



Vivaldi Biosciences Files Patent Application for Delta-19 Combination Covid-19 + Universal Influenza Vaccine

FORT COLLINS, Colorado and VIENNA, Austria – November 23, 2020 – Vivaldi Biosciences, a clinical-stage biotechnology company developing genetically engineered intranasal vaccines for viral respiratory diseases, today announced it has filed a provisional patent application with the US Patent and Trademark Office for its Delta-19 combination vaccine for protection against SARS-CoV-2 (the virus responsible for Covid-19) and all strains of influenza virus.

Simultaneous circulation of SARS-CoV-2 and influenza is a looming public health threat that could cause numerous hospitalizations and deaths, and impose a huge burden on provision of health care, with severe socioeconomic consequences. Delta-19 is a nasal spray vaccine designed to safely provide protection against both SARS-CoV-2 and influenza. Delta-19 also shows the potential to be the first vaccine to provide universal protection against all influenza A and B virus strains, including drifted seasonal influenza strains and emerging strains with pandemic potential.

“We are developing Delta-19 to provide the unprecedented benefit of protection against both Covid-19 and flu. Our Delta-19 program provides the complete package for accelerated development and commercial-scale GMP manufacture, with our clinically-proven vaccine vector technology, and our rapid, high-yield cell-based vaccine manufacturing system,” said William Wick, Chief Executive Officer of Vivaldi.

Vivaldi’s patent application describes compositions and methods of use of a recombinant influenza virus that is safely attenuated, unable to replicate, and expresses key antigenic proteins of SARS-CoV-2 and influenza viruses. Formulated as a vaccine and administered intranasally, the genetically modified virus is designed to generate a broadly protective immune response against both pathogens. Delta-19 rapidly induces the immune signaling protein interferon and IgA antibodies in the nasal passages to neutralize SARS-CoV-2 and influenza viruses at their main point of entry. Interferon generates a self-adjuvant effect that activates CD4+ and CD8+ T cells and antibody-producing B cells for robust systemic immunity.

“Delta-19 builds on Vivaldi’s clinical-stage Delta NS1 vaccine vector technology platform for broadly protective, self-adjuvanting intranasal vaccines. Delta NS1 is a versatile and robust technology platform. We have shown that the Delta NS1 vaccine vector can stably express high levels of foreign proteins and antigens, enabling development of a broad array of prophylactic vaccines for infectious diseases,” said Thomas Muster, PhD, Chief Scientific Officer of Vivaldi.

John R. Costantino, Chairman of Vivaldi Biosciences remarked, “I am delighted to be associated with Vivaldi’s talented and dedicated scientific team, who moved swiftly to make the important innovations of Delta-19 a reality. The ongoing progress continues to be impressive, and I look forward to the data they are generating on this vaccine.”

The “Twindemic” Threat of Covid-19 and Influenza

Influenza causes seasonal epidemics worldwide, leading to millions of cases and hundreds of thousands of deaths each year. Influenza viruses also cause pandemics when a new virus emerges to which humans lack pre-existing immunity. Vaccines are the primary means of preventing influenza infections and their spread, though the effectiveness of available influenza vaccines is limited.

Scientists predict that SARS-CoV-2 will become endemic and adopt a seasonal pattern of annual epidemics, much like influenza. Co-infection of individuals with both influenza and SARS-CoV-2 has been documented. Infection with one virus may make infection with the second virus more severe. Vivaldi’s Delta-19 nasal spray vaccine is designed to address the dual disease threats of Covid-19 and influenza with a superior approach for greater protection against both diseases.

About Vivaldi Biosciences

Vivaldi Biosciences is developing genetically engineered intranasal vaccines for epidemic and pandemic viral respiratory diseases. The company’s lead vaccine candidates are its Delta-19 combination Covid-19 + universal influenza vaccine, in preclinical development, and its DeltaFLU universal influenza vaccine, in Phase 2 clinical development. Vivaldi’s vaccine candidates are based on the company’s proprietary Delta NS1 vaccine vector technology platform. Delta NS1-based vaccines have the unique ability to induce interferon, a signaling protein in the body that triggers a broad-based response from multiple components of the immune system. Upon intranasal administration of Delta NS1 vaccines, rapid induction of interferon and broadly neutralizing antibodies generates a first line of defense in the nasal passages, the main point of entry of respiratory viral pathogens. The self-adjuvanting effect of interferon also creates a second line of defense, activating cytotoxic T cells and antibody-producing B cells for a broadly protective systemic immune response. Vivaldi has developed and implemented a rapid, high-yield Vero-cell based manufacturing system and produced DeltaFLU under GMP for clinical trials. This manufacturing system is readily applied to production of Delta-19 and other Delta NS1-based vaccines. Vivaldi Biosciences is a venture-backed company with operations at the Research Innovation Center at Colorado State University, Fort Collins, CO and in Vienna, Austria. NGN Capital LLC is the company’s lead investor. Learn more at www.vivaldibiosciences.com, and connect with Vivaldi Biosciences on LinkedIn.

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Forward-Looking Statements

This release contains forward-looking statements relating to Vivaldi Biosciences, which are not historical facts and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements included in this communication concerning activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Our actual results, performance or achievements may differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are based on current expectations and projections about future events and involve known and unknown risks, uncertainties and other factors, including, but not limited to, the following: the uncertainty of clinical success and of obtaining regulatory

approvals, the difficulty of predicting FDA approvals, acceptance and demand for new vaccines and other pharmaceutical products, product efficacy or safety concerns resulting in product recalls or regulatory action, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, availability of additional intellectual property rights, availability of future financing sources, the ability to obtain future funding and to obtain such funding on commercially reasonable terms, the regulatory environment and other risks the Company may identify from time to time in the future. These factors are not necessarily all of the important factors that could cause our actual results, performance or achievements to differ materially from those expressed in or implied by any of our forward-looking statements. These forward-looking statements speak only as of the date of this communication and we undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. This press release should not constitute an offer to sell or a solicitation of an offer to buy securities.