NEWS RELEASE

# Inovio Demonstrates 80% 6-Month Progression-Free Survival In Phase 2 Glioblastoma Multiforme (GBM) Study with INO-5401 In Combination with PD-1 Inhibitor Libtayo® (cemiplimab)

11/5/2019

80% of Methylated Patients and 75% of Unmethylated Patients Were Disease Progression-Free at 6 Months

PLYMOUTH MEETING, Pa., Nov. 5, 2019 /PRNewswire/ -- Inovio Pharmaceuticals, Inc. (NASDAQ: INO) announced today positive interim results from Inovio's Phase 2 study (NCT03491683) of newly diagnosed glioblastoma multiforme (GBM) combining Inovio's INO-5401, a T cell-activating immunotherapy encoding for three tumor-associated antigens (hTERT, WT1, and PSMA), and INO-9012, an immune activator encoding IL-12, in combination with Libtayo® (cemiplimab), a PD-1 blocking antibody developed by Regeneron Pharmaceuticals (NASDAQ: REGN) in collaboration with Sanofi. The data will be featured in a late-breaking poster presentation at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting in National Harbor, Maryland, November 6-10.

Key interim data from the 52-patient clinical trial showed that 80% (16 of 20) of MGMT gene promoter methylated patients and 75% (24 of 32) of unmethylated patients were progression-free at six months (PFS6) measured from the time of their first dose, substantially exceeding historical standard-of-care data.

This immunotherapy combination with a PD-1 checkpoint inhibitor also exhibited supportive safety, tolerability, and immunogenicity data and suggested an acceptable safety profile consistent with that of Libtayo and Inovio's platform technology. The majority of patients tested had a T cell immune response to one or more tumor-associated antigens encoded by INO-5401. Immune responses to all three tumor-associated antigens were demonstrated in this study. Inovio plans to report 12- and 18-month overall survival data next year.

Dr. David Reardon, M.D., Coordinating Principal Investigator of the study and the Clinical Director for Neuro-Oncology at the Dana-Farber Cancer Institute, said, "This innovative trial provides promising information that the

combination of INO-5401 plus INO-9012, a T cell-promoting therapy, combined with Libtayo, a checkpoint inhibitor, may provide clinically meaningful benefit in this very difficult to treat disease."

Dr. J. Joseph Kim, Inovio's President & CEO, said, "Our new data demonstrates the potential of our immunotherapies utilizing tumor-associated antigens in cancer treatments. Our goal in this GBM trial is to increase progression-free and overall survival of patients facing a disease where neither the standard of care nor clinical outcomes have significantly advanced in decades. Previously, other checkpoint inhibitor treatment alone in GBM trials did not show any meaningful clinical benefit over standard of care. However, the addition of INO-5401 and its ability to generate antigen-specific T cells demonstrated early efficacy signals in progression-free survival. We look forward to reporting additional data including overall survival at months 12 and 18 from the trial in the coming year."

## Poster Details

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| Poster 858: | An Open-Label, Multi-center Trial of INO-5401 and INO-9012 Delivered by Electroporation (EP) in Combination with Cemiplimab in Subjects with Newly-Diagnosed Glioblastoma (GBM) |
| Category: | Late-Breaker |
| Date/Time: | Friday, Nov. 8th, 12:30 – 2 p.m. and Saturday, Nov. 9th 12:35 – 2:05 p.m. |
| Location: | Displayed in the Potomac Foyer (outside the Plenary session room, Potomac Ballroom) |

## Study Design

The trial was designed to evaluate safety, immunogenicity and preliminary efficacy of INO-5401 and INO-9012 in combination with Libtayo, with radiation and chemotherapy, in subjects with newly-diagnosed glioblastoma (GBM). This is a Phase 1/2, open-label, multi-center trial conducted in 52 evaluable patients with GBM. There were 2 cohorts in this trial. Cohort A were participants with a tumor with an unmethylated O6-methylguanine-deoxyribonucleic acid (DNA) methyltransferase (MGMT) promoter. Cohort B included participants with a tumor with a MGMT methylated promoter or who have indeterminate MGMT status. Both cohorts received INO-5401 and INO-9012 and Libtayo at the same doses and on the same dosing schedule, and both cohorts received radiation and temozolomide (TMZ), if clinically indicated. Interim data presented here and at SITC was obtained as of October 2019 and final study data is expected in Q4 2020. For more information of the clinical study, see **www.clinicaltrials.gov**, identifier NCT03491683.

