Applied DNA and EvviVax Announce Publication of Positive Preclinical Data for LinearDNA™ Platform Approach to Cancer Immunotherapy

- First Published Study Demonstrates LinearDNA Pan-Cancer and Colon Cancer Neoantigen Vaccines -

- LinearDNA Vaccines Elicits Strong Antigen-specific Immune Responses and Significantly Reduces Tumor Growth in Animal Cancer Models -

- Manuscript Summarizing Findings Posted to Preprint Server and Submitted for Peer-Reviewed Publication -

STONY BROOK, N.Y. and ROME, ITALY – February 17, 2022 - Applied DNA Sciences, Inc. (NASDAQ: APDN) (the "Company"), a leader in Polymerase Chain Reaction (PCR)-based DNA manufacturing and nucleic acid-based technologies, and its program development partner, EvviVax, S.R.L. ("Evvivax"), today announced the publication of a manuscript detailing a preclinical study (the "study") showing that LinearDNA™ vaccines used for cancer immunotherapy produced a strong immune and specific antitumoral response in preclinical mouse models. The study investigated the use of the LinearDNA platform to produce DNA vaccines targeting either tumor-associated antigens (TAA) or tumor-specific antigens (TSA or tumor neoantigens). The manuscript, "Linear DNA Amplicons as a Novel Cancer Vaccine Strategy," is published online on the bioRxiv.org preprint server and has been submitted for peer-reviewed publication. LinearDNA is Applied DNA's proprietary, large-scale polymerase chain reaction ("PCR")-based manufacturing platform that allows for the large-scale production of specific DNA sequences.

DNA vaccines that target TAAs hold promise as potential pan-cancer vaccines that, when used in conjunction with existing standards of care, can increase the efficacy of cancer immunotherapies. DNA vaccines targeting TSAs, otherwise known as personalized cancer vaccines, also hold great promise in immunotherapy as they can be customized to induce an immune response only against a patient's tumor, thereby limiting on-target, off-tumor effects.

TAA: TERT Vaccine

One aspect of the study used a DNA vaccine targeting telomerase reverse transcriptase (TERT), a TAA that holds potential as a target for a pan-cancer vaccine. The TERT DNA vaccine was designed by EvviVax and exclusively licensed by the Company for the LinearDNA platform for veterinary applications. In prior clinical trials conducted by EvviVax, a plasmid form of the TERT DNA vaccine administered along with the standard of care chemotherapy was shown to increase the survival of canines with Stage III/IV B cell lymphoma from 37 weeks to 97 weeks. B-cell lymphoma is the most common type of non-Hodgkin lymphoma in canines[1], with lymphoma accounting for 15-20% of new cancer diagnoses in canines[2]. For the study, the TERT DNA vaccine was administered to mice in either plasmid DNA or LinearDNA form and the immune response studied and compared. The study's results demonstrated that both the plasmid DNA and LinearDNA forms of the TERT DNA vaccine induced comparable immune responses in mouse models.

TSA/Neoantigens Vaccine

The second aspect of the study utilized a personalized DNA vaccine specifically targeting several TSAs expressed in a colon cancer mouse model. Personalized cancer vaccines hold great promise in immunotherapy as they can be customized to induce an immune response only against a specific patient's tumor, thereby limiting off-tumor effects and increasing efficacy and therapeutic index. In the study, LinearDNA and plasmid DNA forms of the personalized cancer vaccine were administered to mice in the colon cancer model. For both forms of the DNA vaccine, several cohorts also received immune checkpoint inhibitors (ICI) based on anti-CTLA-4 and/or anti-PD1. The study demonstrated that the LinearDNA personalized vaccine produced an equal or greater immune and antitumoral response than the plasmid form of the same DNA vaccine, particularly when coupled with ICI.

Dr. James A. Hayward, president and CEO of Applied DNA, stated, "The study demonstrates that LinearDNA and plasmid DNA can elicit a comparable immune response in animal cancer models. We believe this study validates the use of LinearDNA as a more cost- and time-efficient alternative to plasmid DNA for DNA-based cancer vaccines. Cancer immunotherapy is relevant to veterinary and human markets; the latter is expected to reach $169 billion by 2028[3]. As the exclusive licensee of the TERT DNA vaccine for veterinary applications, we believe these data support further investigation of the LinearDNA vaccine as a potential veterinary cancer immunotherapy and, beyond that, for human cancer immunotherapy."

