

CytRx Highlights Orphazyme's Update on Planned NDA Resubmission for Arimoclomol in Niemann-Pick Disease Type C

Orphazyme Intends to Request a Type C Meeting in Q2 2022

Orphazyme Plans to Resubmit the NDA During H2 2022, Subject to FDA Discussions

European Medicines Agency Opinion Expected in Q1 2022

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 highlighted Orphazyme A/S's (NASDAQ: ORPH) ("Orphazyme") announced update on the process and anticipated timelines for resubmission of its New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for its investigational product candidate, arimoclomol, for the treatment of Niemann-Pick disease type C ("NPC"). CytRx licensed arimoclomol to Orphazyme in exchange for milestone payments and royalties.

In line with recommendations from the FDA during a Type A Meeting held in October 2021, Orphazyme intends to request a Type C Meeting to discuss additional data, information and analyses addressing certain topics in the Complete Response Letter to align on a path to resubmission for arimoclomol in NPC with the FDA. Orphazyme plans to request the Type C Meeting in Q2 2022. Subject to these discussions, Orphazyme aims to resubmit the NDA during H2 2022.

Separately, Orphazyme's EU Marketing Authorisation Application for arimoclomol for the treatment of NPC was filed with the European Medicines Agency in November 2020. An opinion from the Committee for Medicinal Products for Human Use on this application is expected in Q1 2022.

CytRx will continue to share publicly available updates as they relate to the Company's licensing deal with Orphazyme.

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, aldorubicin, 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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