



Moderna Announces Clinical Updates on Personalized Cancer Vaccine Program

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Interim data from Phase 1 dose expansion cohort of mRNA-4157 in combination with pembrolizumab shared at [The Society for Immunotherapy of Cancer's Annual Meeting 2020](#)

Data support expansion of Head and Neck Squamous Cell Carcinoma (HNSCC) cancer patient cohort

Praveen Aanur, MBBS joins Moderna as Vice President, Therapeutic Area Head for Oncology Development

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 11, 2020-- [Moderna, Inc.](#), (Nasdaq: MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today shared interim data from the expansion cohort of its ongoing Phase 1 study of the Company's mRNA personalized cancer vaccine (PCV) mRNA-4157 in combination with Merck's Keytruda®¹ at The Society for Immunotherapy of Cancer's Annual Meeting (SITC 2020). The dose expansion cohort included 10 patients with HPV(-) Head and Neck Squamous Cell Carcinoma (HNSCC) and 17 patients with Micro-Satellite Stable Colorectal Cancer (MSS-CRC). The data shared today showed that mRNA-4157 given in combination with Keytruda® is well tolerated at all dose levels and produced responses as measured by tumor shrinkage by RECIST 1.1 criteria in HPV(-) HNSCC patients. No responses were observed in the MSS-CRC group of patients.

Tolerability data to date consistently demonstrate that mRNA-4157 is well tolerated. Adverse events are typically low grade and reversible. In the dose expansion cohort, the Overall Response Rate (ORR) in the HPV(-) HNSCC group of patients as measured by RECIST 1.1 is 50% (5/10) with two patients achieving a complete response (CR) with no detectable disease, and three patients achieving partial response (PR), all of which are ongoing. Median progression free survival (mPFS) is 9.8 months, which compares favorably to the published ORR and mPFS of 14.6% and 2.0 months respectively, for Keytruda monotherapy. Including four patients with stable disease, the Disease Control Rate (DCR) is 90% (9/10). Median duration of response has not been reached. The HPV(-) HNSCC cohort continues to recruit and Moderna has decided to expand the size of the current cohort based on the interim data reported today.

Moderna also announced that Dr. Praveen Aanur has joined Moderna as Vice President, Therapeutic Area Head for Oncology Development. Dr. Aanur joins Moderna from Bristol-Myers Squibb (NYSE: BMY) where he was responsible for multiple regulatory submissions across BMS' immuno-oncology portfolio. In his seven years at BMS, Dr. Aanur had a wide range of roles increasing responsibility across Clinical Development and Translational Research. Dr. Aanur started his career as a physician and completed his Hematology-Oncology Fellowship at Oregon Health Sciences University, and a Fellowship in Bone Marrow Transplantation at Memorial Sloan Kettering in New York where he was also a clinical investigator in the Bone Marrow Transplant Unit. He holds an MBBS from Bangalore University, an MPH from the University of Alabama, and an MBA from Columbia University School of Business.

"We are encouraged by these interim data from our personalized cancer vaccine program, which involves designing and manufacturing a unique vaccine for each patient based on their specific tumor," said Stephen Hoge, M.D., President of Moderna. "This study demonstrates the ability of Moderna's mRNA personalized cancer vaccine to elicit clinical activity when given in combination with pembrolizumab. I would also like to welcome Dr. Aanur to Moderna and look forward to working closely with him to continue building our oncology therapeutic area."

About Moderna's Immuno-Oncology Programs

Moderna's oncology programs are currently focused on two main areas: cancer vaccines and intratumoral immuno-oncology (I/O) therapies. Moderna is developing these potential mRNA treatments with strategic collaborators Merck and AstraZeneca. The company currently has five I/O programs in development, including two programs in Phase 2 trials.

An advantage of Moderna's mRNA platform is that it allows for investigational medicines that combine in a single mRNA therapy several different approaches to activate the immune system to attack cancer, either with mRNA encoding for common tumor proteins found across cancer types or multiple mRNAs encoding for various immunomodulatory proteins.

Moderna's investigational PCVs are designed to use neoantigens identified from an individual's tumor to program the body's immune system to elicit a more effective anti-tumor response. Upon sequencing the tumor, Moderna's proprietary algorithms predict the neoantigens (antigens encoded by tumor-specific mutated genes) most likely to trigger the immune system to attack a particular cancer. Today, mRNA encoding up to 34 unique neoantigens can be delivered in a single vaccine. Moderna develops and manufactures these investigational PCVs at its personalized vaccines unit within its Massachusetts manufacturing facility.

About Moderna

Moderna is advancing messenger RNA (mRNA) science to create a new class of transformative medicines for patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane or secreted proteins that can have a therapeutic or preventive benefit and have the potential to address a broad spectrum of diseases. The company's platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, providing Moderna the capability to pursue in parallel a robust pipeline of new development candidates. Moderna is developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases and cardiovascular diseases, independently and with strategic collaborators.

Headquartered in Cambridge, Mass., Moderna currently has strategic alliances for development programs with AstraZeneca PLC and Merck & Co., Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense, and the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Moderna has been named a top biopharmaceutical employer by *Science* for the past six years. To learn more, visit www.modernatx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding: the ability of Moderna's personalized cancer vaccine (mRNA-4157) to elicit a response when given in combination with pembrolizumab, the tolerability of mRNA-4157 in patients, and the potential for mRNA-based therapies to activate the immune system to attack cancer. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: preclinical and clinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to or in the clinic; no commercial product using mRNA technology has been approved and may never be approved; mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with the Company's regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the fact that the rapid response technology in use by Moderna is still being developed and implemented; potential adverse impacts due to the global COVID-19 pandemic such as delays in clinical trials, preclinical work, overall operations, regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

¹ Keytruda® is a registered trademark of Merck & Co., Inc.

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