



Vivaldi Biosciences Files PCT Patent Application for Universal Flu and Covid-19 Combination Vaccine

FORT COLLINS, Colorado and VIENNA, Austria – November 29, 2021 – Vivaldi Biosciences, a clinical-stage biotechnology company developing nasal-spray vaccines for viral respiratory diseases, today announced it has filed an international patent application for its combination vaccine for SARS-CoV-2 (the virus responsible for Covid-19) and all strains of influenza virus. The vaccine, based on a recombinant influenza viral vector, generates a multi-pronged immune response to rapidly and simultaneously protect against both diseases. Protection begins immediately through induction of interferon and antibodies in the nasal passages. The self-adjuvant effect of interferon activates T cells and antibody-producing B cells for robust systemic immunity.

Preclinical studies in the ferret model showed that Vivaldi Biosciences' universal flu and Covid-19 combination vaccine, called Delta-19, generated neutralizing antibodies against SARS-CoV-2 and influenza viruses, and protected 100% of the immunized animals against challenge with a wild-type strain of SARS-CoV-2. The immunized ferrets had negligible amounts of SARS-CoV-2 challenge virus in their noses and mouths, while the virus proliferated to high levels in the noses and mouths of control ferrets. These findings suggest the possibility of achieving sterilizing immunity with Delta-19, preventing replication of SARS-CoV-2 and influenza viruses in the upper respiratory tract and transmission to other individuals.

“With these encouraging proof-of-concept results and intellectual property, Vivaldi is positioned to develop the first needle-free vaccine protective against influenza and Covid-19. What’s more, our Delta-19 combination vaccine is not locked into immunizing against a limited set of known seasonal flu strains, but is designed to protect against all flu strains, including new variants that emerge unexpectedly,” said Bill Wick, CEO of Vivaldi Biosciences. “The promise of this combination vaccine is further supported by the fact that we’ve already demonstrated safety and immunogenicity of the influenza vaccine components of Delta-19 in clinical trials.”

The Patent Cooperation Treaty (PCT) application, entitled “Influenza virus encoding a truncated NS1 protein and a SARS-CoV receptor binding domain” builds on Vivaldi’s Delta NS1 technology platform for vaccines that generate immediate and broad protection. Based on genetically modified influenza virus strains, Delta NS1 vaccines are unique in their ability to rapidly induce interferon, a signaling protein in the body that triggers a protective immune response in the nasal passages, the point of entry of respiratory viral pathogens. Interferon also enhances the systemic immune response of B cells and T cells, and achieves a stronger, faster recall response. Vivaldi Biosciences has shown in four Phase 1 and 2 clinical trials that its Delta NS1 vaccines are safe, immunogenic, and generate broadly cross-reactive antibodies to diverse influenza strains.

“This PCT application further strengthens Vivaldi’s growing patent portfolio,” added Vivaldi Sciences’ Wick. “In the last 24 months we’ve filed key patent applications for our DeltaFLU universal influenza vaccine, in Phase 2 development for protection against all influenza A and B viruses, and our high-

efficiency Vero cell vaccine production system, with which we've reached yields of 80%, versus 15-30% yields for live viral vaccine commercial cell culture."

About Vivaldi Biosciences

Vivaldi Biosciences develops genetically engineered intranasal vaccines for epidemic and pandemic viral respiratory diseases. The company's lead vaccine candidates are its DeltaFLU universal influenza vaccine in Phase 2 clinical development, and Delta-19 combination Covid-19 and universal influenza vaccine in preclinical development. Vivaldi Biosciences' vaccine candidates are based on the company's proprietary Delta NS1 technology platform. Delta NS1 is a vaccine vector based on genetically modified, influenza virus strains. Delta NS1 vaccine strains are replication-deficient and unable to form viral progeny, which makes them safe. Vivaldi Biosciences has developed a rapid, high-yield Vero-cell based manufacturing system and produced Delta NS1 vaccines under cGMP for clinical trials. 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

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