## About Glioblastoma Multiforme (GBM)

GBM is the most common and aggressive type of brain cancer and remains a devastating disease for both patients and caregivers. Its prognosis is extremely poor, despite a limited number of new therapies approved over the last 10 years. The median overall survival for patients receiving standard of care therapy is approximately 15 months and the median progression-free survival is approximately 7 months. In the U.S., the estimated annual incidence of GBM is 11,362 cases or 3.21 cases per 100,000 persons and the median age at diagnosis is 65 years.

## About INO-5401 and INO-9012

INO-5401 encodes for Inovio's SynCon® antigens for hTERT, WT1, and PSMA, and has the potential to be a powerful cancer immunotherapy in combination with checkpoint inhibitors. The National Cancer Institute previously highlighted hTERT, WT1, and PSMA among a list of important cancer antigens, designating them as high priorities for cancer immunotherapy development. These three antigens were reported to be over-expressed, and often mutated, in a variety of human cancers, and targeting these antigens may prove efficacious in the treatment of patients with cancer. INO-9012 encodes for IL-12, which is a T cell immune activator.

## About Inovio Pharmaceuticals, Inc.

Inovio is an innovative biotechnology company focused on the discovery, development, and commercialization of its synthetic DNA technology targeted against cancers and infectious diseases. Inovio's proprietary technology platform applies antigen sequencing and delivery to enable in vivo protein expression, which can activate potent immune responses to targeted diseases. The technology has been demonstrated to consistently activate robust and fully functional T cell and antibody responses against targeted cancers and pathogens. Inovio's most advanced clinical program, VGX-3100, is in Phase 3 development for the treatment of HPV-related cervical pre-cancer. Also in development are Phase 2 immuno-oncology programs targeting HPV-related cancers and GBM, as well as externally funded platform development programs in Zika, MERS, Lassa, and HIV. Partners and collaborators include ApolloBio Corporation, AstraZeneca, The Bill & Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations (CEPI), Defense Advanced Research Projects Agency, GeneOne Life Science, HIV Vaccines Trial Network, Medical CBRN Defense Consortium (MCDC), National Cancer Institute, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Regeneron, Roche/Genentech, the University of Pennsylvania, Walter Reed Army Institute of Research and The Wistar Institute. For more information, visit **www.inovio.com**.

This press release contains certain forward-looking statements relating to our business, including our plans to develop DNA-based immunotherapies, our expectations regarding our research and development programs, including the planned initiation and conduct of clinical trials and the availability and timing of data from those trials.

Actual events or results may differ from the expectations set forth herein as a result of a number of factors, including uncertainties inherent in pre-clinical studies, clinical trials and product development programs, the availability of funding to support continuing research and studies in an effort to prove safety and efficacy of electroporation technology as a delivery mechanism or develop viable DNA vaccines, our ability to support our pipeline of SynCon® active immunotherapy and vaccine products, the ability of our collaborators to attain development and commercial milestones for products we license and product sales that will enable us to receive future payments and royalties, the adequacy of our capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by us or our collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that we and our collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide us with meaningful protection from others using the covered technologies, whether such proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity and whether we can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of our technology by potential corporate or other partners or collaborators, capital market conditions, the impact of government healthcare proposals and other factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, and other filings we make from time to time with the Securities and Exchange Commission. There can be no assurance that any product candidate in our pipeline will be successfully developed, manufactured or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market products, or that any of the forward-looking information provided herein will be proven accurate. Forward-looking statements speak only as of the date of this release, and we undertake no obligation to update or revise these statements, except as may be required by law.

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