NuGenerex Immuno-Oncology, a Subsidiary of Generex Biotechnology (NGIO) has developed our proprietary, patented Ii-Key immune system activation technology that holds promise for stopping pandemic viral outbreaks like the current SARS-COV-2 coronavirus epidemic in China. NGIO has invested over $50 million in the last 15 years to develop the Ii-Key technology for infectious disease and cancer immunotherapy. Though the current focus of NGIO is on cancer immunotherapy, the company previously maintained a robust research and development effort for potentially pandemic viruses avian flu (H5N1), swine flu (H1N1) and SARS, creating on-demand peptide vaccines that have been extensively studied through human clinical trials. NGIO’s Ii-Key antigenic peptides have been shown to supercharge the immune system up to 100 times more than peptides alone. The activity and safety of Ii Key peptide vaccines has been proven in Phase I and II clinical trials involving over 300 patients or volunteers, so new Ii-Key vaccines should be able to proceed directly to human studies without significant pre-clinical toxicology testing. With human clinical data in hundreds of patients that demonstrate safety and immune system activation against infectious disease and tumor antigens, as well as preclinical in vitro and in vivo studies that prove the mechanism of T-Cell activation, the Ii-Key technology offers a rapid path to human protection from the SARS-COV-2 and COVID-19 epidemic.

NGIO is working with EpiVax to utilize their proprietary computational vaccinology algorithms and databases to guide the rapid development of Ii-Key peptide vaccines to protect against the spread of SARS-COV-2. EpiVax has developed a suite of online computational vaccinology tools for the accelerated design of proteome-derived, epitope-driven vaccines. NGIO and EpiVax are generating new patents and intellectual properties from this collaborative agreement.

**Rapid Path to SARS-COV-2 Vaccine: 3 Months to Human Vaccination**

1. Generex & Epivax have identified SARS-COV-2 amino acid peptides for epitope evaluation
2. Synthesize 2019-nCoV epitope peptides for screening (standard peptide chemistry – 11 - 15 amino acids)
3. Screen common HLA-DR alleles in vitro vs SARS-COV-2 sequences
4. Test chemical linkers with for best fit for Ii-Key (LRMK) hybrid vaccine – optimize for immunogenicity
5. Select Ii-Key Hybrid/2019-nCoV peptides for vaccine evaluation
6. Collect blood samples & isolate PBMCs from 2019-nCoV infected & recovered individuals
7. Test Ii-Key/ SARS-COV-2 hybrid peptide vaccines vs. PBMcs
8. Conduct Elispot analysis to test for IFN-γ expression indicating CD-4 T-cell activation
9. Select active Ii-Key/ SARS-COV-2 hybrid peptide vaccines for human clinical testing
10. Conduct Clinical Trial with Lead Ii-Key/SARS-COV-2 Peptides
    • Evaluate safety & immunogenicity (DTH Assay)
11. Select peptides for Multi-valent Ii-Key/ SARS-COV-2 Peptide Vaccine
12. Commercial Manufacturing & Distribution in 5 to 9 months
II-Key Hybrid Technology for Rapid Response to Pandemics
Many non-cellular vaccines are based on protein and peptide sequences derived from infectious disease agents, including recombinant peptide vaccines for influenza, hepatitis and HPV. II-Key Hybrid vaccines are synthetic, peptide-based agents that are engineered to stimulate strong and specific CD4+ T cell responses. We have published extensively on the development of II-Key peptide vaccines for potentially pandemic viruses such as the H5N1 (avian flu) and H1N1 (swine flu) influenza strains. The advantage of the technology is that synthetic production methods are rapid, cost effective, and scalable, enabling the speedy production of very large batches in a matter of months. The II-Key addition significantly augments MHC Class II loading and presentation by directly charging MHC Class II molecules on the surface of antigen presenting cells, bypassing the usual intracellular processing mechanism. By this means, II-Key hybrids effectively hijack MHC Class II molecules on the surface of any antigen presenting cell to potently activate CD4+ T helper cells in an antigen-specific manner, resulting in stronger cellular and humoral immunity through the interaction of CD4+ cells with CD8+ and B cells, respectively.

Avian (Bird) Flu, Swine Flu & SARS Vaccine Research Program
In the mid-2000’s, NGIO launched a major R&D initiative to combat the SARS virus, which caused significant morbidity and mortality as well as billions in economic losses. At that time, the company identified several promiscuous HLA-DR-restricted SARS epitopes that react with >80% of the tested SARS-recovered immune system cells (PBMCs). As SARS is also a coronavirus the II-Key-SARS vaccine, which can be synthetically manufactured in weeks, may have immunologic reactivity with 2019-nCoV. NGIO can test the II-Key-SARS peptide vaccines for reactivity against the bloods of individuals who have recovered from 2019-nCoV infections. If found to be reactive, an II-Key coronavirus peptide vaccine could be produced in weeks. Also, bird Flu is emerging in Wuhan Provence alongside the coronavirus outbreak. NGIO has Phase I human data in 100 individuals demonstrating the safety and immune system activation by our II-Key-H5N1 peptide vaccine. This vaccine can be made immediately available for large-scale clinical trials in China.