[1] https://www.ctsaonehealthalliance.org/research/animal-disease-models/diffuse-large-b-cell-lymphoma#:~:text=Diffuse%20large%20B%2Dcell%20lymphoma%20(DLBCL)%20is%20a%20hematopoietic,15%2D30%20per%20100%2C000%20dogs.

[2] https://vcahospitals.com/know-your-pet/lymphoma-in-dogs

[3] https://www.biospace.com/article/cancer-immunotherapy-market-size-to-reach-usd-168-48-billion-by-2028-reports-and-data/

Dr. Luigi Aurisicchio, CEO and chief scientific officer of Evvivax S.R.L., commented, “We believe that DNA vaccines for cancer hold immense promise for both human and veterinary applications. One obstacle to DNA vaccine manufacturing is their current production as plasmid DNA. We believe that the completely cell-free LinearDNA platform avoids the numerous pitfalls of plasmid DNA-based production, making it ideal for DNA vaccine manufacturing broadly, and in cancer immunotherapy, specifically.”

About Applied DNA Sciences

Applied DNA is commercializing LinearDNA™, its proprietary, large-scale polymerase chain reaction ("PCR")-based manufacturing platform that allows for the large-scale production of specific DNA sequences.

The LinearDNA platform has utility in the nucleic acid-based *in vitro* diagnostics and preclinical nucleic acid-based drug development and manufacturing market. The platform is used to manufacture DNA for customers as components of *in vitro* diagnostic tests and for preclinical nucleic acid-based drug development in the fields of adoptive cell therapies (CAR T and TCR therapies), DNA vaccines (anti-viral and cancer), RNA therapies, clustered regularly interspaced short palindromic repeats (CRISPR) based therapies, and gene therapies.

The LinearDNA platform also has non-biologic applications, such as supply chain security, anti-counterfeiting and anti-theft technology. Key end-markets include textiles, pharmaceuticals and nutraceuticals, and cannabis, among others.

Leveraging its deep expertise in nucleic acid-based technologies, the Company has also established safeCircle™, a high-throughput turnkey solution for population-scale COVID-19 testing. safeCircle is designed to look for infection within defined populations or communities utilizing high throughput testing methodologies that increase testing efficiencies and provide for rapid turn-around-times.

Visit adnas.com for more information. Follow us on Twitter and LinkedIn. Join our mailing list.

The Company's common stock is listed on NASDAQ under ticker symbol 'APDN,' and its publicly traded warrants are listed on OTC under ticker symbol 'APPDW.'

Applied DNA is a member of the Russell Microcap® Index.

About Evvivax

Evvivax, whose name is derived from Engineered Veterinary Vectored Immunotherapy and Vaccines, is a spin-off of Takis Biotech (www.takisbiotech.it). Evvivax pursues the discovery and development of innovative Therapeutic Veterinary Cancer Vaccines based on proprietary viral vectors and DNA platform technologies. Evvivax frontline candidates are two therapeutic cancer vaccines for canine tumors: Tel-eVax and Erb-eVax. Evvivax aims at translating scientific breakthrough achievements in Cancer Immunotherapy into marketed innovative products in Veterinary and subsequently in Human Oncology. More recently, Evvivax has moved to developing innovative vaccines against zoonotic diseases, including a vaccine against COVID-19 for pets.

Visit www.evvivax.com for more information.

Forward-Looking Statements

The statements made by Applied DNA in this press release may be "forward-looking" in nature within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Forward-looking statements describe Applied DNA's future plans, projections, strategies and expectations, and are based on assumptions and involve a number of risks and uncertainties, many of which are beyond the control of Applied DNA. Actual results could differ materially from those projected due to, its history of net losses, limited financial resources, limited market acceptance, the uncertainties inherent in research and development, future clinical data and analysis, including whether any of Applied DNA's or its partner's therapeutic candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the U.S. Food and Drug Administration (FDA), United State Department of Agriculture (USDA) or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final or conditional approval from the FDA, USDA or equivalent foreign regulatory agencies, the unknown outcome of any applications or requests to FDA, USDA or equivalent foreign regulatory agencies, whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials, the unknown ability to manufacture the therapeutic grade DNA in large quantities, the fact that there has never been a commercial drug product utilizing PCR-produced DNA technology approved for therapeutic use, and various other factors detailed from time to time in Applied DNA's SEC reports and filings, including our Annual Report on Form 10-K filed on December 9, 2021, its Quarterly Report on Form 10-Q filed on February 10, 2022 and other reports it files with the SEC, which are available at www.sec.gov. Applied DNA undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date hereof or to reflect the occurrence of unanticipated events, unless otherwise required by law.

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