businesswire
A BERKSHIRE HATHAWAY COMPANY

# CytRx Issues Statement Regarding Orphazyme's Global Offering

September 30, 2020 08:00 AM Eastern Daylight Time

LOS ANGELES--(BUSINESS WIRE)--CytRx Corporation (OTCQB:CYTR) ("CytRx" or the "Company"), a specialized biopharmaceutical company focused on research and development for the oncology and neurodegenerative disease categories, today congratulated Orphazyme A/S (ORPHA.CO) (NASDAQ:ORPH) ("Orphazyme") on the September 29, 2020 pricing of its global offering, consisting of an initial public offering of American Depositary Shares in the U.S. and a concurrent private placement of ordinary shares in Europe. According to Orphazyme, the aggregate gross proceeds from its global offering will amount to approximately DKK 534,534,637 ($83,777,606 using a DKK/USD exchange rate of 6.3804) (assuming no exercise of the option to purchase additional shares) and DKK 614,714,770 ($96,344,237 using a DKK/USD exchange rate of 6.3804) (assuming full exercise of the option to purchase additional shares). CytRx has an agreement with Orphazyme that can yield milestone payments and royalties based on potential future sales of arimoclomol.

In connection with Orphazyme's global offering, it disclosed receipt of a filing communication from the U.S. Food and Drug Administration ("FDA") relating to the agency's ordinary course review of its new drug application ("NDA") for arimoclomol in the treatment of Niemann-Pick disease Type C ("NPC"). The filing communication follows acceptance on a Priority Review basis by the FDA of Orphazyme's NDA for arimoclomol in NPC and the agency's establishment of the Prescription Drug User Fee Act ("PDUFA") target action date of March 17, 2021. Orphazyme stated that its receipt of the filing communication does not impact the FDA's acceptance of its NDA, the target PDUFA action date or the Priority Review determination. Orphazyme's disclosure notes that the filing communication constitutes preliminary notice from the FDA of potential review issues as part of its ordinary course review of the NDA and is not necessarily indicative of deficiencies that may be identified during the review. Orphazyme has stated that it intends to discuss the filing communication with the FDA.

In accordance with applicable securities laws, Orphazyme amended the registration statement on Form F-1 on file with the U.S. Securities and Exchange Commission. For further information concerning the FDA filing communication, we refer you to the "Recent Developments" section on Page 6 of Orphazyme's amended Form F-1 filed on September 28, 2020.

CytRx will continue to provide updates that are relevant to its agreement with Orphazyme.

**About CytRx Corporation**

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 drug candidate, arimoclomol, was sold to Orphazyme A/S (Nasdaq Copenhagen exchange: ORPHA.CO) in exchange for milestone payments and royalties. Orphazyme is developing arimoclomol in four indications including amyotrophic lateral sclerosis ("ALS"), Niemann-Pick disease Type C ("NPC"), Gaucher disease and sporadic Inclusion Body Myositis ("sIBM"). Learn more at www.cytrx.com.

**About Orphazyme**

Orphazyme is a biopharmaceutical company focused on bringing novel treatments to patients living with life threatening or debilitating rare diseases. Their research focuses on developing therapies for diseases caused by misfolding of proteins including lysosomal storage diseases. Arimoclomol, the company's lead candidate, is in clinical development for four orphan diseases: Niemann-Pick disease Type C, Gaucher disease, sporadic Inclusion Body Myositis, and Amyotrophic Lateral Sclerosis. The Denmark-based company is listed on Nasdaq Copenhagen (ORPHA.CO). For more information, please visit www.orphazyme.com.

**About NPC**

Niemann-Pick disease Type C (NPC) is a rare, genetic and progressive disease that impairs the ability of the body to move cholesterol and other fatty substances (lipids) inside the cells. The result is an accumulation of lipids within the body's tissue, including the brain tissue, causing damage to the affected 2 areas. The symptoms upon onset of NPC vary from fatality during the first months after birth to a progressive disorder not diagnosed until adulthood. The disease affects neurologic and psychiatric functions as well as various internal organs. Systemic symptoms of NPC are more common in infancy or childhood and the rate of progression is usually much slower in individuals with onset of symptoms during adulthood. NPC is usually fatal and the majority of individuals with the disease die before the age of 20. NPC has been granted Orphan Drug Designation (EU and U.S.) for the treatment of NPC. It is estimated the incidence of NPC to be one in 100,000 live births and the number of NPC patients in the United States and in Europe to be approximately 1,800 individuals. There are no approved treatments for NPC in the U.S. and only one approved product in Europe called miglustat.

**About Arimoclomol**

Arimoclomol is an investigational drug candidate that amplifies the production of heat-shock proteins (HSPs). HSPs can rescue defective misfolded proteins, clear protein aggregates, and improve the function of lysosomes. Arimoclomol is administered orally, crosses the blood brain barrier, and has been studied in seven Phase 1, four Phase 2 and one pivotal Phase 2/3 clinical trial. Arimoclomol is in clinical development at Orphazyme for the treatment of NPC, Gaucher disease, sIBM and ALS. Arimoclomol has received orphan drug designation for NPC, sIBM and ALS in the US and EU, as well as fast-track designation from the US Food and Drug Administration (FDA) for NPC, sIBM and ALS. In addition, arimoclomol has received breakthrough therapy designation and rare-pediatric disease designation from the FDA for NPC.

**Forward-Looking Statements**

This press release contains forward-looking statements, including statements relating to the Company's receipt of future milestone and royalty payments from Orphazyme and the achievement of long-term value for the Company's stockholders. 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, including risks and uncertainties relating to the ability of Orphazyme to obtain regulatory approval for, manufacture and commercialize its products and therapies that use arimoclomol; the results of future clinical trials involving arimoclomol; the amount, if any, of future milestone and royalty payments that we may receive from Orphazyme; and other risks and uncertainties described in the most recent annual and quarterly reports filed by the Company with the SEC and current reports filed since the date of the Company's most recent annual report. All forward-looking statements are based upon information available to the Company on the date the statements are first published. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

## Contacts

For Investors:
Profile
Greg Marose / Charlotte Kiaie, 347-343-2999
gmarose@profileadvisors.com / ckiaie@profileadvisors.com