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### VGX-3100 drives regression of HPV16/18 CIN2/3 and robust cellular immune responses in blood and cervical tissue in a blinded, randomized, placebo controlled phase 2b study

**Objectives:** Assessment of the safety, efficacy and immunogenicity of VGX-3100 in women with biopsy-proven CIN2/3 with HPV16 and or HPV18 infection.

**Methods:** Randomized, placebo controlled, double blind study, stratified by age and severity of CIN, evaluated cervical tissue changes after three 6 mg intramuscular doses of VGX-3100 followed by electroporation with Inovio's CELLECTRA®2000 device at weeks 0, 4 and 12.

**Results:** Among 167 vaccinated women, the study met its primary efficacy endpoint; the percentage of patients who had regression of CIN2/3 to CIN1 or no disease at 6 months post third dose was significantly higher in VGX-3100 recipients compared to placebo ( $p=0.034$ ). VGX-3100 cleared HPV16/18 infection concurrent with regression of CIN2/3 ( $p=0.003$ ). Post-hoc immune analysis revealed significantly elevated immune responses in treated patients who had CIN2/3 regression concurrent with HPV16/18 clearance when compared to those who did not. This included the presence of CD8<sup>+</sup> T cells in the blood exhibiting CD137 expression concurrent with perforin ( $p=0.032$ ) as well as perforin in addition to granzyme A ( $p=0.036$ ) as well as an influx of CD8<sup>+</sup> T cells into cervical tissue ( $p=0.008$ ).

**Conclusion:** The successful phase 2b results represent a significant milestone in the development of active immunotherapies to treat HPV related dysplasia and cancer. The data generated from the trial reveal a significant clinical benefit afforded by treatment with VGX-3100 and underscore the mechanism of action of HPV specific T cells. Thus VGX-3100 has the potential to provide an important alternative or adjunct to surgery in treating CIN 2/3.

### Biography

Mark L Bagarazzi has received his MD degree with honors from UMDNJ: New Jersey Medical School and holds a BS in Electrical Engineering magna cum laude from New Jersey Institute of Technology. He was board certified in both Pediatrics and Pediatric Infectious Diseases and joined Inovio Pharmaceuticals as Chief Medical Officer in 2010 from Merck Research Laboratories where he was responsible for the licensure of RotaTeq™. He was an Assistant Professor of Pediatrics at Drexel College of Medicine, lectures on immunotherapeutics at the Perelman School of Medicine, University of Pennsylvania, USA. He has published dozens of scientific papers in peer reviewed journals.

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