II-Key Partnerships

Generex has a signed contract for the clinical & commercial development of II-Key peptide vaccines with partners in China, and we are seeking government and private partners to develop and distribute the eventual II-Key-SARS-COV-2 peptide vaccine on a global basis.

NGIO has signed a development and commercial licensing agreement with partners in China to develop a vaccine against the SARS-COV-2 coronavirus. The agreement provides exclusive rights to the II-Key- SARS-COV-2 peptide vaccines in China; NGIO retains worldwide rights to the II-Key peptide vaccines.

Shenzhen BioScien Pharmaceuticals. NGIO has a research partnership with Merck to evaluate the II-Key-HER-2/neu peptide vaccine AE37 in combination with Keytruda® for the treatment of triple negative breast cancer. We have also signed a licensing and research agreement with Shenzhen BioScien Pharmaceuticals Co., Ltd. to develop AE37 for prostate cancer in China. Under the terms of the deal, Shenzen is financing and conducting the Phase II trials in the European Union and China, and Phase III trials globally under ICH guidelines, with NuGenerex retaining the rights to all clinical data for regulatory submissions and commercialization in the rest of the world outside China.

Contact Richard Purcell, Executive Vice President R&D rpurcell@nugenerex.com 732-492-1797
**The NuGenerex/EpiVax COVID-19 Response Team**

**Eric von Hofe, PhD**, Chief Scientific Officer at NGIO, has led the Ii-Key development program since its inception. As President of Antigen Express, he oversaw the development of Ii-Key peptide vaccines for cancer and infectious diseases, including SARS, HIV, and Swine and bird flu. Dr. von Hofe has extensive experience with technology development projects, including his previous position at Millennium Pharmaceuticals as Director of Programs & Operations, Discovery Research. He received his Ph.D. from the University of Southern California in Experimental Pathology and was a postdoctoral fellow at both the University of Zurich and Harvard School of Public Health.

**Jason Terrell**, MD, CMO at Generex and NGIO is an expert in cancer diagnostics and oncology research. He is also Assistant Clinical Professor of Oncology, University of Texas at Austin Dell Medical School. Dr. Terrell is a summa cum laude graduate from Hardin-Simmons University with a degree in Biochemistry. He graduated as recipient of the Holland Medal of Honor for the top graduate in the School of Science and Mathematics. Dr. Terrell was honored with the Hardin-Simmons University Outstanding Young Alumni Award and currently serves on the University’s Board of Development. Dr. Terrell attended The University of Texas School of Medicine in Houston and received General Medicine Internship and Pathology Residency training at the Texas Tech University Health Sciences Center.

**Richard Purcell**, EVP R&D at Generex and NGIO has extensive experience in the field of infectious disease and immunology, including his research in the mid-80’s on HIV while at Roche, his clinical strategy consulting work on FluMist influenza vaccine, a clinical data program with Wyeth and the Department of Defense to expand the stockpile of smallpox vaccine following 9/11, and his work with the development of viral vectors and peptide vaccines for cancer therapy.

**Anne DeGroot, MD**, is the CEO and CSO of EpiVax. She is internationally known for her research on the human immune system’s response to vaccines and therapeutics. She graduated from Smith College in 1978 and earned her medical degree at University of Chicago in 1983. After internal medical residency, she obtained advanced training in immunoinformatics and vaccinology with Michael Good, Russell Howard and Jay Berzofsky at the National Institutes of Health, and then returned for a fellowship in ID at New England Medical Center.

**William Martin** is the principal architect and developer of the EpiMatrix System, which powers the computational prediction & discovery of antigenic epitopes for many Class I and Class II HLA alleles. Mr. Martin has worked with Dr. DeGroot since 1998 developing a suite of protocols, ancillary tools and database structures allowing for fast and efficient analysis of input protein sequences for vaccine development. His innovations in computational vaccinology result in new and expanded patent portfolios for EpiVax and their partners.

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**Special Note Regarding Forward-Looking Statements:** Certain statements included or incorporated by reference in this Platform Summary, including information as to the future financial or operating performance of the Company and its drug development programs, constitute forward-looking statements. The words "believe," "expect," "anticipate," "contemplate," "target," "plan," "intend," "continue," "budget," "estimate," "may," "schedule" and similar expressions identify forward-looking statements. Forward-looking statements include, among other things, statements regarding future plans, targets, estimates and assumptions. Forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable by the Company, are inherently subject to significant business, economic and competitive uncertainties and contingencies. Many factors could cause the Company's actual results to differ materially from those expressed or implied in any forward-looking statements made by, or on behalf of, the Company. Due to these various risks and uncertainties, actual events may differ materially from current expectations. Investors are cautioned that forward-looking statements are not guarantees of future performance and, accordingly, investors are cautioned not to put undue reliance on forward-looking statements due to the inherent uncertainty therein. Forward-looking statements are made as of the date of this news release and the Company disclaims any intent or obligation to update publicly such forward-looking statements, whether as a result of new information, future events or results or otherwise.

**Contact** Richard Purcell, Executive Vice President R&D rpurcell@nugenerex.com 732-492-1797