LadRx Planning NDA Submission under 505(b)(2) for Aldoxorubicin

and Other Updates

Company expects package will not require additional human clinical studies, potentially accelerating path to market

Los Angeles, CA, December 11, 2024 – (BUSINESS WIRE) -- LadRx Corporation (OTCQB: LADX) ("LadRx" or the "Company"), a biopharmaceutical innovator focused on research and development of life-saving cancer therapeutics, is pleased to announce that the Company is restarting a process to seek marketing approval of aldoxorubicin under the provisions of the FDA's Section 505(b)(2).

The 505(b)(2) pathway is designed for a new drug composition whose active ingredient is the same active ingredient as a drug previously approved by the US Food and Drug Administration (FDA). Given that the active component of the tumor-targeted drug aldoxorubicin is the already-marketed drug doxorubicin, the 505(b)(2) pathway is available for aldoxorubicin, and greatly reduces the regulatory burden of getting aldoxorubicin to the market by relying on the non-clinical and clinical data history of doxorubicin to demonstrate efficacy and safety. Additionally, the market exclusivity awarded to drugs that have received orphan designation for certain rare diseases, as is the case for aldoxorubicin, is available for drugs approved through the 505(b)(2) process for new drugs.

In 2017, following discussions between LadRx and the FDA (see announcement on June 8, 2017), LadRx initiated work to assemble the data to support a marketing approval under section 505(b)(2) for aldoxorubicin for the treatment of soft tissue sarcoma. While this work was ongoing, LadRx entered a license agreement with Nantcell, Inc. (see announcement on June 8, 2017), which stopped the 505(b)(2) process. With the termination of the aldoxorubicin license agreement between LadRx and NantCell in June 2024, LadRx regained control of aldoxorubicin.

LadRx has restarted the 505(b)(2) process for obtaining marketing authorization for aldoxorubicin for the treatment of soft-tissue sarcoma. LadRx expects this process to encompass some bridging studies in animals to bridge the data between doxorubicin and aldoxorubicin, but does not expect to conduct additional human clinical studies. Subject to receiving additional funding, LadRx plans to request a pre-NDA meeting with the FDA mid-2025 to confirm the requirements that were discussed between the Company and the FDA prior to the out-licensing of aldoxorubicin in 2017. Completion of the NDA-related activities and subsequent marketing application and approval are dependent on agreement by the FDA, and on gaining additional funding, neither of which can be guaranteed.

Stephen Snowdy, PhD, CEO of LadRx commented, "Patients who are suffering the burden of cancer deserve the best treatments science can offer. In soft tissue sarcoma in particular, oncologists have shared with us the significant unmet need that still exists for this patient population. We feel that aldoxorubicin will add a valuable therapy to oncologists' armory. We are encouraged by the conversations that have taken place between LadRx and the FDA, and we feel that the planned 505(b)(2) pathway to approval is appropriate, and if successful, would represent a rapid and low-cost path to market for aldoxorubicin that requires no further human clinical study. Combined with our clinic-ready tumor-targeted drug LADR-7, and several pre-clinical assets, we have a full pipeline of opportunity to potentially help those suffering from solid

tumors. We believe strongly in the potential of our chemotherapies, and are cointinuing to evaluate financing and strategic alternatives to see these therapies through to the patients who need them".

LadRx is also pleased to announce that it has received a $1 million milestone payment related to arimoclomol. LadRx is currently evaluating pathways to funding its activities, which may include, but are not limited to, mergers, out-licensing, and equity and non-equity financings.

About Aldoxorubicin

Aldoxorubicin is a rationally engineered cytotoxic which combines doxorubicin, a widely used chemotherapeutic agent, with a novel linker molecule that binds in inactive form to circulating albumin, the most abundant protein in the bloodstream. Protein-hungry tumors concentrate albumin, which facilitates the delivery of the chemotoxin to tumor sites. In the acidic environment of the tumor, but not the neutral environment of healthy tissues, doxorubicin is released in active form. Typically, 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. Using this acid-sensitive linker technology, aldoxorubicin delivers greater doses of doxorubicin (3 ½ to 4 times). To date, there has been no evidence of clinically significant effects of aldoxorubicin on heart muscle, even at cumulative doses of the drug well in excess of 5,000 mg/m2. Aldoxorubicin is the first-ever single agent to show superiority over doxorubicin in a randomized clinical trial in first-line soft tissue sarcoma.

About Soft Tissue Sarcoma

Soft tissue sarcoma is a cancer occurring in muscle, fat, blood vessels, tendons, fibrous tissues and connective tissue. It can arise anywhere in the body at any age. STS remains a high unmet medical need because of the difficulty in treating the more than 50 types of this aggressive cancer. According to the American Cancer Society, in 2024 more than more than 13,000 new cases are expected to be diagnosed in the U.S. and approximately 5,200 Americans are expected to die from this disease. Globally, in 2021, there were approximately 96,000 people diagnosed with soft tissue sarcoma (Global Burden of Disease 2021). In addition, there are approximately 167,000 people in the US living with soft tissue sarcoma (www.cancer.gov, data from 2022).

Forward-Looking Statements

This press release may contain certain statements relating to future results which are forward-looking statements, including, without limitation, whether the company will be able to secure new financing to fund its operations and clinical programs, or receive clearance from the FDA of its 505(b)(2) application for Aldoxorubicin. These statements are not historical facts, but instead represent only LadRx's belief regarding future events, many of which, by their nature, are inherently uncertain and outside of LadRx's control. 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; and other risks and uncertainties described in the most recent annual and quarterly reports filed by LadRx with the SEC, including disclosures under the heading "Risk Factors," and current reports filed since the date of the LadRx's most recent annual report. All forward-looking statements are based upon information available to LadRx on the date the statements are first published. LadRx undertakes no obligation to publicly update

or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

About LadRx

LadRx Corporation (OTCQB: LADX) is a biopharmaceutical company developing new therapeutics to treat patients with cancer. LadRx Corporation's website is www.ladrxcorp.com.

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