# CytRx Comments on Fiscal Year 2020 Results and Highlights Strategic Progress

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 commented on its results for the fourth quarter and fiscal year ended December 31, 2020. In addition, CytRx highlighted developments pertaining to its licensing agreements with ImmunityBio, Inc. (NASDAQ: IBRX) (“ImmunityBio”) and Orphazyme A/S (NASDAQ: ORPH) ("Orphazyme") as well as Centurion Biopharma. The Company’s 10-K has been filed with the U.S. Securities and Exchange Commission.

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

"The past year was a transformative one for CytRx. We executed a strategic pivot that has positioned us to cut corporate costs, maintain a stable capital position, and nimbly manage our portfolio of licensing agreements and strategic assets. Our Board of Directors also took concrete steps to strengthen the Company’s corporate governance, including commencing a search for a new independent director with strong biotechnology experience. We are very excited about the year ahead now that Orphazyme is preparing for prospective regulatory approvals for arimoclomol in the treatment of Niemann-Pick disease Type C and ImmunityBio is expanding its scope of clinical trials involving aldoxorubicin to treat advanced-stage pancreatic cancer. In our view, CytRx has achieved robust momentum and operating tailwinds as fiscal year 2021 begins.”

**Fiscal Year 2020 Financial Overview**

- CytRx concluded the fiscal year ended December 31, 2020 with cash on hand of approximately $10 million, which management believes is sufficient to fund ongoing operations for the foreseeable future.

- The Company recorded a net loss of $6.7 million for the fiscal year ended December 31, 2020, compared to a net loss of $7.2 million for the fiscal year ended December 31, 2019.

    - General and administrative expenses were $6 million for the fiscal year 2020, compared with $7.4 million in 2019. This sizable decrease was primarily due to a reduction in stock-based compensation expenses.

    - Research and development expenses were $0.8 million for the fiscal year, compared with $0.4 million for 2019. This was due to increased consulting expenditures related to the establishment of a regulatory plan and new strategic initiatives for Centurion Biopharma’s assets.

- Based on a current projection of expenditures for fiscal year 2021, the Company’s monthly cash burn rate is estimated to be approximately $406,000 per month. This twelve-month estimate is down from a previous projection of approximately $423,000 per month at the close of the third quarter of fiscal year 2020.

**Fiscal Year 2020 Highlights**

***Orphazyme Highlights***

- As previously disclosed, CytRx’s agreement with Orphazyme can deliver up to $120 million in potential milestone payments and future single- and double-digit royalties paid on sales of arimoclomol.

- CytRx is positioned to receive up to $10 million in potential milestone payments in 2021 based on possible U.S. and European approvals for arimoclomol to treat Niemann-Pick disease Type C ("NPC").

- In September 2020, Orphazyme announced that the U.S. Food and Drug Administration ("FDA") accepted, with Priority Review, its New Drug Application ("NDA") for arimoclomol for the treatment of NPC.

- In November 2020, Orphazyme announced that it submitted a Marketing Authorisation Application ("MAA") to the European Medicines Agency ("EMA") for approval of arimoclomol in the treatment of NPC.

- In early December 2020, Orphazyme announced the expansion of its U.S. presence and workforce ahead of potential FDA approval of arimoclomol in the treatment of NPC.

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

- In late December 2020, Orphazyme disclosed that the FDA extended its review period with a standard extension of three months in order to complete its NDA review. The updated Prescription Drug User Fee Act ("PDUFA") target action date is June 17, 2021.

- Recently, Orphazyme announced the appointment of Christophe Bourdon as its new Chief Executive Officer, effective as of April 1, 2021.

    - As reported by Orphazyme, Mr. Bourdon has successfully launched a variety of products in demanding environments, making him an ideal individual to lead Orphazyme as it prepares for a potential commercial launch of arimoclomol.

    - He joins from Amgen, Inc., where he has held the role of Senior Vice President, General Manager for the U.S. Oncology Business. He was leading commercialization planning and execution for several products.

