



## **Applied DNA and Takis Biotech/Evvivax to Launch Clinical Trial for Veterinary Use of Linear COVID-19 Vaccine Candidate**

***- Domestic Feline Companion Animals May Serve as Reservoir  
for SARS-CoV-2 Infections in Humans -***

**STONY BROOK, N.Y.** – September 16, 2020 - Applied DNA Sciences, Inc. (NASDAQ: APDN) (“Applied DNA” or the “Company”), a leader in Polymerase Chain Reaction (PCR)-based DNA manufacturing that enables *in vitro* diagnostics, preclinical nucleic acid-based therapeutic drug candidates, supply chain security, anti-counterfeiting and anti-theft technology, today announced that it and Evvivax, S.R.L., a spin-out of Takis Biotech focused on engineered veterinary immunotherapy and vaccines, are expected to initiate a veterinary clinical trial of one of the Company’s five LineaDNA™ vaccine candidates upon approval of the clinical plan by the U.S. Department of Agriculture. The goal of the vaccine trial is to evaluate the vaccine candidate as a strategy for the prevention of SARS-CoV-2 (COVID-19) (a zoonotic disease) infections in companion felines of humans. The clinical trial will seek to understand the immune response in cats by utilizing a vaccination strategy of interest in people that could yield valuable data for both cats and humans.

In addition to curbing feline SARS-CoV-2 infections, the vaccine may have a secondary benefit of preventing transfer of the SARS-CoV-2 virus from cats to their human owners. While no such transfer has been formally documented to date, there is still much that is unknown about the disease and its transmission across species. The vaccine trial also serves the additional purpose of generating data on larger animals required as part of the Company’s preclinical development work on its vaccine candidates for potential human development.

## **Veterinary COVID-19 Trial Design**

The clinical trial is a New York State-based, single-center trial that intends to enroll 30 healthy domestic feline companion animals and follow them for six months. The study will evaluate domestic feline immune response, safety, and tolerability of the LineaDNA vaccine candidate, which will be injection once per month at 1mg/month for the first three months of the trial. Dosing will be administered intramuscularly via gene electrotransfer utilizing electroporation technology. The primary endpoint is to determine evidence of antibody and T-cell response in the companion felines.

The trial will take place at Guardian Veterinary Specialists in Brewster, N.Y., under the supervision of Dr. Joseph Impellizzeri, DVM, DACVIM (O), MRCVS from Veterinary Oncology Services, LLC ([link](#)). Applied DNA and Evvivax will co-sponsor the trial. Applied DNA's participation is approximately \$100,000, and the Company will supply a quantity of the linear DNA vaccine candidate.

## **Rationale for COVID-19 Linear DNA Vaccine Candidate for Veterinary Use**

In an article titled ‘Susceptibility of ferrets, cats, dogs, and other domesticated animals to SARS-coronavirus 2’ published in Science Magazine on May 29, 2020, the authors of the article conducted research that found that “in cats the virus replicated in the nose and throat and caused inflammatory pathology deeper in the respiratory tract, and airborne transmission did occur between pairs of cats”<sup>1</sup>. According to the CDC, roughly 60% of human infectious diseases are zoonotic, such as rabies, Lyme disease, West Nile virus, and MERS, among others. Globally and in the [United States](#), COVID-19 positive cats have been reported in small numbers. The World Organization for Animal Health (OIE) indicates that “infection of animals with COVID-19 virus meets the criteria of an emerging disease<sup>2</sup>.”

Applied DNA’s LineaDNA vaccine candidates for COVID-19 have [previously demonstrated evidence of production of antibody and T-cell responses at low doses of linear DNA in preclinical mouse models](#). The Company believes that linear DNA vaccines have inherent advantages over conventional DNA and RNA vaccines: they contain only the desired therapeutic DNA sequence with reduced risk of antibiotic resistance and genomic integration; they hold the advantages of speed and scalability when manufactured by the Company’s LinearDNA manufacturing platform; they are manufactured at high levels of purity and with very simple means of production; they are much more stable during storage and shipments than RNA-based vaccines which is a practical advantage during a worldwide deployment.

Dr. James A. Hayward, president and CEO of Applied DNA, stated, “Animal health offers an efficient regulatory path with the U.S Department of Agriculture that serves as a second avenue through which to potentially commercialize our linear DNA COVID-19 vaccine development work while having the ancillary benefit of progressing our human related preclinical development work with the data generated from this domestic cat study. Because animals and people can both be affected by this zoonotic virus, and with much of the world’s COVID-19 efforts centered on humans with very little known about its effects on

our closest companions with whom we share our homes, we believe it prudent to pursue this avenue for the therapeutic benefit of animals and humans alike.

“The collaboration between Applied DNA and Takis/Evvivax is a natural outgrowth of cooperation between the companies that has its roots in the field of cancer research with the development of a linear DNA telomerase (anti-cancer) vaccine that was progressed to COVID-19 vaccine development work. We now seek to apply the same linear DNA vaccine candidates, whose results in small animal models echo the effectiveness announced by some of the COVID-19 vaccines already in human trials, to a veterinary vaccine candidate.”

Commenting on the collaboration, Dr. Luigi Aurisicchio, Chief Executive and Scientific Officer of Takis Biotech and Evvivax, said, “The holy grail would be to prevent COVID-19 as opposed to waiting for it to start and then treating it. The implications of success of this cat study would be quite large, both for cats and people.”

<sup>1</sup> <https://science.sciencemag.org/content/sci/368/6494/1016.full.pdf>

<sup>2</sup> <https://www.oie.int/en/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019novel-coronavirus/>

## About Applied DNA Sciences



Applied DNA is a provider of molecular technologies that enable supply chain security, anti-counterfeiting and anti-theft technology, product genotyping and pre-clinical nucleic acid-based therapeutic drug candidates.

Visit [adnas.com](http://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<sup>®</sup> Index.

## About Evvivax S.R.L.



Evvivax, whose name is derived from Engineered Veterinary Vectored Immunotherapy and Vaccines, is a spin-off of Takis Biotech ([www.takisbiotech.it](http://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, Evvix has moved to developing innovative vaccines against zoonotic diseases, including a vaccine against COVID-19 for pets. Evvix is currently seeking investors for further expanding the collaboration with ADNAS and other Institutions.

Visit [www.evvix.com](http://www.evvix.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 the possibility of a failure to make timely payment on its outstanding secured convertible notes and resulting enforcement by noteholders of remedies on collateral which includes substantially all of Applied DNA’s assets, 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 partners vaccine 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), the 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 or licensure from the U.S. FDA, the 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 have 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, the unknown outcome of any applications or requests to U.S. FDA, USDA, or equivalent foreign regulatory agencies, disruptions in the supply of raw materials and supplies, 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 12, 2019 and our subsequent quarterly reports on Form 10-Q filed on February 6, 2020, May 14, 2020 and August 6, 2020, and other reports we file with the SEC, which are available at [www.sec.gov](http://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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