Aadi Bioscience Appoints Brendan Delaney as Chief Operating Officer

September 20, 2021

LOS ANGELES, Sept. 20, 2021 (GLOBE NEWSWIRE) -- Aadi Bioscience, Inc. (“Aadi”) (Nasdaq: AADI), a clinical-stage biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced the appointment of Brendan Delaney to the role of Chief Operating Officer (COO). Brendan has had an established career in oncology-focused commercial leadership roles, launching multiple groundbreaking new products and building effective and cohesive commercial teams. Most recently Brendan was Chief Commercial Officer at Constellation Pharmaceuticals, which was acquired by MorphoSys AG for $1.4 billion prior to a commercial launch of pelabresib a first-in-class BETi inhibitor with blockbuster potential across multiple hematology indications. Prior to this, as Chief Commercial Officer at Immunomedics, Inc. Brendan led the launch of TRODELVY®, the first TROP-2 directed antibody-drug conjugate for the treatment of triple-negative breast cancer which was acquired by Gilead Sciences, Inc. for $21 billion.

“Brendan and I collaborated closely when I was Executive Chairman of Immunomedics to bring TRODELVY to market, and I am delighted to be reunited with Brendan in his new capacity as Aadi becomes a fully integrated biopharmaceutical company,” stated Behzad Aghazadeh, Ph.D., Managing Partner and Portfolio Manager, Avoro Capital and member of Aadi’s Board of Directors. “Brendan has a stellar track record of bringing orphan oncology drugs to market, leading commercial teams at three major oncology companies that have now been acquired. Aside from being an invaluable addition to the Company at this time, Brendan will also establish Aadi’s presence on the East Coast since he is based in the tri-state area.”

“We are delighted that Brendan has accepted the role of COO. His commercial expertise will be critical as we get ready to launch ABI-009 for malignant PEComa and expand our focus to the broader applications of this exciting product,” stated Neil Desai, Chief Executive Officer of Aadi. “In his role as COO we will be able to leverage his extensive leadership experience to build out across various functions in this important growth phase of the Company.”

Mr. Delaney began his career at Bristol-Myers, Genentech and Chiron in roles of increasing responsibility in oncology marketing and strategy, and led global branding, strategy and franchises in Novartis’ oncology division for blockbuster brands. At Immunomedics, Mr. Delaney led the build-out of the marketing, sales, market access and commercial operations teams related to TRODELVY. Prior to his Chief Commercial Officer roles at Constellation and Immunomedics, Mr. Delaney was Vice President, U.S. Commercial Hematology Oncology of Celgene Corporation, prior to its acquisition by Bristol-Myers Squibb in 2019.

Mr. Delaney commented, “I am thrilled to join Aadi at this pivotal time ahead of the November 26, 2021 Prescription Drug User Fee Act (PDUFA) target date of its investigational candidate, ABI-009 for PEComa. I look forward to leveraging my commercialization expertise to bring this promising investigational candidate to market, and to maximize the utility of the *nab*-sirolimus technology platform in tumor agnostic indications – such as in patients with solid tumors harboring *TSC1* or *TSC2* inactivating alterations, for which we plan to initiate a registrational trial by year-end.”

Mr. Delaney has an M.B.A. from the Stern School of Business at New York University and a B.A. in Biology from Rutgers University.

About Aadi Bioscience and FYARRO™

Aadi is a clinical-stage biopharmaceutical company developing precision therapies for genetically-defined cancers. 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 lead product candidate is FYARRO ™ (sirolimus albumin-bound nanoparticles for injectable suspension; *nab*-sirolimus; ABI-009), an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, greater mTOR target suppression, and increased tumor growth inhibition 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[1], a type of cancer with the highest known alteration rate of *TSC1* or *TSC2* genes. 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 for this indication and the FDA accepted the NDA in July 2021 and granted Aadi Priority Review status with a Prescription Drug User Fee Act (“PDUFA”) target action date of November 26, 2021.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* inactivating alterations[3], and following discussions with the FDA, Aadi plans to initiate a tumor-agnostic registrational trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations 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.

Forward-Looking Statements

Aadi Bioscience, Inc. (“Aadi”, “The Company”) cautions you that certain statements included in this press release that are not a description of historical facts are forward-looking statements. These statements are based on Aadi’s current beliefs and expectations. Forward-looking statements include statements regarding: FYARRO, including expectations regarding the clinical responses and safety profile, regulatory approval and commercialization, and the timing of the initiation of additional clinical trials. Actual results could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to Aadi’s ability to obtain, or the timeline to obtain, regulatory approval from the FDA and other regulatory authorities for FYARRO in advanced malignant PEComa; risks related to Aadi’s ability to successfully commercialize, including the timing of a commercial launch of FYARRO in advanced malignant PEComa; uncertainties associated with the clinical development and regulatory approval of FYARRO, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of clinical trials may not be reproduced and do not necessarily predict final results; the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing FYARRO; risks associated with the failure to realize any value from FYARRO in light of inherent risks and difficulties involved in successfully bringing product candidates to market; risks related to Aadi’s estimates regarding future expenses, capital requirements and need for additional financing; and risks related to the impact of the COVID-19 outbreak on Aadi’s operations, the biotechnology industry and the economy generally.

Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" and elsewhere in Aadi’s reports and other documents that Aadi has filed, or will file, with the SEC from time to time and available at www.sec.gov.

All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Aadi undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

FYARRO™ is a trademark of Aadi Bioscience, Inc.

References:

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

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

[3] ASCO 2021 Abstract: https://meetings.asco.org/abstracts-presentations/197602

Contacts

Investors:

Investors:
Irina Koffler
ikoffler@lifesciadvisors.com

Source: Aadi Bioscience