



Vivaldi Biosciences Acquires Clinical-Stage Influenza Vaccine Assets

October 10, 2013

Fort Collins, CO – Vivaldi Biosciences Inc. (Vivaldi), a biotechnology company developing live attenuated influenza vaccines (LAIVs) against pandemic and seasonal influenza, today announced that it has acquired from Baxter Healthcare SA (Glattpark, Switzerland) research and development assets, including intellectual property, clinical data, know-how and materials, for LAIVs in which the gene for influenza nonstructural protein 1 (NS1) has been fully deleted. These assets previously were owned by AVIR Green Hills Biotechnology AG (Vienna, Austria).

NS1 is a multifunctional virulence factor of influenza. The NS1 gene is highly conserved in influenza type A, B and C viruses. LAIVs with fully deleted NS1 (known as delta-NS1 LAIVs) have been evaluated in 160 volunteer recipients in four clinical trials conducted at the Medical University of Vienna by AVIR Green Hills Biotechnology. In a Phase 1 clinical study of a delta-NS1 LAIV for highly pathogenic avian influenza A(H5N1) (“bird flu”), two Phase 1 studies of delta-NS1 LAIVs for seasonal H1N1 influenza strains, and a Phase 1/2 study of a trivalent delta-NS1 LAIV for seasonal influenza, the candidate vaccines were well-tolerated and generated positive immunogenicity data in a dose-dependent manner. The vaccines evaluated in the four clinical studies were produced using Vero cell substrate technologies.

The acquired assets complement and substantially broaden Vivaldi’s LAIV platform and product development opportunities in pandemic preparedness and seasonal influenza. Vivaldi’s platform uses proprietary reverse genetics and plasmid rescue technologies to engineer a specific truncation in the NS1 gene, generating LAIVs with partially-deleted NS1 that are attenuated for safety and provide a potent, protective immune response, including cross-protection against unmatched strains, as demonstrated in preclinical studies.

“Acquisition of these assets catapults Vivaldi into a very favorable position for further advancing in clinical trials multiple NS1 technology based LAIVs to address the most pressing public health issues of influenza: the need for effective protection against emerging pandemic influenza strains, and the need for greater protection of the most vulnerable population groups – seniors and the very young – against seasonal influenza. The considerable achievements by AVIR Green Hills in the development, cell-based manufacture and clinical evaluation of delta-NS1 LAIVs, combined with Vivaldi’s technology platform and programs, give us a range of NS1 technology based approaches for LAIVs for these significant unmet needs,” said Doug Given, MD, PhD, President and CEO of Vivaldi. “The delta-NS1 programs received €20 million in non-dilutive funding from the EU and Austrian government. Having successfully completed Phase 1 studies, under Vivaldi these programs may be eligible for significant levels of additional advanced development funding from government agencies.”

About Vivaldi Biosciences Inc.

Vivaldi Biosciences is developing live attenuated influenza vaccines (LAIVs) with the potential for increased effectiveness in the prevention of emerging pandemic influenza and seasonal influenza. Vivaldi's LAIVs are designed using proprietary reverse genetics and plasmid rescue technologies to truncate the influenza NS1 gene. The unique method of attenuation and mode of action of Vivaldi's LAIVs, demonstrated in preclinical studies, results in potent, protective immunity without viral replication, and without the need for adjuvants. Administered as a nasal spray, Vivaldi's LAIVs stimulate the body's production of interferon, which acts as a natural adjuvant, enhancing antibody production and activating the cellular immune response. This robust immune response has been shown to protect against matched influenza strains and cross-protect against unmatched strains. Vivaldi is headquartered in Fort Collins, CO. The company is privately held. Additional information about Vivaldi can be found at www.vivaldibiosciences.com.

Forward-Looking Statements

This release contains forward-looking statements relating to Vivaldi Biosciences. 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. 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 difficulty of predicting FDA approvals, acceptance and demand for new vaccines and other pharmaceutical products, 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 regulatory environment and other risks the Company may identify from time to time in the future. 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.

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