Aadi Bioscience Appoints Loretta Itri as Chief Medical Officer

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LOS ANGELES, Oct. 25, 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 Loretta M. Itri, M.D., FACP®, to the role of Chief Medical Officer (CMO). Dr. Itri’s extensive career spans clinical and regulatory global-leadership roles at both major pharmaceutical and biopharmaceutical companies. Most recently, Dr. Itri was Chief Medical Officer at Immunomedics, Inc, where she oversaw the development program and approval of TRODELVY®, the first TROP-2 directed antibody-drug conjugate for the treatment of unresectable locally advanced or metastatic triple-negative breast and urothelial cancers. Immunomedics was subsequently acquired by Gilead Sciences, Inc.

“We are fortunate at Aadi to be able to tap into the experience of another valued former colleague from Immunomedics,” stated Behzad Aghazadeh, Ph.D., Managing Partner and Portfolio Manager, Avoro Capital and member of Aadi’s Board of Directors. “Loretta’s insight and experience was critical to Immunomedics gaining FDA approval for TRODELVY. I am excited that she will be lending her extensive development experience to Aadi as we advance *nab*-sirolimus (ABI-009) forward.”

“We are thrilled to have Loretta join Aadi as CMO,” stated Neil Desai, Ph.D., Founder, President and Chief Executive Officer of Aadi. “Her deep drug development experience in targeted oncology therapeutics will be crucial as we drive forward our registrational study in *TSC1* and *TSC2* inactivating alterations. Her unparalleled expertise and track record in designing and executing clinical studies will be invaluable as we broaden the applications of our mTOR inhibitor.”

Prior to joining Immunomedics, Dr. Itri was the Executive Vice President of Global Health Sciences and Regulatory Affairs at The Medicines Company (acquired by Novartis) where she oversaw the development and regulatory approval of a variety of products, including the early development of inclisiran, and other cardiovascular drugs and antibiotics. Before that, she was President of Pharmaceutical Development and Chief Medical Officer at Genta, Inc., playing a vital role in the development of diverse therapeutic agents that helped treat conditions such as breast cancer and chronic lymphocytic leukemia.

Dr. Itri has also previously served as Senior Vice President of Medical and Regulatory Affairs at Johnson & Johnson’s Pharmaceutical Research Institute, where she oversaw the development and approval of several therapeutic products, including Procrit, Cladribine, and Tramadol. In addition, she served as Senior Vice President of Clinical Affairs and Chief Medical Officer for Ortho Biotech Inc., where she was responsible for the hematology, oncology and immunology product lines. Dr. Itri began her career at Hoffmann-La Roche, where she served in various positions of increasing responsibility, including most recently as Assistant Vice President of Clinical Development in immunology, virology, hematology, and oncology.

Dr. Itri commented, “I feel fortunate to be joining Aadi at this critical time and ahead of the November 26, 2021 PDUFA target date of its investigational candidate for PEComa. I look forward to leveraging my drug development expertise to further advance and expand the opportunities for ABI-009. I believe that ABI-009 represents both a significant advance for patients with PEComa and potentially also a transformative medicine for patients with solid tumors harboring *TSC1* or *TSC2* inactivating alterations. With an outstanding group of new colleagues at Aadi, I look forward to initiating our registrational trial PRECISION-1 in this population.”

Dr. Itri received her M.D. from New York Medical College, completed her medical residency at SUNY-Stony Brook and her fellowship in medical oncology at Memorial Sloan-Kettering Cancer Center where she was an adjunct attending physician for more than 15 years. Dr. Itri has served as a member of the National Cancer Institute Board of Scientific Counselors in both the Division of Cancer Treatment and the Division of Cancer Prevention and Control. She is the author or co-author of numerous articles in peer-reviewed journals, book chapters and abstracts related to the clinical development of therapeutic agents.

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[1].

Aadi’s registration trial of FYARRO in advanced malignant PEComa (the “AMPECT trial”) demonstrated meaningful clinical efficacy in malignant PEComa[2], 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 or early 2022. 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] AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics 2021 Abstract: https://aadibio.com/wp-content/uploads/2021/10/ABI-009-Poster-091321-Final-Oral.pdf

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

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

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