

# **Inovio Receives Milestone Payment from MedImmune for MEDI0457 Checkpoint Inhibitor Combination**

**Inovio Pharmaceuticals, Inc. {NASDAQ: INO}** announced today it has received a milestone payment from MedImmune as MEDI0457 (formerly called INO-3112 which MedImmune in-licensed from Inovio) in combination with durvalumab (MEDI4736) satisfactorily completed the phase 1 safety review portion of the study and has advanced to the phase 2 efficacy stage of the trial.



**Inovio Receives Milestone Payment from MedImmune as MEDI0457 and Checkpoint Inhibitor Combination Trial in Head and Neck Squamous Cell Cancer Advances to Phase 2**

**First efficacy trial to evaluate Inovio's cancer immunotherapy targeting HPV in combination with durvalumab**

PLYMOUTH MEETING, Pa. – January 8, 2018 – **Inovio**

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As part of a \$700 million 2015 license and collaboration agreement, MedImmune, the global biologics research and development arm of AstraZeneca, is evaluating MEDI0457 in combination with durvalumab, its PD-L1 checkpoint inhibitor, in patients with recurrent/metastatic HPV-associated head and neck squamous cancer (HNSCC) in a clinical trial with an estimated enrollment of 50 patients.

Under the 2015 agreement, MedImmune acquired exclusive rights to Inovio's MEDI0457 immunotherapy. MEDI0457 targets cancers caused by human papillomavirus (HPV) types 16 and 18 which are responsible for more than 70 percent of cervical pre-cancers and cancers and are involved in the development of other tumors as well such as HNSCC. Within the broader license and collaboration agreement, MedImmune and Inovio will develop two additional DNA-based cancer therapy products not included in Inovio's current product pipeline, which MedImmune has exclusive rights to develop and commercialize. Inovio will receive development, regulatory and commercialization milestone payments and will be eligible to receive royalties on worldwide net sales for these additional cancer vaccine products.

**Dr. Ildiko Csiki, MD, PhD, Inovio Vice President, Clinical Development** said, *"We are pleased to see this combination study advance to the efficacy portion of the trial. Published preclinical studies suggest that treatment with HPV targeted*

*immunotherapeutic approach in combination with PD-1/PD-L1 inhibition may be synergistic, and potentially increase efficacy of checkpoint inhibitors."*

**Dr. J. Joseph Kim, Inovio's President and Chief Executive Officer, said,** *"Inovio's primary goal is to become the global leader in HPV-related disease treatment. Along with MEDI's development of MEDI0457 for HPV-related cancer, Inovio's VGX-3100, is currently being tested in global phase 3 pivotal trials for cervical pre-cancer as well as a treatment for vulvar and anal pre-cancers caused by HPV. Overall, these products could be well-positioned to comprehensively treat HPV-related diseases across the continuum of HPV infections from pre-cancerous conditions to cancer in both women and men."*

In a phase 1 study of MEDI0457 in 22 HPV-positive patients with HNSCC, Inovio has previously demonstrated that MEDI0457 generated robust antigen-specific CD8+ killer T cell responses in both tumor tissue and peripheral blood. One patient in that trial who initially displayed a slight increase in T cell immune responses developed progressive disease at 11 months into the study and subsequently received a PD-1 checkpoint inhibitor. The patient had a sustained complete response after only four doses of a checkpoint inhibitor, and continues on anti PD-1 therapy with no evidence of disease 18 months after initiation of the checkpoint inhibitor.

**About MEDI0457 and VGX-3100** MEDI0457 (formerly called INO-3112 (VGX-3100, plus IL-12) which MedImmune in-licensed from Inovio) is under evaluation by MedImmune to treat HPV-associated cancers. Inovio is investigating VGX-3100, a DNA-based immunotherapy for the treatment of HPV-16 and HPV-18

infection and pre-cancerous lesions of the cervix (phase 3) and vulva (phase 2). 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. VGX-3100 works by stimulating a specific immune response to HPV-16 and HPV-18, which targets the infection and causes destruction of 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. VGX-3100 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.