

# CytRx Highlights ImmunityBio's Completion of Enrollment in Phase 2 Study of Advanced Metastatic Pancreatic Cancer Treatment

*Highlights Early Efficacy of CytRx's Licensed Drug Aldoxorubicin in ImmunityBio's Phase 2 Trial of Nant Cancer Vaccine for Third Line or Greater Pancreatic Cancer Patients*

*Notes 90% of All Evaluable Patients and 87% of Patients With Extremely Advanced Disease Upon Enrollment Have Exceeded the Historical Survival Rates to Date*

*Indicates Mature Data Is Expected in Q1 2022*

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 ImmunityBio, Inc.'s (NASDAQ: IBRX) (“ImmunityBio”) [announced completion of enrollment](#) in its Phase 2 trial studying a combination immunotherapy (Nant Cancer Vaccine) – which includes aldoxorubicin – in advanced metastatic pancreatic cancer.

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.

According to ImmunityBio, the majority of participants in the study to date remain on therapy and 90% (43/48) of the evaluable patients have exceeded the approximately two-month historical survival rate. Of the 48 evaluable patients, 23 (48%) had extremely advanced disease upon enrollment (i.e. had progressed after three to six prior lines of therapy) and, of these patients, 20 out of 23 (87%) have exceeded historical survival rates. On the strength of this early data and significant unmet medical need, ImmunityBio has submitted an amendment to increase enrollment in Cohort C.

Patrick Soon-Shiong, M.D., Founder and Global Chief Scientific and Medical Officer of ImmunityBio, commented:

“Patients with advanced metastatic pancreatic cancer who have failed all standards of care have very grave prognoses with few treatment options. This study was to explore if the Nant Cancer Vaccine could address this unmet need. It is gratifying to note that patients in this study, who had progressed after up to six lines of prior therapy, have exceeded historical survival rates despite having very advanced pancreatic cancer upon enrollment. Achieving robust enrollment in this patient group and early promising efficacy evidence are important milestones in ImmunityBio’s effort to develop this therapeutic with the potential to improve survival rates and provide a replacement for toxic chemotherapy. As the historical survival rate for third- to sixth-line pancreatic cancer patients is approximately two months, we are encouraged by this early data and have decided to open this cohort to more patients with advanced metastatic disease who have no further treatment options.”

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

"With each of our licensing agreements, CytRx's primary goal is to put greater energy and resources behind innovative clinical programs working to combat cancer and rare diseases. We are highly encouraged by ImmunityBio's milestone achievement of robust enrollment in its QUILT-88 study and early evidence of promising efficacy of the Nant Cancer Vaccine, which includes our licensed aldoxorubicin drug, to treat severe cases of pancreatic cancer. We look forward to continuing to monitor the trial's progress when mature data is released in Q1 2022, ahead of ImmunityBio's plans to meet with the U.S. Food and Drug Administration in 2022 to discuss the path for the approval of combination therapies for pancreatic cancer."

## **QUILT-88 Study Details**

This Phase 2, randomized, three-cohort, open-label study will evaluate the comparative efficacy and overall safety of standard-of-care chemotherapy versus standard-of-care chemotherapy, in combination with PD-L1 t-haNK, Anktiva (N-803), and aldoxorubicin in subjects with locally advanced or metastatic pancreatic cancer (NCT04390399). Each treatment setting, as well as each first- and second-line or later maintenance treatment, will be evaluated independently as Cohorts A, B, and 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) per RECIST V1.1, and the objective of Cohort C is overall survival (OS). 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).

Currently, three trial sites have been 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, which serves patients in the tri-state area (Iowa, Nebraska and South Dakota).

## **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 recent 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 drug candidate, arimoclomol, was sold to Orphazyme A/S in exchange for milestone payments and royalties. Orphazyme is developing arimoclomol in two indications, including Niemann-Pick disease Type C (NPC), and Gaucher disease. CytRx Corporation's website is [www.cytrx.com](http://www.cytrx.com).

## **About ImmunityBio**

ImmunityBio is a leading late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio has a comprehensive immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated)—of which 25 are at Phase II and III stages of development—across 19 indications in solid and liquid cancers and infectious diseases. Currently 17 first-in-human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. Anktiva™ (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC).

The company's platforms are based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform.

ImmunityBio is a leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical

trial, and regulatory operations and development teams. For more information, please visit: [www.immunitybio.com](http://www.immunitybio.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, including risks and uncertainties relating to the ability of ImmunityBio, to obtain regulatory approval for its products that use aldoxorubicin; the ability of 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; and other risks and uncertainties described in the most recent annual and quarterly reports filed by the Company with the Securities and Exchange Commission (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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