Aerpio Provides Second Update on Aadi Bioscience Presentation at the ASCO 2021 Virtual Meeting

June 4, 2021

CINCINNATI, June 04, 2021 (GLOBE NEWSWIRE) -- Aerpio Pharmaceuticals, Inc. (“Aerpio”) (Nasdaq: ARPO) announced that Aadi Bioscience, Inc. (“Aadi”), a privately-held biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today issued a press release disclosing that a poster has been presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting. As previously disclosed, on May 16, 2021, Aerpio entered into an Agreement and Plan of Merger among Aerpio, Aadi, and Aspen Merger Subsidiary, Inc.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 for indications in which Aerpio believes that activation of Tie2 may have therapeutic potential. For more information, please visit www.aerpio.com.

About Aadi Bioscience, Inc. (“Aadi”) and FYARRO™

Aadi’s primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations such as alterations in *TSC1* or *TSC2* genes, where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. Aadi’s product FYARRO ^{TM} (sirolimus albumin-bound nanoparticles for injectable suspension; *nab*-sirolimus; ABI-009) is an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, mTOR target suppression, and enhanced tumor growth suppression over other mTOR inhibitors in preclinical models.[2]

Aadi’s registration trial of FYARRO in advanced malignant PEComa (the AMPECT trial) demonstrated meaningful clinical efficacy in malignant PEComa, a type of cancer with the highest known alteration rate of *TSC1* or *TSC2* genes. In long-term follow-up data presented on the AMPECT study at ASCO 2020[3], an analysis of 31 RECIST-evaluable advanced PEComa patients treated with FYARRO demonstrated a 39% (95% CI: 22%-58%) independently reviewed confirmed overall response rate (ORR) including 1 complete response (CR) and 11 partial responses (PRs). The median duration of response had not yet been reached (range 5.6 to 42.4+ months, with 50% of the responders having a response duration that is 25.8 months or longer) and the majority of the responders were still on treatment. The response rate in the patients with metastatic disease was 46% (12/26, 95% CI: 27%-67%). In the patients with locally advanced, inoperable disease, 2 of 5 (40%) were able to undergo surgery following tumor shrinkage and remained disease-free in excess of 3 years. The median progression-free survival was 8.9 months (95% CI: 5.5 – not reached) and the one-year overall survival rate was 89%. In an exploratory analysis of the subset of patients with *TSC1* or *TSC2* alterations, the independently reviewed response rate was 64% (9/14, 95% CI: 34%-87%). Thirty-four patients were evaluable for safety. Most treatment-related adverse events (TRAEs) were grade 1 or 2. No grade 4 or 5 TRAEs occurred. The most common nonhematologic TRAEs of any grade were mucositis (79%), fatigue (59%), and rash (56%). The most common hematologic TRAEs were anemia (47%) and thrombocytopenia (32%). Noninfectious pneumonitis occurred in 18% of patients and was grade 1 or 2. Two patients stopped therapy due to a TRAE (grade 2 anemia and grade 1 cystitis). Dose reductions occurred in 13/34 (38%) of patients; 11 patients had a dose reduction from 100 mg/m^2 to 75 mg/m^2 and 2 patients had a dose reduction to 56 mg/m^2. FYARRO has received Breakthrough Therapy, Fast-Track and Orphan Designations from the U.S. Food and Drug Administration (FDA). A rolling New Drug Application (NDA) submission was completed in May 2021.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* inactivating alterations, and following discussions with the FDA, Aadi plans to submit an Investigational New Drug application (IND) for a tumor-agnostic registrational trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations and initiate the study by the end of 2021. Aadi also has ongoing studies to evaluate dosing of FYARRO in combination regimens. FYARRO is an investigational drug that has not been approved by the FDA for commercial distribution in the United States. More information is available on the Aadi website at www.aadibio.com.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

Additional Information about the Proposed Transaction for Investors and Shareholders

This communication relates to the proposed transaction involving Aerpio and Aadi and may be deemed to be solicitation material in respect of the proposed transaction. In connection with the proposed transaction between Aerpio and Aadi, Aerpio will file a proxy statement with the Securities and Exchange Commission (“SEC”). This communication is not a substitute for the proxy statement or any other documents that Aerpio may file with the SEC or send to Aerpio shareholders in connection with the proposed transaction. Before making any voting decision, investors and security holders are urged to read the proxy statement and all other relevant documents filed or that will be filed with the SEC in connection with the proposed transaction as they become available because they will contain important information about the proposed transaction and related matters.

Investors and security holders may obtain free copies of the proxy statement and all other documents filed or that will be filed with the SEC regarding the proposed transaction at the website maintained by the SEC at www.sec.gov. Once filed, the proxy statement will be available free of charge on Aerpio’s website at www.aerpio.com or by contacting Aerpio’s Vice President of Finance by email at gmarek@aerpio.com.

Participants in the Solicitation

Aerpio, Aadi and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Aerpio in connection with the proposed transaction. Information about Aerpio's directors and executive officers is set forth in Aerpio's Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 11, 2021, and in subsequent filings made by Aerpio with the SEC. Other information regarding the interests of such individuals, as well as information regarding Aadi's directors and executive officers and other persons who may be deemed participants in the proposed transaction, will be set forth in the proxy statement and other relevant materials to be filed with the SEC when they become available. You may obtain free copies of these documents as described in the preceding paragraph.

Forward Looking Statements

This communication contains "forward-looking statements" based upon Aerpio's and Aadi's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements about the structure, timing and completion of the proposed transaction; the combined company's listing on Nasdaq after the closing of the proposed transaction; the business of the combined company, including Aadi's product candidates, the development therefor and the therapeutic potential thereof; the proposed PIPE and its terms; the use of proceeds from the proposed PIPE; Aerpio's product candidates, including the opportunity for Aerpio shareholders to receive value from such assets through the proposed contingent value rights. Actual results and the timing of events may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation: (i) risks associated with Aerpio's ability to obtain the stockholder approval required to consummate the proposed transaction or to complete the PIPE financing, and the timing of the closing of the proposed transaction, including the risks that a condition to closing would not be satisfied within the expected timeframe or at all or that the closing of the proposed transaction, including the PIPE financing, will not occur (ii) the response of Aerpio's stockholders to the proposed transaction; (iii) risks related to Aerpio's ability to manage its operating expenses and its expenses associated with the proposed transaction pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed transaction; (v) the risk that as a result of adjustments to the exchange ratio, Aerpio stockholders and Aadi stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of Aerpio's common stock relative to the exchange ratio; (vii) unexpected costs, charges, expenditures or expenses resulting from the proposed transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed transaction; (ix) Aerpio's ability to retain personnel as a result of the announcement or completion of the proposed transaction; and (x) risks associated with the possible failure to realize certain anticipated benefits of the proposed transaction, including with respect to future financial and operating results and (xi) the risk that any potential payment of proceeds pursuant to the CVR Agreement may not be distributed at all or result in any value to Aerpio stockholders. Actual results and the timing of events may differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in Aerpio's Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 11, 2021 and in other filings that Aerpio makes and will make with the SEC in connection with the proposed transaction, including the Proxy Statement described above under "Additional Information about the Proposed Transaction and Where to Find It." You should not place undue reliance on these forward-looking statements, which apply only as of the date of this communication. Aerpio expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

These forward-looking statements are made as of the date of this press release, and Aerpio assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents Aerpio files with the SEC available at www.sec.gov.

References:

[1] AACR 2019 Abstract: https://cancerres.aacrjournals.org/content/79/13_Supplement/348

[2] ASCO 2020 Abstract: https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.11516?af=R

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