



Regeneron and Inovio Enter Immuno-Oncology Clinical Study Agreement for Glioblastoma Combination Therapy

May 8, 2017

TARRYTOWN, N.Y. and PLYMOUTH MEETING, Pa., May 8, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Inovio Pharmaceuticals, Inc. (NASDAQ: INO) today announced a clinical study agreement for a Phase 1b/2a immuno-oncology trial. The study will be conducted by Inovio in patients with newly-diagnosed glioblastoma multiforme (GBM) and will evaluate Regeneron's PD-1 inhibitor, REGN2810, in combination with Inovio's INO-5401 T cell activating immunotherapy encoding multiple antigens and INO-9012, an immune activator encoding IL-12.

The open-label trial, which is expected to begin later this year, is designed to evaluate the safety and efficacy of the combination therapy in approximately 50 patients. The study will be conducted at 30 U.S. sites and the primary endpoints are safety and tolerability. The study will also evaluate immunological impact, progression-free survival and overall survival.

GBM is a devastating disease for both patients and caregivers. It is the most aggressive brain cancer and its prognosis is extremely poor, despite a limited number of new therapies approved over the last ten years. The median overall survival for patients receiving standard of care therapy is approximately 15 months and the average five-year survival rate is less than three percent.

"The unmet need for effective therapies in GBM remains extremely high. Certain immune checkpoint inhibitors have shown efficacy in certain cancers, but evidence increasingly suggests that the benefit of checkpoint inhibitors can be enhanced when used in combination with therapies that generate T cells," said David Reardon, MD, Clinical Director of the Center for Neuro-Oncology at Dana-Farber Cancer Institute and Professor of Medicine at Harvard Medical School. "Inovio has an innovative immunotherapy platform which has shown the ability to generate antigen-specific T cells in disease areas including cancer. We look forward to exploring the potential of combining a T cell generating immunotherapy encoding multiple antigens with REGN2810, a PD-1 checkpoint inhibitor."

Under the terms of the agreement, the trial will be solely conducted and funded by Inovio, based upon a mutually agreed upon study design, and Regeneron will supply REGN2810. Inovio and Regeneron will jointly conduct immunological analyses in support of the study. Regeneron, in collaboration with Sanofi, is developing REGN2810 both alone and in combination with other therapies for the treatment of various cancers.

"Regeneron's approach to oncology includes evaluating the combination of innovative therapies that act on diverse pathways and targets," said Israel Lowy, MD, PhD, Vice President of Translation Sciences and Oncology, Regeneron. "Using our PD-1 inhibitor as a therapeutic backbone alongside Inovio's T cell-generating therapies offers a new path for exploration and heightens the potential to develop new, desperately-needed treatment options for patients."

"I am a strong believer in this combination regimen approach in immuno-oncology: use Inovio immunotherapies to generate killer T-cells to turn 'cold' tumors into 'hot' tumors, then block T cell suppression via checkpoint inhibition," said J. Joseph Kim, PhD, Inovio's President and Chief Executive Officer. "This step with INO-5401 is very important for us in 2017, as we believe INO-5401 has the potential to be a powerful cancer immunotherapeutic in combination with promising checkpoint inhibitors such as Regeneron's REGN2810, and we look forward to investigating its potential for GBM and multiple other challenging cancers."

About Glioblastoma

Glioblastoma, also known as glioblastoma multiforme (GBM), is the most common and aggressive type of brain cancer. GBM is usually found in the area of the brain which controls some of the most advanced processes such as speech and emotions. GBM treatment is often limited by the tumor location and ability of a patient to tolerate surgery. Consequently, it is a particularly difficult cancer to treat. Worldwide there are an estimated 240,000 cases of brain and nervous system tumors per year; GBM is the most common and most lethal of these tumors.

About INO-5401

INO-5401 includes Inovio's SynCon® antigens for WT1, hTERT and PSMA and has the potential to be a powerful cancer immunotherapy in combination with checkpoint inhibitors. The National Cancer Institute previously highlighted WT1, hTERT and PSMA among a list of attractive cancer antigens, designating them as high priorities for cancer immunotherapy development. WT1 was at the top of the list. The hTERT antigen relates to 85 percent of cancers, and WT1 and PSMA antigens are also widely prevalent in many cancers.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: [REGN](#)) is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL-cholesterol, atopic dermatitis and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, pain, cancer and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow [@Regeneron](#) on Twitter.

About Inovio Pharmaceuticals, Inc.

Inovio is taking immunotherapy to the next level in the fight against cancer and infectious diseases. We are the only immunotherapy company that has reported generating T cells *in vivo* in high quantity that are fully functional and whose killing capacity correlates with relevant clinical outcomes with a favorable safety profile. With an expanding portfolio of immune therapies, the company is advancing a growing preclinical and clinical stage product pipeline. Partners and collaborators include Regeneron, MedImmune, The Wistar Institute, University of Pennsylvania, DARPA, GeneOne Life Science, Plumblin Life Sciences, ApolloBio Corporation, Drexel University, NIH, HIV Vaccines Trial Network, National Cancer Institute, U.S. Military HIV Research Program, and Laval University. For more information, visit www.inovio.com.

Regeneron Forward-Looking Statements and Use of Digital Media

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation Regeneron's immuno-oncology program, REGN2810 (Regeneron's PD-1 inhibitor), and the Phase 1b/2a clinical trial evaluating the combination therapy consisting of REGN2810 and Inovio Pharmaceuticals, Inc.'s T cell activator INO-5401 and immune activator INO-9012 in patients with newly-diagnosed glioblastoma multiforme (the "GBM Combination Therapy"); unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's and its collaborators' product candidates in clinical trials, such as the GBM Combination Therapy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs (such as the trial evaluating the GBM Combination Therapy), and business, including those relating to patient privacy; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labelling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's clinical study agreement with Inovio Pharmaceuticals, Inc. discussed in this news release, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation relating to Praluent[®] (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or commercially manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended March 31, 2017. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

Inovio Forward-Looking Statements

This press release contains certain forward-looking statements relating to our business, including our plans to develop electroporation-based drug and gene delivery technologies and DNA vaccines, our expectations regarding our research and development programs and our capital resources. 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, including the cancer immunotherapy INO-5401, 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 broad 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 the company or its collaborators, including alternatives that may be more efficacious or cost effective than any therapy or treatment that the company and its collaborators hope to develop, issues involving product liability, issues involving patents and whether they or licenses to them will provide the company 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 the company can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of the company's 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, 2016, and other regulatory filings from time to time. There can be no assurance that any product in Inovio's pipeline will be successfully developed or manufactured, that final results of clinical studies will be supportive of regulatory approvals required to market licensed products, or that any of the forward-looking information provided herein will be proven accurate.

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