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CytRx Highlights Use of Licensed Drug Aldoxorubicin in ImmunityBio's Expanded Phase 2 Study of Pancreatic Cancer Treatment

Third-Line Cohort Added to Phase 2 Pancreatic Cancer Trial for Combination Immunotherapy That Includes Aldoxorubicin, ImmunityBio's N-803 and NantKwest's PD-L1 t-haNK

Three Trial Sites in California and South Dakota Will Initially Enroll 298 Patients Across the Cohorts, With 40 Patients Already Enrolled or Being Evaluated

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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 highlighted that ImmunityBio, Inc. and NantKwest, Inc. (collectively, the "Companies") have announced the addition of a third cohort to their ongoing Phase 2 study of a novel combination immunotherapy – which includes CytRx's licensed drug aldoxorubicin – for locally advanced or metastatic pancreatic cancer (QUILT-88). According to the Companies, the third cohort will enable pancreatic cancer patients who have failed all approved standards of care to participate in the study.

As previously noted in CytRx's October 7, 2020 press release regarding the reportedly promising treatment delivered to former Senator Harry Reid for his stage IV pancreatic cancer, this randomized, open-label study is evaluating the safety and efficacy of a combination immunotherapy that includes aldoxorubicin, ImmunityBio's IL-15 superagonist Anktiva (N-803), NantKwest's PD-L1 t-haNK, and standard of care. The study results will be compared to standard of care chemotherapy for first- and second-line treatment. However, the third-line cohort is a single arm with no comparator. Each cohort will be evaluated independently to provide more precise comparative data for each disease stage.

Trial Sites and Enrollment

There are presently three trial sites activated: Hoag Memorial Hospital Presbyterian in Orange County, Calif., The Chan Soon-Shiong Institute for Medicine in Los Angeles County, Calif., and Avera McKennan Hospital and University Health Center in Sioux Falls, South Dakota. The latter site will serve patients in the tri-state area (Iowa, Nebraska and South Dakota). Forty patients are currently enrolled in or being evaluated for the trial.

The Companies' combination immunotherapy is designed to harness the body's immune system to target, kill, and "remember" cancer cells. The agents being assessed in the study are designed to find pancreatic cancer cells and initiate a large immune response against them, which may allow the body to develop its own antibodies to fight the cancer.

Study Details

Each treatment setting, as well as each first- and second-line or later maintenance treatment, will be evaluated independently as Cohort A, Cohort B, and Cohort C, respectively, with Cohorts A and B having independent experimental and control arms. The study will initially enroll 298 subjects across all three cohorts. The primary objective of Cohorts A and B is progression-free survival (PFS) and the objective of Cohort C is overall survival (OS) per RECIST V1.1. Secondary objectives include initial safety and additional efficacy measures, including overall response rate (ORR), complete response (CR) rate, durability of response (DoR), disease control rate (DCR), and overall survival (OS).

“Pancreatic cancer is the fourth leading cause of cancer-related deaths in the United States and requires significant advancements in treatment to improve outcomes for patients,” said Steven A. Kriegsman, CytRx’s Chairman and Chief Executive Officer. “We commend the Companies for adding a third cohort and expanding this Phase 2 study of their combination immunotherapy that includes aldoxorubicin. We are encouraged that aldoxorubicin continues to play a role in their mission to recruit and amplify the power of the human body’s own immune system to target and destroy even the most difficult cancer cells.”

CytRx out-licensed global development, manufacturing and commercialization rights for aldoxorubicin to ImmunityBio in 2017. The Company has an agreement with ImmunityBio that can yield up to $343 million in potential milestone payments as well as prospective royalties on sales of aldoxorubicin.

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 most advanced drug conjugate, aldoxorubicin, is an improved version of the widely used anti-cancer drug doxorubicin and has been out-licensed to ImmunityBio, Inc. In addition, CytRx's other drug candidate, arimoclomol, was sold to Orphazyme A/S (Nasdaq Copenhagen exchange: ORPHA.CO) in exchange for milestone payments and royalties. 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). CytRx Corporation’s website is www.cytrx.com.

About Pancreatic Cancer

Pancreatic cancer kills an estimated 47,000 people annually; it is the fourth leading cause of cancer-related death in the U.S., and 57,600 new cases are expected in 2020. Less than 5% of these patients will live for more than five years after diagnosis, and the median survival prognosis is 5 to 8 months. Pancreatic cancer is a disease in which malignant (cancerous) cells form in the tissues of the pancreas. The pancreas is a gland located behind the stomach and in front of the spine. The most common type of pancreatic cancer, adenocarcinoma of the pancreas, starts when exocrine cells in the pancreas start to grow out of control. Most of the pancreas is made up of exocrine cells which form the exocrine glands and ducts. The exocrine glands make pancreatic enzymes that are released into the intestines to help you digest foods (especially fats). The enzymes are released into tiny tubes called ducts which eventually empty into the pancreatic duct. The pancreatic duct merges with the common bile duct (the duct that carries bile from the liver), and empties into the duodenum (the first part of the small intestine) at the ampulla of Vater. Endocrine cells make up a smaller percentage of the cells in the pancreas. These cells make important hormones like insulin and glucagon (which help control blood sugar levels) and release them directly into the blood. Pancreatic neuroendocrine tumors start in the endocrine cells.

About ImmunityBio

ImmunityBio is a privately held immunotherapy company with a broad portfolio of biological molecules at clinical stages of development. ImmunityBio’s goals are to employ this portfolio to activate endogenous Natural Killer (NK) and CD8+ T cells in the fields of cancer and infectious disease. Specifically, in regards to cancer, ImmunityBio’s goal is to develop a memory T-cell cancer vaccine to combat multiple tumor types—without the use of high-dose chemotherapy. Regarding infectious disease, ImmunityBio is addressing HIV, influenza, and the coronavirus SARS-CoV-2.

ImmunityBio’s first-in-human platform of technologies has enabled it to achieve one of the most comprehensive, late-stage clinical pipelines, activating both the innate (natural killer cell) and the adaptive immune systems. The product pipeline includes an albumin-linked chemotherapeutic (Aldoxorubicin), a novel IL-15 cytokine superagonist (N-803), checkpoint

inhibitors, macrophage polarizing peptides, bi-specific fusion proteins targeting TGFb and IL-12, adenovirus, and yeast vaccine therapies targeting tumor-associated antigens and neoepitopes.

In December 2019, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to N-803 for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC). Other indications currently at registration-stage trials include BCG-unresponsive papillary bladder cancer, first- and second-line lung cancer, and metastatic pancreatic cancer.

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 and lysosomal dysfunction. 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.

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 NantKwest and ImmunityBio to obtain regulatory approval for its products that use aldoxorubicin; the ability of NantKwest and ImmunityBio 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; the results of future studies and trials of cancer treatments and therapies that include aldoxorubicin, including combination immunotherapies; 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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