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PHASE III TRIAL FOR IMMUNOTHERAPY OF HIGH-GRADE CERVICAL DYSPLASIA CAUSED BY HUMAN PAPILLOMAVIRUS

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VGX-3100 is an immunotherapy designed using SynCon® approach to treat HPV-16 and HPV-18 infection and pre-cancerous lesions of the cervix (phase 3) and vulva (phase 2). The immunogenicity and efficacy of VGX-3100 is enabled by the CELLECTRA® electroporation delivery system. When VGX-3100 is delivered with the CELLECTRA® device it stimulates a specific immune response to HPV-16 and HPV-18 E6 and E7, to clear the infection and eliminate pre-cancerous cells. In a randomized, double-blind, placebo-controlled phase 2b study in 167 adult women with histologically documented HPV-16/18 cervical HSIL (CIN2/3), treatment with VGX-3100 resulted in a statistically significantly greater decrease in cervical HSIL and clearance of HPV infection vs. placebo. The most common side effect was injection site pain, and no serious adverse events were reported. The VGX-3100 approach which utilizes the patient's own immune system to clear HPV-16 and HPV-18 infection and pre-cancerous lesions without the increased risks associated with surgery, such as loss of reproductive health and negative psychosocial impacts is now being evaluated in a global phase three study. VGX-3100 has the potential to be the first approved treatment for HPV infection of the cervix and the first non-surgical treatment for pre-cancerous cervical lesions.

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