# CytRx Corporation Highlights Significant Positive Events From its Two Licensed Drugs Arimoclomol and Aldoxorubicin

*CytRx Licensee Orphazyme A/S Granted Breakthrough Therapy Designation for Arimoclomol In Niemann-Pick Disease Type C (NPC)*

*Licensee Orphazyme A/S Receives Fast Track Designation in Sporadic Inclusion Body Myositis (sIBM)*

*CytRx Licensee ImmunityBio, Inc., Previously NantCell, Inc., Presents Positive Data from Refractory Triple Negative Breast Cancer with Its Human Natural Killer Cell Combination Immunotherapy Including Aldoxorubicin*

*Arimoclomol and Aldoxorubicin Were Developed and Out Licensed by CyRrx - Positive Events That Build on The Potential for CytRx to Receive Substantial Milestone and Royalty Payments*

**LOS ANGELES – December 19, 2019 –** CytRx Corporation (OTCQB: CYTR), a biopharmaceutical research and development company, today highlighted Orphazyme A/S received FDA Breakthrough Therapy Designation for arimoclomol for NPC. Breakthrough Therapy Designation is a program intended to expedite the development and review of drugs to treat serious or life-threatening diseases in cases where preliminary clinical evidence shows that the drug may provide substantial improvements over available therapy.

Orphazyme also announced they have received Fast Track status from the FDA for arimoclomol in sIBM. This is their second Fast Track Designation for arimoclomol, which CytRx licensed to Orphazyme in 2011. Receiving the designation on multiple occasions shows the significant potential of arimoclomol in orphan diseases.

Arimoclomol has been shown to have a clinically meaningful effect on disease progression in NPC that is further supported by a biomarker effect indicating an effect on the biological underpinnings of the disease and a favorable safety and tolerability profile. Orphazyme is committed to bringing this product to patients as soon as possible. Breakthrough Therapy Designation is designed to expedite the development and review of products for serious diseases with the direct involvement of senior staff at Orphazyme working closely with the FDA to further advance arimoclomol. Preparations for filing in the U.S. are underway and the company has indicated it is on track to submit a New Drug Application in H1 2020.

“It is very gratifying to see the advances being made with arimoclomol, which CytRx developed and licensed to Orphazyme. We expect that patients who are diagnosed with these serious orphan diseases will soon have a treatment with arimoclomol”, said Eric Curtis, President and Chief Operating Officer of CytRx.

CytRx has an agreement with Orphazyme that will pay CytRx up to $120 million in milestones, plus single and double-digit royalties for arimoclomol.

ImmunityBio, Inc. (“ImmunityBio”) announced Results of its Landmark Trial of First-in-Human Natural Killer Cell Combination Immunotherapy with Durable, Complete Response Data and 78% Disease Control in Refractory Triple Negative Breast Cancer at the San Antonio Breast Cancer Symposium. This immunotherapy includes CytRx’s aldoxorubicin as part of its innovative chemoradiation therapy.

“We are very pleased to see aldoxorubicin being utilized in this promising protocol for triple negative breast cancer patients who so desperately need advances in therapy to fight their disease”, said Eric Curtis, President and Chief Operating Officer of CytRx.

CytRx out-licensed global development, manufacturing, and commercialization rights for aldoxorubicin to ImmunityBio in July 2017. CytRx has an agreement with ImmunityBio that will pay CytRx up to $343 million in milestones, plus single and double-digit royalties for aldoxorubicin.

**About CytRx Corporation**
CytRx Corporation (OTCQB: CYTR) is a biopharmaceutical company with expertise in discovering and developing new therapeutics to treat patients with high unmet needs. CytRx's most advanced drug conjugate, aldoxorubicin, is an improved version of the widely used anti-cancer drug doxorubicin and has been out-licensed to ImmunityBio In addition, CytRx's other drug candidate, arimoclomol, has been out-licensed to Orphazyme A/S (Nasdaq Copenhagen exchange: ORPHA). Orphazyme is testing arimoclomol in four indications including amyotrophic lateral sclerosis (ALS), Niemann-Pick disease Type C (NPC), Gaucher disease and sporadic Inclusion Body Myositis (sIBM).

**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, visit www.orphazyme.com.

**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 trials. Arimoclomol is in clinical development for NPC, Gaucher disease, sIBM, and ALS.

**About Niemann-Pick Disease Type C**
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. Arimoclomol 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 sIBM**

Sporadic Inclusion Body Myositis (sIBM) is a progressively debilitating muscle-wasting disease. sIBM is characterized by a build-up of protein aggregates and atrophy of muscle cells, which leads to weakness and over time severe disability. The estimated prevalence of sIBM is 45.6 per million or 40,000 patients in the USA and Europe. There are no approved treatments for sIBM. Arimoclomol has been granted Orphan Drug Designation (EU and U.S.) for the treatment of sIBM.

**About ImmunityBio**

ImmunityBio is a privately held immunotherapy company with one of the broadest portfolios of biological molecules spanning albumin-linked chemotherapeutics, peptides, fusion proteins, cytokine, monoclonal antibodies, adenovirus and yeast vaccine therapies.

**About Triple Negative Breast Cancer**

**TNBC** is an aggressive subtype of breast cancer with limited treatment options for which immunotherapy has demonstrated clinical benefit in selected patients. ImmunityBio hypothesized rationally-based, thoughtfully-sequenced orchestration of both innate and adaptive immune system responses would elicit anti-tumor efficacy. They further hypothesize that by activating the entire immune system, the immunogenic cell death in this disease will be durable and associated with a low risk of adverse events.

**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 A/S 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; the ability of ImmunityBio, Inc., to obtain regulatory approval for its products that use aldoxorubicin; the ability of ImmunityBio, Inc., to manufacture and commercialize products or therapies that use aldoxorubicin; the amount, if any, of future milestone and royalty payments that we may receive from ImmunityBio, Inc.; 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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