CytRx Announces Orphazyme’s U.S. Expansion Ahead of Potential Regulatory Approval of Arimoclomol for Niemann-Pick Disease Type C

Highlights Orphazyme’s Establishment of U.S. Headquarters in Chicago and Recruitment of More Than 30 U.S. Employees

Comments That Orphazyme’s Investments in the U.S. are Intended to Support Regulatory Efforts and the Prospective Commercialization of Arimoclomol for Niemann-Pick Disease Type C and Possibly Other Rare Diseases in the Future

LOS ANGELES--(BUSINESS WIRE)--CytRx Corporation (OTCQB: CYTR) (“CytRx” or the “Company”), a specialized biopharmaceutical firm focused on research and development for the oncology and neurodegenerative disease categories, today highlighted that Orphazyme A/S (NASDAQ: ORPH) (“Orphazyme”) has announced the expansion of its U.S. presence and workforce ahead of potential Food and Drug Administration (“FDA”) approval of arimoclomol for the treatment of Niemann-Pick disease Type C (“NPC”). CytRx has an agreement with Orphazyme that can yield potential milestone payments and future royalties paid on sales of arimoclomol.

In addition to establishing its U.S. headquarters in Chicago, Orphazyme has already recruited more than 30 U.S. employees. Orphazyme has also named three U.S. leaders to its global executive team:

- Molly Painter, U.S. President, is heading the launch and commercial operations in the market.
- Terri Stevens, Chief Business Officer, is responsible for global strategy, corporate development, and business development and licensing.
- Molly Carey Poarch, Global and U.S. Head of Corporate Communications.

Orphazyme’s U.S. team, which is focused on regulatory review efforts and a first potential commercial launch in 2021, includes legal, commercial, finance, advocacy relations, and regulatory and medical affairs functions.

Illinois State Senator Mattie Hunter issued the following statement last week:

“I am excited to welcome Orphazyme, a fresh and innovative biopharmaceutical to Chicago’s robust group of health care companies. I believe their methodology will make leeway in the fight against rare neurodegenerative diseases while bringing job growth to the city.”

Orphazyme’s Chief Executive Officer delivered the following statement last week:

“We have established a U.S. headquarters in Chicago to allow us to more closely engage with our partners and community members as we work together to pursue innovation for debilitating neurodegenerative diseases based on our pioneering science. Our U.S. growth will be fueled by the team of industry experts we have been assembling. We are excited to add three key U.S.-based leaders to our corporate executive team as we expand to support our ambition of serving rare disease communities around the world.”

Steven A. Kriegsman, Chairman and Chief Executive Officer of CytRx, commented:

“We are very pleased to see Orphazyme establish a strong U.S. footprint by investing in headquarters in Chicago and retaining more than 30 employees ahead of potential commercialization of arimoclomol for NPC upon prospective FDA approval in the first quarter of 2021. In our view, Orphazyme is taking the right steps to begin future distribution and deepen engagement with U.S. providers, patients, regulators, and the clinical testing community in 2021. It is also noteworthy that during the year 2021, Orphazyme may receive
a response to its submission for regulatory approval in Europe for arimoclomol to treat NPC. Also, on or before June 30, 2021, Orphazyme is expected to report Phase 3 data on arimoclomol for sporadic Inclusion Body Myositis and Amyotrophic Lateral Sclerosis. We remain optimistic about Orphazyme’s continued progress.”

We will continue to provide updates that are relevant to our 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. Orphazyme is headquartered in Denmark and has operations in the U.S. and Switzerland. Orphazyme shares are listed on Nasdaq (ORPHA). 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 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 potential receipt of EMA and FDA approval of arimoclomol, the Company’s potential 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 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.

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