Applied DNA and Evvivax Initiate Phase I of Clinical Trial to Evaluate LinearDNA™ COVID-19 Vaccine Candidate for Feline Veterinary Market

- Vaccine Candidate Previously Demonstrated Antibodies and T-cell Response in Mouse Models -

- Clinical Trial to Serve as Initial Validation of LinearDNA Platform in Large Mammals with Potential Advantages in Manufacturing, Storage, and Distribution over Other Vaccines -

STONY BROOK, N.Y. and ROME, ITALY – March 2, 2021 - Applied DNA Sciences, Inc. (NASDAQ: APDN) (the "Company"), a leader in Polymerase Chain Reaction (PCR)-based DNA manufacturing, and its program development partner, Evvivax, S.R.L. ("Evvivax"), today announced the initiation of Phase I of a two-phase clinical trial to evaluate a LinearDNA™ COVID-19 vaccine candidate for the feline veterinary market. The goal of the trial is to evaluate the vaccine candidate as a strategy for the prevention of SARS-CoV-2, the virus that causes COVID-19, in feline companions of humans that may mitigate the animals as a potential reservoir for infections in humans. If successful, the clinical trial will also serve as an important initial validation of LinearDNA, Applied DNA's large-scale, PCR-based manufacturing platform, for vaccines.

The clinical trial utilizes a PCR-produced LinearDNA COVID-19 vaccine candidate initially developed by Applied DNA and Takis Biotech, the parent company of Evvivax, for human use. The human vaccine candidate yielded strong antibody and T-cell responses at low doses of LinearDNA in mouse models. If the veterinary vaccine candidate demonstrates effectiveness against active disease in cats, the two companies intend to apply for a USDA Animal and Plant Health Inspection Service (APHIS) conditional license (9 CFR 102.6) to enable commercial veterinary sales for domestic felines. The American Veterinary Medical Association lists approximately 58.4 million cats living in households in the United States in 2018[1].

Phase I initiation follows the completion of a second and final round of preclinical testing overseen by Evvivax at an independent third-party testing laboratory on a lyophilized (freeze-dried) form of the vaccine candidate administered in the clinical trial. Phase I is being conducted in Brewster, N.Y. by Veterinary Oncology Services at Guardian Veterinary Specialists (GVS), a multi-specialty veterinary hospital, with a primary endpoint of demonstrating the safety and immunogenicity (detection of neutralizing antibodies and T-cell response) of the vaccine candidate in negative, client-owned felines.

On the assumption that the Phase I endpoint is met, Applied DNA and Evvivax are expected to initiate Phase II that will involve the placement of seroconverted vaccinated non-client-owned cats among infected cats, with the primary endpoint being the percent of vaccinated cats that resist infection. On the assumption that primary endpoints of the two Phases of the clinical trial are met, Applied DNA and Evvivax are expected to apply for APHIS conditional license.

“The start of our veterinary clinical trial puts us on a path to potential future commercial sales of our vaccine candidate while also serving a significant step in the positioning and validation of DNA produced on our LinearDNA manufacturing platform as an alternative to plasmid-produced DNA,” said Dr. James A. Hayward, president and CEO, Applied DNA. “Perhaps our greatest concern should be that the SARS-CoV-2 virus can mutate within an animal population before jumping back to people, possibly in a form that renders current vaccines less effective or makes the virus more transmissible. We hope that a safe and effective LinearDNA COVID-19 vaccine can help mitigate this risk as it relates to domestic felines.”

Concluded Dr. Hayward, “We believe that our LinearDNA platform has certain advantages over existing nucleic acid-based vaccines such as the speed and simplicity of production, the potential of high levels of expression, the simplicity of design, and stability during shipment without the need for refrigeration. Beyond vaccines, we believe our platform applies to a host of other cutting edge therapeutic modalities, including CAR T, mRNA, and AAV.”

Dr. Luigi Aurisicchio, chief executive officer and chief scientific officer, Evvivax and Takis Biotech, commented, “It is of concern when you have a disease that can go from people to animals and then back to people again. This has recently happened with minks, who are highly susceptible to the infection and with serious consequences to their health. Domestic felines are a known COVID-19 reservoir and can transmit the virus to other felines. This clinical trial will help us determine an efficacious path forward while expanding the genetic approach to other zoonotic diseases and cancer vaccines.”

Trial Supervising Investigator and Diplomate of the American College of Veterinary Internal Medicine, Dr. Joseph Impellizeri of GVS, stated, "We are hopeful that the information obtained through this initial trial will create a pathway for better understanding of the feline role for prophylactic immunotherapy against COVID-19."

To learn more about LinearDNA, Applied DNA’s large-scale polymerase chain reaction (PCR)-based manufacturing platform, click: https://www.linearxdna.com/

Footnote:

[1] https://www.avma.org/resources-tools/reports-statistics/us-pet-ownership-statistics

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. Applied DNA has also established a COVID-19 diagnostic and testing offering that is in the early stages of commercialization and is grounded in the Company's deep expertise in DNA.

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.

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.

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 (U.S. FDA), U.S. Department of Agriculture (USDA) or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final approval from the U.S. FDA, USDA or equivalent foreign regulatory agencies, the unknown outcome of any applications or requests to U.S. FDA, USDA or equivalent foreign regulatory agencies, the unknown ability to manufacture the vaccine candidates in large quantities, the fact that the safety and efficacy of the vaccine candidates has not yet been established, the unknown ability of the vaccine candidates to generate revenue or profit for Applied DNA, 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 17, 2020, and Form 10-Q filed on February 11, 2021 and other reports we file 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.

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. Evvivax is currently seeking investors for further expanding the collaboration with ADNAS and other Institutions.

Visit www.evvivax.com for more information.

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