



## **Nasal-Spray Combined Vaccine for Covid and Flu Shows Protection**

FORT COLLINS, Colorado and VIENNA, Austria – October 6, 2021 – Vivaldi Biosciences, a clinical-stage biotechnology company developing genetically engineered intranasal vaccines for viral respiratory diseases, today announced positive preclinical data supporting further development of Delta-19, its combination vaccine for protection against COVID-19 and all strains of influenza. SARS-CoV-2, the virus responsible for COVID-19, is expected to become endemic and adopt a seasonal pattern, much like influenza. Delta-19 is designed to address the dual disease threats of Covid-19 and influenza with a superior approach for greater protection against both diseases.

In a small proof-of-concept study in the ferret model, 6 of 8 animals immunized intranasally with Delta-19 generated SARS-CoV-2 spike-specific neutralizing antibodies. All 8 (100%) ferrets immunized with Delta-19, including those without measurable neutralizing antibody titers, were protected against challenge with a wild-type strain of SARS-CoV-2. Importantly, 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 in the upper respiratory tract and transmission to other individuals.

Vivaldi Biosciences already has shown in clinical trials that the influenza vaccine component of Delta-19 is safe, immunogenic, and generates broadly cross-protective antibodies to diverse influenza strains. Delta-19 builds on Vivaldi Biosciences' DeltaFLU universal influenza vaccine, which has been successfully evaluated in four Phase 1 and 2 clinical trials. DeltaFLU shows potential for universal protection against all influenza A and B virus strains, including drifted seasonal influenza strains and emerging pandemic strains.

“With these strong proof of concept data we are ready to advance our Delta-19 program toward clinical trials. We filed a patent application last year, and we are prepared to undertake an accelerated development program, employing our expertise in vaccine strain optimization and cell-based production, and access to BSL-3 facilities for completing our preclinical studies,” said Bill Wick, CEO of Vivaldi Biosciences.

Delta-19 and DeltaFLU are based on Vivaldi Biosciences' Delta NS1 vaccine vector. Delta-19 is a chimeric SARS-CoV-2 Delta NS1 vaccine that expresses key immunogenic antigens of SARS-CoV-2 and influenza viruses. Upon intranasal administration, Delta NS1 vaccines rapidly induce the immune signaling protein interferon and IgA antibodies to neutralize viruses in the nasal passages. Interferon generates a self-adjuvant effect that activates CD4+ and CD8+ T cells and antibody-producing B cells for robust systemic immunity.

Delta-19 may provide important advantages over mRNA vaccines for Covid-19. Unlike mRNA vaccines, which are administered by intramuscular injection, intranasal administration of Delta-19 is needle-free and pain-free. Reactogenicity and side effects of mRNA vaccines may impair patient acceptance. In

contrast, clinical trials Delta NS1 vaccines show only mild side effects in some recipients. The stringent and expensive cold chain requirements of mRNA vaccines will not apply to Delta NS1 vaccines.

### **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 Biosciences' vaccine candidates are based on the company's proprietary Delta NS1 technology platform. Delta NS1 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 point of entry of respiratory viral pathogens. The self-adjuvanting effect of interferon also creates a second line of defense, activating T cells and antibody-producing B cells for a broadly protective systemic immune response. 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](http://www.vivaldibiosciences.com), and connect with Vivaldi Biosciences on LinkedIn.

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### **Forward-Looking Statements**

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