CytRx Comments on Orphazyme's Update on European Union Regulatory Review of Arimoclomol in Niemann-Pick Disease Type C

Notes CytRx's Core Assets Are Unaffected by European Medicines Agency's Assessment of Arimoclomol

Highlights Positive Developments Regarding Company's Core Assets, Including Aldoxorubicin

LOS ANGELES--(BUSINESS WIRE)--CytRx Corporation (OTCQB: CYTR) (“CytRx” or the “Company”), a biopharmaceutical company focused on research and development for the oncology and neurodegenerative disease categories, today commented on Orphazyme A/S's (NASDAQ: ORPH) ("Orphazyme") announced update on the ongoing review of the Marketing Authorisation Application (MAA) for its investigational product candidate, arimoclomol, for the treatment of Niemann-Pick disease type C ("NPC") by the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA"). CytRx licensed arimoclomol to Orphazyme in exchange for milestone payments and royalties.

While Orphazyme was encouraged by the positive feedback of the ad-hoc expert group meeting held on February 17, 2022, Orphazyme has been notified by the CHMP of a negative trend vote on the MAA for arimoclomol in NPC following an Oral Explanation. The trend vote indicates that the CHMP's current orientation is to not approve arimoclomol when it convenes by the end of March 2022. Orphazyme considers it unlikely that this position will change before the formal vote is undertaken next month. Orphazyme plans to continue discussions with the U.S. Food and Drug Administration regarding its planned resubmission of a New Drug Application for arimoclomol for the treatment of NPC.

In connection with the news, CytRx issued the following statement:

"While we are disappointed by the CHMP's regulatory stance regarding arimoclomol for NPC in the European Union ahead of next month's formal vote, it is important to note that arimoclomol is a non-core in/out license for CytRx and is not part of the Company's valuable core assets built from our LADR™ technology. We are pleased to see the recent positive clinical developments from ImmunityBio, Inc.'s study of aldoxorubicin, the first generation of our LADR™ technology, and are excited by the development of next-generation LADR™ chemotherapeutics coming through our pipeline. As previously noted, CytRx out-licensed aldoxorubicin to ImmunityBio via an agreement that can yield royalties on sales and up to $343 million in potential milestones. ImmunityBio is currently studying aldoxorubicin in late-stage clinical trials in pancreatic cancer and in earlier-stage clinical studies in glioblastoma, triple negative breast cancer and head and neck cancer. We look forward to advancing into clinic CytRx’s other potentially life-saving cancer therapies employing our LADR™ technology."

About CytRx

CytRx Corporation (OTCQB: CYTR) is a biopharmaceutical company with expertise in discovering and developing new therapeutics principally to treat patients with cancer and neurodegenerative diseases. CytRx’s most recent advanced drug conjugate, aldoxorubicin, is an improved version of the widely used anti-cancer drug doxorubicin and has been out-licensed to ImmunityBio, Inc. In addition, CytRx’s drug candidate, arimoclomol, was sold to Orphazyme A/S in exchange for milestone payments and royalties. Orphazyme is developing arimoclomol in two indications, including Niemann-Pick disease Type C (NPC), and Gaucher disease. CytRx Corporation’s website is www.cytrx.com.

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