09/aldoxorubicin-the-drug-cytrx-investors-should-be-w.aspx>

CytRx recently received FDA approval to extend the dosing in a phase 3 clinical trial to evaluate aldoxorubicin as a second-line treatment for soft-tissue sarcomas (STS). The extended dosing could allow CytRx to demonstrate even higher progression-free survival (PFS) efficacy results compared to the phase 2b trial for advanced STS with this drug. The company plans to initiate the phase 3 trial in the first quarter of 2014.

In December 2013, CytRx reported highly statistically significant phase 2b trial results, per investigator assessment and central lab review. In this study, aldoxorubicin demonstrated 80-100 percent superiority over doxorubicin in regards to PFS. Additional phase 2b trial data determined ratios for the primary endpoint of PFS, an important measure of the reliability and uniformity of the PFS data.

Approximately 40,000 new cases of STS are diagnosed annually, resulting in nearly 13,000 deaths in the United States and Europe. This provides aldoxorubicin with tremendous growth potential as a first or second-line treatment for this disease. CytRx expects to report the results of the second-line treatment study for STS by mid-2016. The company anticipates filing the New Drug Application with the FDA by the end of that year.

In January 2014, CytRx commenced a phase 2 trial to evaluate aldoxorubicin for the treatment of unresectable glioblastoma multiforme (GBM), a deadly form of brain cancer. Multiple preclinical studies demonstrated aldoxorubicin's capability in limiting GBM tumor cell growth in the brain without affecting healthy brain tissue. The preliminary results from this trial phase are expected during the third quarter of 2014.

"Positive results from the Phase 2 trial will support CytRx in pursuing the rapid development of aldoxorubicin for unresectable GBM," writes Johnson. "This will also allow the company to file for the "breakthrough therapy" designation with the FDA, which is expected to expedite aldoxorubicin's marketing approval. This will enable CytRx to enhance its presence in the oncology drug market to treat GBM, and strengthen its financial position. The approval of aldoxorubicin for GBM could generate revenue of roughly \$300 million during its peak sales period."

CytRx also recently initiated a phase 2 clinical trial for the treatment of HIV-infected patients suffering from Kaposi's sarcoma (KS), a common HIV-related tumor. In this study, CytRx will evaluate the preliminary efficacy and safety of aldoxorubicin in treating this indication. If positive results are achieved, the company plans to discuss with the FDA the necessary requirements to file an NDA for Kaposi's sarcoma. The phase 2 results are expected during the second quarter of 2015.

Johnson writes in conclusion, "Aldoxorubicin, with its superior efficacy and safety profile, could be the blockbuster drug for CytRx. It will generate higher growth opportunities for CytRx and allow the company to deepen its footprint in the oncology space. In light of this, several analysts raised their price target on CytRx shares. The most recent upgrade came from Aegis, which raised their target from \$9 to \$12. ... Further, the positive results of aldoxorubicin in future studies will significantly increase shareholder confidence and boost the company's valuation."

For more information, visit www.cytrx.com

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