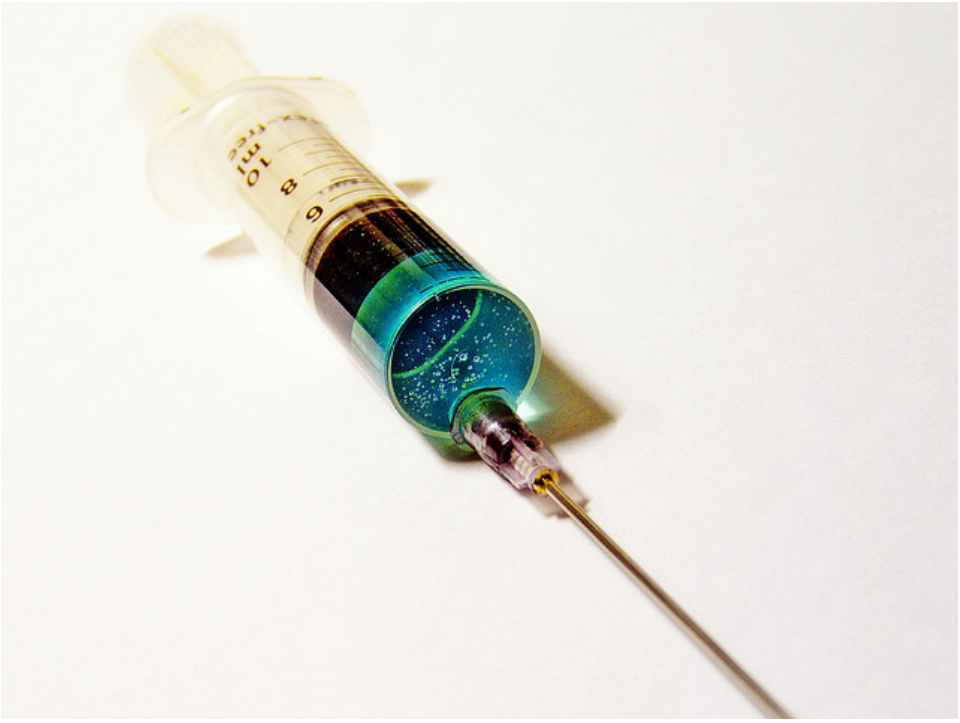
CytRx Is Heading to a Pivotal Trial

JOHN RIVERS | MORE ARTICLES
FEBRUARY 04, 2014



Source: http://www.flickr.com/photos/andresrueda/

CytRx Corp. (NASDAQ:CYTR) is a U.S. research and biopharmaceutical company specializing in the field of oncology. The medical field of oncology is a branch of internal medicine and is concerned with early cancer recognition, cancer diagnosis, and treatment (including chemotherapy and radiotherapy), as well as post-

rehabilitation support. Cancer is a deadly disease and is characterized by uncontrolled abnormal cell growth.

Cancer can affect all vital organs of the human body (colon, lung, prostate, etc.), and it remains one of the most pressing public health concerns of our time. The American Cancer Association estimated that 1,660,290 new cancer cases would be diagnosed in the United States in 2013 alone and that 580,350 Americans would die as a result of cancer the same year. Cancer is responsible for one in four deaths in the United States, which highlights the importance of both early cancer recognition and the need for successful cancer therapies. Substantial research and development expenses are incurred by pharmaceutical companies in the U.S. and Europe to develop marketable solutions to the cancer epidemic.

Background

CytRx's oncology pipeline accentuates the clinical development of aldoxorubicin, which aims to be a superior improvement over doxorubicin, a well-established chemotherapeutic agent. The development of aldoxorubicin seems to be a promising bet for CytRx as the company steadily progresses through the phases of the clinical research cycle.