    - Previously, Mr. Bourdon was Senior Vice President of Europe, Middle East, Africa and Canada at Alexion Pharmaceuticals Inc. as the company launched two breakthrough ultra-orphan drugs and negotiated payor access across the United Kingdom, Germany, France, Italy and Canada. He holds an MBA from IMD business school (Switzerland) and a BA from ISG (France).

- Recently, Orphazyme also announced MIPLYFFA as the global brand name for arimoclomol and expanded its NPC Early Access Program in the U.S. and opened similar programs in France and Germany.

***ImmunityBio Highlights***

- As previously disclosed, CytRx's agreement with ImmunityBio can deliver up to $343 million in potential milestones and future single- and double-digit royalties paid on sales of aldoxorubicin's use for multiple tumor types.

- This past summer, the Chief Executive Officer of ImmunityBio spoke about the successful experimental treatment delivered to former Senate Majority Leader Harry Reid for his stage IV pancreatic cancer. Former Nevada Senator Reid has described himself as being in "complete remission" after receiving experimental combination immunotherapy that included aldoxorubicin.

- In October 2020, ImmunityBio and NantKwest, Inc. ("NantKwest") announced the addition of a third cohort to their ongoing Phase 2 study of a novel combination immunotherapy, which includes aldoxorubicin, for locally advanced or metastatic pancreatic cancer (QUILT-88). The third cohort will enable pancreatic cancer patients who have failed all approved standards of care to participate in the study.

- In December 2020, ImmunityBio and NantKwest announced their proposed merger and plans to create a leading immunotherapy and cell therapy company.

    - In their announcement, the companies noted the combination of ImmunityBio's immunotherapy platforms – including aldoxorubicin – and NantKwest's Natural Killer cell platform have already resulted in complete responses in aggressive and late-stage metastatic cancers.

- In January 2021, ImmunityBio and NantKwest announced that their ongoing Phase 2 clinical trials of a novel combination immunotherapy – which includes aldoxorubicin – for locally advanced or metastatic pancreatic cancer had produced early indications of increased survival rates for patients with no other approved treatment options.

    - Interim results of the three-cohort trials, known as QUILT 88, showed median survival rates of more than double that of the historic rate in patients with advanced metastatic pancreatic cancer (for which no other FDA approved treatment exists).

- Recently, ImmunityBio and NantKwest announced the closing of their merger, with ImmunityBio now trading on the NASDAQ under ticker symbol IBRX.

***Additional Corporate Highlights***

- In August 2020, CytRx announced its plan to add a new independent member to its Board of Directors by no later than the one-year anniversary of the 2020 Annual Meeting of Shareholders. The Company has retained a leading recruitment firm to support the search process.

- Throughout 2020, Mr. Kriegsman and Lead Director Louis Ignarro, PhD have pursued third-party financing and strategic partnership opportunities to advance pre-clinical and clinical studies for Centurion BioPharma's high-potential assets.

    - Discussions with prospective partners and investors remain ongoing. There are no formal strategic financing updates to report at this time.

- As of December 31, 2020, CytRx maintained federal and state net operating loss carryforwards – not subject to limitation under Section 382 of the Internal Revenue Code – of $258.3 million and $252.7 million, respectively, available to offset against future taxable income.

- In February 2021, CytRx announced that it is now a part of the LD Micro Index (the "Index").

    - The Index is designed to give the most accurate representation of the intraday activity of microcap stocks in North America.

- In March 2021, CytRx participated in the H.C. Wainwright Global Life Sciences Conference and the Virtual 33rd Annual ROTH Conference.

    - Mr. Kriegsman's virtual presentation may be accessed on the News and Events page of the CytRx website.

**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 four indications including amyotrophic lateral sclerosis ("ALS"), Niemann-Pick disease Type C ("NPC"), Gaucher disease and Inclusion Body Myositis ("IBM"). CytRx Corporation's website is www.cytrx.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 Orphazyme to obtain regulatory approval for, manufacture and commercialize its products and therapies that use arimoclomol; the results of future clinical trials involving arimoclomol; the amount, if any, of future milestone and royalty payments that we may receive from Orphazyme; 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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