



Biomica Announces Positive Pre-Clinical Results, Demonstrating Efficacy of BMC128 in Melanoma

Biomica's live biotherapeutic drug candidate, BMC128, significantly increased anti-tumor activity in combination with Immune Checkpoint Inhibitors in Melanoma. First-in-human, proof of concept study expected later this year

Rehovot, Israel – April 13, 2021 – Biomica Ltd., an emerging biopharmaceutical company developing innovative microbiome-based therapeutics and a subsidiary of Evogene Ltd. (NASDAQ: EVGN, TASE: EVGN), today announced additional positive pre-clinical results in its immuno-oncology program demonstrating efficacy of its live biotherapeutic product (LBP) consortium BMC128, this time in melanoma. In these studies, Biomica tested BMC128, which consists of four live bacterial strains, in a mouse model of melanoma.

Dr. Elran Haber, CEO of Biomica, stated: "We are very excited with the results of this study demonstrating the effectiveness of BMC128 in treating additional types of solid cancer tumors. These positive pre-clinical results indicate the potential of BMC128 to become best-in-class in the treatment of solid cancer tumors, and help validate Biomica's computational-based drug design approach. We look forward to providing incremental updates as we work towards a first-in-human, proof of concept clinical trial."

Treatment with BMC128 in combination with Immune Checkpoint Inhibitors (ICI) immunotherapy significantly enhanced anti-tumor activity, resulting in an increased response of melanoma tumors to anti-PD1, as demonstrated in an improved Objective Response Rate (ORR) and Percent Tumor Growth Inhibition (%TGI). The group treated with only anti-PD1 showed no response (ORR = 0%) as measured by the Response Evaluation Criteria in Solid Tumors (RECIST), while the group treated with a combination of BMC128 and anti-PD1 demonstrated a total of 13% response (ORR = 13%). The %TGI was increased by 100% in the BMC128 and anti-PD1 combination treated group compared to the group treated by anti-PD1 alone. Response to BMC128 was correlated with a desired anti-tumor immunological profile. BMC128 changed the course of response to ICI, leading to stimulation of the immune system which shifted cold-tumors into hot-tumors.



These positive results supplement previous pre-clinical data using BMC128 in combination with ICI in a breast cancer mouse model that demonstrated pronounced anti-tumor activity as manifested in an increase of almost 50% in ORR. The current results demonstrate the potential applicability of BMC128 and its relevance to treating multiple types of solid tumors.

Biomica's immuno-oncology program is based on the premise that the gut microbiome affects the efficacy of cancer immunotherapy, specifically that of the ICI involving the blockade of PD-1 or PD-L1 and CTLA-4 as suggested in scientific literature.^{1,2} Fecal microbial transplantation has been recently reported to increase response in patients resistant to immune-checkpoint therapy^{3,4}, however the specific microbial entities driving this response are currently unknown. BMC128 is a rationally-designed microbial consortium identified and selected through a detailed functional microbiome analysis using PRISM, a proprietary high-resolution microbiome analysis platform powered by Evogene's MicroBoost AI platform.

As previously reported, Biomica has initiated scale-up processes and Good Manufacturing Practice (GMP) production of its drug candidate in its immuno-oncology program in preparation for the first-in-human proof-of-concept clinical trial expected later this year.

Mr. Ofer Haviv, Chairman of Biomica and Evogene President & CEO, stated: "We are proud of the results that Biomica reported today. These results support the computational biology capabilities developed by Evogene and Biomica which predicted that the microbes that make up BMC128 can be utilized to improve the efficacy of ICI in solid tumors. We look forward to validating the same computational forecasting capabilities in additional successful programs led by Biomica such as IBD and IBS."

¹ Zitvogel et al. 2018, Science 359 (6382)

² Thompson J, et al. Microbiome & immunotherapy: Antibiotic use is associated with inferior survival for lung cancer patients receiving PD-1 inhibitors. J Thorac Oncol 12(suppl 2):S1998, 2017

³ Baruch E, et al. 2021. Fecal microbiota transplant promotes response in immunotherapy-refractory melanoma patients. Science, 371 (6529)

⁴ Davar D, et al. 2021. Fecal microbiota transplant overcomes resistance to anti-PD-1 therapy in melanoma patients. Science, 371 (6529)



About Biomica Ltd.:

Biomica is an emerging biopharmaceutical company developing innovative microbiome-based therapeutics utilizing a dedicated Computational Predictive Biology platform (CPB), licensed from Evogene. Biomica aims to identify and characterize disease-related microbiome entities and to develop novel therapeutics based on these understandings. The company is focused on the development of therapies for antibiotic resistant bacteria, immuno-oncology, and microbiome-related gastrointestinal (GI) disorders. Biomica is a subsidiary of Evogene Ltd. (NASDAQ: EVGN, TASE: EVGN). For more information, please visit www.biomicamed.com.

About Evogene Ltd.:

Evogene (NASDAQ: EVGN, TASE: EVGN) is a leading computational biology company focused on revolutionizing product discovery and development in multiple life-science based industries, including human health and agriculture, through the use of our broadly applicable Computational Predictive Biology (CPB) platform. The CPB platform, incorporating a deep understanding of biology leveraged through the power of Big Data and Artificial Intelligence, has been designed to computationally discover and uniquely guide the development of life-science products based on microbes, small molecules and genetic elements. Utilizing the CPB platform, Evogene and its subsidiaries are now advancing product pipelines for human microbiome-based therapeutics through Biomica Ltd., medical cannabis through Canonic Ltd., ag-biologicals through Lavie Bio Ltd., ag-chemicals through AgPlenus Ltd., and ag-solutions for castor oil production through Castera Ltd. For more information, please visit www.evogene.com.



Forward Looking Statements

This press release contains “forward-looking statements” relating to future events. These statements may be identified by words such as “may”, “could”, “expects”, “intends”, “anticipates”, “plans”, “believes”, “scheduled”, “estimates” or words of similar meaning. For example, Biomica and Evogene are using forward-looking statements in this press release when they discuss the potential applicability, efficacy and relevance of BMC128 for treating multiple types of solid tumors and the potential of BMC128 to become best-in-class in the treatment of such cancer tumors, and Biomica’s first-in-human proof-of-concept clinical trial expected later during 2021. Such statements are based on current expectations, estimates, projections and assumptions, describe opinions about future events, involve certain risks and uncertainties which are difficult to predict and are not guarantees of future performance. Therefore, actual future results, performance or achievements of Evogene and its subsidiaries may differ materially from what is expressed or implied by such forward-looking statements due to a variety of factors, many of which are beyond the control of Evogene and its subsidiaries, including, without limitation, the global spread of COVID-19, or the Coronavirus, the various restrictions deriving therefrom and those risk factors contained in Evogene’s reports filed with the applicable securities authorities. In addition, Evogene and its subsidiaries rely, and expect to continue to rely, on third parties to conduct certain activities, such as their field-trials and pre-clinical studies, and if these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines (including as a result of the effect of the Coronavirus), Evogene and its subsidiaries may experience significant delays in the conduct of their activities. Evogene and its subsidiaries disclaim any obligation or commitment to update these forward-looking statements to reflect future events or developments or changes in expectations, estimates, projections and assumptions.

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