CytRx's most recent 10-Q filing with the U.S. Securities and Exchange Commission summarized the development portfolio as follows:

> "CytRx is conducting a global Phase 2b clinical trial with aldoxorubicin as a treatment for soft tissue sarcoma, has completed a Phase 1b/2 clinical trial primarily in the same indication, a Phase 1b study 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 initiate under a Special Protocol Assessment, or "SPA," granted by the U.S. Food and Drug Administration, or the "FDA," a potential pivotal Phase 3 global trial of

STORIES YOU'LL LOVE


Fight the Addiction: 7 Ways to Stay Awake Without Caffeine


Top 10 Healthiest Cities in the U.S.


Top 10 States With Exploding Home Prices


5 Must-Have Stocks in Your 2014 Portfolio


8 Reasons Why the Lakers Are So Despondent Right

aldoxorubicin as a therapy for patients with soft tissue sarcoma whose tumors have progressed following treatment with chemotherapy. The Company also is initiating Phase 2 clinical trials with aldoxorubicin in patients with late-stage glioblastoma (brain cancer) and AIDS-related Kaposi's sarcoma. CytRx plans to expand its pipeline of oncology candidates based on a linker platform technology that can be utilized with multiple chemotherapeutic agents and may allow for greater concentration of drug at tumor sites."

CytRx also holds exclusive worldwide rights to aldoxorubicin, which could lead to a large windfall in the future should aldoxorubicin make it through the clinical testing process and be approved by the U.S. Food and Drug Administration.

Positive news flow

CytRx delivered a series of positive news lately, which drove the share price well above the $7 mark. On December 11, the company released statistically significant results from its Phase 2b trial with aldoxorubicin in first-line soft tissue sarcomas. On January 21, the company reported that it received approval from the FDA to extend aldoxorubicin dosing cycles until disease progression in its upcoming pivotal global phase 3 trial for second-line soft tissue sarcomas.

As a reaction to the news, CytRx's share price jumped to $7.76 up from a closing price of $7.04 the previous Friday (an increase of 10 percent). On January 23, the company announced that it initiated an open-label Phase 2 clinical trial at Louisiana State University Health Sciences Center in New Orleans to determine preliminary efficacy and safety of aldoxorubicin for HIV-infected patients with Kaposi's sarcoma. In response to the news, shares of CytRx jumped 12 percent.

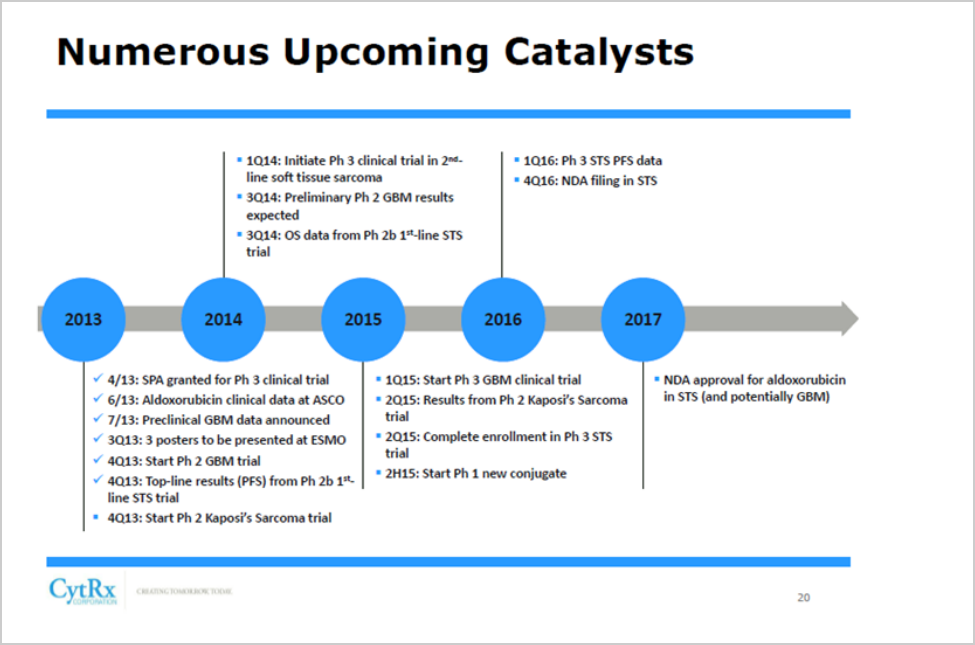
CytRx CEO and President Steven A. Kriegsman said: "Aldoxorubicin has demonstrated effectiveness against a range of tumors in both

