



CytRx Corporation Highlights Orphazyme’s Rolling Submission of its New Drug Application with the U.S. FDA for Arimoclomol in Niemann-Pick Disease Type-C

EMA Marketing Authorisation Application Submission Expected in H2 2020

LOS ANGELES – June 1, 2020 – CytRx Corporation (OTCQB: CYTR), a biopharmaceutical research and development company specializing principally in oncology and neurodegenerative diseases, today highlighted that Orphazyme A/S announced they have initiated the submission of their New Drug Application (NDA) for a rolling review by the U.S. Food and Drug Administration (FDA) for arimoclomol for the treatment of Niemann-Pick Disease Type-C (NPC).

Arimoclomol has received Fast Track and Breakthrough Therapy Designations for the treatment of NPC, in addition to Orphan Drug and Rare Pediatric Disease Designations. The FDA’s rolling review allows the company to submit portions of the NDA to the FDA as they are completed. Orphazyme has announced that they expect to complete submission of the remaining portions of the NDA to the FDA in the next couple of months.

Earlier this year, Orphazyme announced their Early Access Program was now operational for arimoclomol for the treatment of NPC.

Orphazyme also indicated they are continuing their commercial preparations for the launch of arimoclomol in the U.S. and other key markets, upon approval. They also announced they expect to submit a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for arimoclomol in NPC in the second half of this year.

“We are excited to see Orphazyme continue to make progress in the hopes of bringing arimoclomol to the market to address this devastating neurodegenerative disease,” said Steven A. Kriegsman, CytRx’s Chairman and CEO.

CytRx would receive milestone payments of \$6 million in the U.S., \$4 million in Europe and \$2 million in Japan upon approval of arimoclomol in Orphazyme’s first non-ALS indication, plus royalties.

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. In addition, one of CytRx’s drug candidates, arimoclomol, was sold to Orphazyme A/S 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). CytRx Corporation’s website is www.cytrx.com.

About Orphazyme A/S

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 conservatively estimated that the number of potential NPC patients in the United States and in the EU is between 1,000 and 2,000 individuals in total. 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 and three Phase 2 clinical trials. Arimoclomol is in clinical development at Orphazyme for the treatment of NPC, Gaucher disease, sIBM, and ALS.

Forward-Looking Statements

This press release contains forward-looking statements. 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, such as the risks and uncertainties relating to the ability of Orphazyme to obtain regulatory approval for its products that use arimoclomol; the ability of Orphazyme A/S to manufacture and commercialize products or therapies that use arimoclomol; the amount, if any, of future milestone and royalty payments that we may receive from Orphazyme A/S; and other risks and uncertainties described in the most recent annual and quarterly reports filed by CytRx with the Securities and Exchange Commission and current reports filed since the date of CytRx's most recent annual report. All forward-looking statements are based upon information available to CytRx on the date the statements are first published. CytRx undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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