VGX Pharmaceuticals announces filings of two separate INDs covering novel DNA vaccines: one for the cervical cancer therapy (VGX-3100) and one for avian influenza (VGX-3400)

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VGX Pharmaceuticals announced today that it has submitted two separate investigational new drug (IND) applications to the U.S. Food and Drug Administration (FDA) for Phase I clinical studies of VGX-3100 and VGX-3400. Both candidate vaccines are based on VGX's SynCon™ vaccine technology, and they have been developed using VGX's integrated DNA Vaccines and Therapies Platform.

VGX-3100 is a DNA-based therapeutic vaccine that has the potential to treat cervical cancer caused by the human papilloma virus (HPV). VGX-3100 utilizes synthetic consensus sequences based on HPV antigens that offer coverage across different viral sub-types (types 16 and 18), which could potentially treat 71% of all cervical cancers. Although prophylactic vaccines for HPV, including Merck's Gardasil® and GSK's Cervarix™, have been recently approved, no therapeutic vaccine for HPV has been approved to date. Furthermore, studies suggest that these approved prophylactic vaccines do not have any therapeutic effects in women who are already infected with HPV.

VGX-3400 is a SynCon™ DNA-based preventative vaccine targeting avian influenza (AI). In pre-clinical studies, vaccination with VGX-3400 generated protective levels of hemagglutination inhibition (HAI) titers in 100% of the immunized animals in five separate animal models - mice, ferrets, rabbits, pigs, and rhesus monkeys. Vaccination with VGX-3400 also protected 100% of the animals from an unmatched, pathogenic H5N1 virus challenge in mouse and ferret models. VGX-3400 also induced significant levels of antigen-specific CD8+ killer T cell responses.

"Filing of these INDs with the FDA marks a significant milestone for our Company," stated Dr. J. Joseph Kim, President and Chief Executive Officer. "Using our vertically integrated product development platform, we have taken three independent product programs from 'Bench to IND filing' within 12 months. These accomplishments demonstrate the potential and efficiency of our product development platform."

VGX Pharmaceuticals' SynCon™ DNA vaccine antigens are designed by aligning numerous primary sequences and choosing the most common and/or relevant amino acid at each site using high-powered and patented approaches. The gene sequences are then further optimized for expression and immunogenicity. The SynCon™ DNA vaccines in combination with the CELLECTRA® delivery device provide greater levels of cross-reactive immune responses than those produced by more traditional vaccines. In pre-clinical animal studies, delivery of both VGX-3100 and VGX-3400 was improved with the CELLECTRA® device.

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About VGX Pharmaceuticals

VGX Pharmaceuticals is a biopharmaceutical company with small molecule and biologic product candidates for the treatment of infectious diseases, cancer, and inflammatory diseases. The Company's clinical development programs include PICTOVIR™ for HIV infection, which is in Phase II clinical trials, PENNVAX™-B for HIV infection, which is in 2 separate Phase I clinical trials, and VGX-1027 for inflammatory diseases, which is in Phase I clinical trials. In addition, The Company has filed an IND for VGX-3200, a novel DNA therapy that utilizes GHRH for the treatment of cancer cachexia and anemia. VGX has established a vertically-integrated DNA Vaccines and Therapies Platform with extensive capabilities including SynCon™ DNA-based product candidates, the CELLECTRA® delivery device, and efficient cGMP plasmid manufacturing facilities. The cGMP facilities are used for VGX's own product supplies and for contract manufacturing. Vertical control over key aspects of product development has enabled the Company to consistently develop multiple product candidates, from "bench-to-IND filing", within 1 year. The product candidates and technology programs are protected by the Company's extensive global intellectual property portfolio. More information about VGX can be found at www.vgxp.com.

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