human and animal studies, thus we are optimistic in regard to a potential treatment for Kaposi's sarcoma. The current standard-of-care for severe dermatological and systemic KS is liposomal doxorubicin (Doxil). However, many patients exhibit minimal to no clinical response to this agent, and that drug has significant toxicity and manufacturing issues."

Positive news flow with respect to aldoxorubicin and increased buyer interest after news dissemination show that CytRx's share price is highly news sensitive. Further positive news with respect to the initiation of CytRx's phase 3 clinical trial for second-line soft tissue sarcoma, which is expected in the first quarter of 2014, could be another substantial, short-term catalyst.

CytRx's investor presentation (especially valuable for investors who want to get a deeper understanding of pharmaceutical data relating to aldoxorubicin and doxorubicin) from December highlights a roadmap for CytRx's development portfolio, while every milestone achievement could be a meaningful catalyst for CytRx's share price.

Near-term catalysts with respect to CytRx's development portfolio are summarized in the chart below:



Exercise of over-allotment options indicates strong investor demand for CytRx stock

On October 8, the company announced the public offering of 10 million shares at an offering price of $2.25 for gross proceeds of $22.5 million in order to fund the development of its aldoxorubicin agent. In addition, the company attached an over-allotment option to its offering in order to be able to cover stronger-than-anticipated investor demand. Given the progress the company has made with respect to the development of aldoxorubicin, CytRx ultimately sold an additional 1.5 million shares via the exercise of the over-allotment option for total gross proceeds of $25.9 million.

Strong investor demand for secondary offerings and particularly the exercise of over-allotment options are usually bullish signs. I have also repeatedly written that above-average returns can often be found in investments that fly below the radar. Smaller capitalization companies like CytRx (the company currently fetches a market capitalization of $305 million) are typically under-covered by research firms, which makes it likely that security prices are not as efficient as those for larger capitalization companies.

Conclusion

CytRx pursues the ambitious goal of replacing the standard chemotherapeutic agent doxorubicin with aldoxorubicin, an agent that appears to have better efficacy and safety. If CytRx's past share performance is any indicator of its future performance, investors can expect future news releases with respect to milestone achievements in its product portfolio to be highly security sensitive. Strong investor demand for CytRx's secondary stock offering also indicates that interest in aldoxorubicin and its possible applications in cancer treatments is high.

In anticipation of strong news flow, CytRx's shares have increased by more than 200 percent since December 10. If CytRx delivers positive results for its three clinical trials and manages to get FDA approval for its blockbuster product aldoxorubicin, the share price could run

substantially higher. The fact that CytRx holds the exclusive worldwide rights to aldoxorubicin only adds to the appeal of this under-followed biopharmaceutical play.

Don't Miss: You Snooze, You Lose: 7 Tips for Working Out in the AM.

reddit this!

See Also

1.
2.
3.

More Articles About: biopharmaceuticals CytRx Corp. drug pipeline Investing oncology pharmaceuticals pharmacy positive news positive news flow research and development share prices shares Steven A. Kriegsman Stocks Wall Street

To contact the reporter on this story:
staff.writers@wallstcheatsheet.com
To contact the editor responsible for this story:
editors@wallstcheatsheet.com

Add a comment...

Co

Facebook social plugin

Wall St. Cheat Sheet has been featured in these fine media outlets:

YAHOO! FINANCE | Harvard Business Review | MarketWatch | THE WALL STREET JOURNAL. | FT.com | CNNMoney | FOX BUSINESS