Vivaldi Biosciences Presents Data at the World Vaccine Congress Demonstrating Potential of deltaFLU as Universal Influenza Vaccine

– deltaFLU Outperformed Licensed Vaccine Against Drifted and Shifted Influenza Strains –

FORT COLLINS, Colorado – April 4, 2018 − Vivaldi Biosciences announced that Thomas Muster, PhD, Chief Scientific Officer, will deliver a presentation today on the company's clinical-stage deltaFLU universal influenza vaccine candidate at the World Vaccine Congress in Washington, DC. Dr. Muster will present data from a new nonclinical study showing that deltaFLU provided protection against distantly drifted and shifted influenza strains, while a leading licensed influenza vaccine lacked protection against these unmatched strains.

Currently licensed influenza vaccines generally rely on an antigenic match between vaccine strains and circulating strains for protective efficacy. Mismatches between vaccine and circulating strains frequently occur, reducing vaccine effectiveness. Overall effectiveness of available influenza vaccines typically is just 40-60%. The US Centers for Disease Control and Prevention (CDC) reports overall influenza vaccine effectiveness of 36% for the current flu season, with effectiveness of only 25% for influenza A/H3N2, the strain causing most influenza infections.

Vivaldi's nonclinical study demonstrated that deltaFLU provided protection against influenza A and B strains with significant antigenic differences from the strains comprising the deltaFLU vaccine. In particular, the study showed that a single immunization with deltaFLU containing the 2017-2018 influenza A/H1N1 vaccine strain provided statistically significant measures of protection against an A/H1N1 strain that circulated before the 2009 influenza A/H1N1 pandemic. These data indicate the potential of a single dose of deltaFLU to protect against an antigenically shifted influenza strain. Antigenic shift is an infrequent, abrupt, and major genetic change generating an influenza strain with new viral surface antigens to which most people have no immunity. The 2009 influenza A/H1N1 pandemic was the result of an antigenic shift.

Vivaldi's study evaluated deltaFLU in comparison with a licensed vaccine and placebo in an established model of human influenza infection, the ferret. The deltaFLU vaccine and licensed vaccine contain the three or four influenza vaccine strains, respectively, recommended by the World Health Organization for the current influenza season. Immunized ferrets were challenged by intranasal administration of an influenza A/H1N1, A/H3N2, or B strain that circulated in 2008 and 2009. These challenge strains represent the problems of influenza antigenic shift and antigenic drift for vaccine effectiveness. Drifted strains, the result of mutations in the viral surface antigens, may lead to mismatches and reduced effectiveness of conventional influenza vaccines. The A/H3N2 challenge strain in the study has six antigenic drifts from the A/H3N2 vaccine strain, and the B challenge strain has three antigenic drifts from its vaccine strain counterpart. The A/H1N1 challenge strain is antigenically shifted from the A/H1N1 vaccine strain.

deltaFLU showed protection against all three challenge strains, as indicated by established parameters of influenza infection including fever and shedding of challenge virus. Ferrets immunized with a single dose of deltaFLU had statistically significant reductions in body temperature and titer of shed challenge

virus. Only 2 of the 24 ferrets immunized with deltaFLU and subsequently challenged with 1 of the 3 unmatched strains reached body temperatures indicating moderate fever (40.0-40.4°C). In contrast, the licensed vaccine generally failed to protect immunized and challenged animals from fever. Fourteen of the 24 ferrets immunized with the licensed vaccine exhibited fever (≥40.0°C) after challenge, including 6 ferrets that exhibited severe fever (≥40.5°C).

Lack or reduction of shedding of challenge virus is another measurable indicator of protection against influenza infection. deltaFLU showed greater protection versus the licensed vaccine in evaluations of shedding of the A/H1N1 and B challenge viruses. Moreover, the virus shedding data corroborated the fever data for ferrets in the A/H1N1 and B challenge groups. The A/H3N2 strain was a low-shedding virus in all groups; however, this challenge strain produced fever ≥40.0°C in 7 out of 8 animals in the licensed vaccine group and in only 1 out of 8 animals in the deltaFLU group. Other symptoms of influenza infection, such as sneezing and nasal discharge, were in line with the findings on fever and shedding.

Data from completed clinical and nonclinical studies of deltaFLU demonstrate protective mechanisms against a broad range of influenza A and B strains, and indicate the potential of deltaFLU as a universal influenza vaccine. deltaFLU has been evaluated successfully in Phase 1 and 2 clinical studies and has been shown in humans to be safe and immunogenic. Moreover, in study volunteers deltaFLU has been shown to induce IgA antibodies that cross-neutralize influenza strains with significant antigenic differences from strains in the deltaFLU vaccine. For example, a deltaFLU vaccine strain of subtype A/H1N1 induced human local nasal IgA antibodies that neutralize influenza viruses of the A/H3N2 and A/H5N1 subtypes.

deltaFLU is produced in Vivaldi's high-yield Vero cell production process. Vero cells are an established production substrate for human vaccines. Vivaldi's Vero cell process generally takes approximately 12 weeks from strain selection to product release for clinical use. Traditional egg-based production may take up to 6 months, and may induce antigenic changes that reduce vaccine efficacy.

About Vivaldi Biosciences

Vivaldi Biosciences is developing its deltaFLU influenza vaccine to provide broad protection and superior efficacy in the prophylaxis of seasonal and pandemic influenza. Administered as a nasal spray, deltaFLU generates cross-neutralizing IgA antibodies in the mucous membranes of the nasal passages, forming a first line of defense at the point of entry of circulating viruses. deltaFLU is composed of influenza vaccine strains modified by deletion of the gene for nonstructural protein 1 (NS1). This influenza protein blocks interferon, a key component of the immune system's response to viral infection. Lacking NS1, deltaFLU strains induce high levels of interferon, achieving a natural adjuvant effect that stimulates cell-mediated and antibody-mediated immunity. In contrast, some approaches to developing a universal influenza vaccine require addition of synthetic adjuvants to enhance the immune response. Moreover, deltaFLU immunogenicity and cross-protection do not require sequential or co-administration with a second type of influenza vaccine, as do some universal influenza vaccine strategies focusing on the hemagglutinin "stalk" or other conserved protein domains. Vivaldi Biosciences is based at the Research Innovation Center at Colorado State University and in Vienna, Austria. NGN Capital LLC is the lead investor in Vivaldi Biosciences. Additional information can be found at http://www.vivaldibiosciences.com.

Contact:
Bill Wick, CEO, Vivaldi Biosciences

Tel: +1 650-400-8915
bill.wick@vivaldibiosciences.com

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.