MediciNova Announces Development Progress on Intranasal Formulation of SARS-CoV-2 Vaccine for COVID-19

September 1, 2020

New information for Spike protein specific antibody response after a single intranasal dose

LA JOLLA, Calif., Sept. 01, 2020 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (NASDAQ:MNOV) and the JASDAQ Market of the Tokyo Stock Exchange (Code Number: 4875), today announced development progress on its intranasal SARS-CoV-2 vaccine for COVID-19 utilizing BC-PIV, a viral vector platform technology developed by Mie University and BioComo.

We have designed multiple vaccine prototypes using a number of combinations of modality and antigen which are highly expected to induce immunity. Among these multiple prototypes, we have confirmed that the SARS-CoV-2 specific protein antigen mounted on their membrane surfaces binds with ACE2, which is a known receptor of SARS-CoV-2.

We also examined the induction of specific antibodies against the SARS-CoV-2 Spike protein by inoculating mice with these vaccine prototypes using a single intranasal dose. Induction of specific antibodies against this SARS-CoV-2 antigen was measured using ELISA tests and compared. We narrowed the vaccine prototypes down to several candidates that induced a stronger specific antibody response for future development.

We are currently in the process of analyzing neutralizing antibody titers through in-vivo testing. In addition to this, we plan to conduct the following tests.

1. Induction of mucosal immunity and measurement of the antibody titer;
2. Analysis of cell-mediated immunity (CD4/CD8-positive T cells);
3. In-vivo study to test the vaccine prototype’s efficacy by nasal spray to prevent viral infection.

BioComo, our development partner, has already converted packaging cells into a master cell bank. We are preparing to start production of vaccine candidates for safety toxicology tests and clinical trials.

Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to confirm that we now have multiple COVID-19 vaccine prototypes that induced a strong antibody response against the SARS-CoV-2 Spike protein after administration of only one intranasal dose. This is a critical step in our development of an effective vaccine. We look forward to reporting additional results as soon as possible.”

About ACE2

ACE2 is an enzyme attached to the membranes of cells in the lungs, arteries, heart, kidneys, and intestines. As a transmembrane protein, ACE2 serves as the main entry point into cells for some coronaviruses, including HCoV-NL63, SARS-CoV (the virus that causes SARS) and SARS-CoV-2 (the virus that causes COVID-19).

About Packaging Cells

Packaging cells are essential cells used to produce a viral vector which contains a helper virus genome.

About Master Cell Bank

A Master Cell Bank (MCB) is produced from the original producing cell line. It is usually cryopreserved in multiple vials to prevent genetic variation and potential contamination by eliminating the total number of times a cell line is passaged or handled during the manufacturing process.

About the BC-PIV SARS-CoV-2 Vaccine

BC-PIV, an innovative non-transmissible viral vector co-developed by BioComo and Mie University, is derived from the recombinant human parainfluenza virus type 2 (hPIV2). It is highly efficient in its ability to transfer multiple foreign proteins to recipients and has a strong safety profile as no secondary infectious virus is produced. BC-PIV is designed to display not only the gene but also the foreign protein itself on the surface and inside of the viral membrane. Therefore, it can carry the large membrane proteins of viruses and signal transduction receptors/ligand proteins on the viral surface. BC-PIV is able to carry the proteins that require a proper three-dimensional structure or multimeric structure while maintaining the structure. BC-PIV elicits good immunogenicity against antigen proteins without adjuvants. The BC-PIV SARS-CoV-2 vaccine prototype has been developed to include the specific SARS-CoV-2 antigen protein in order to express maximum antigenicity. The BC-PIV SARS-COV-2 vaccine can be developed as an intranasal vaccine in addition to an intramuscular injection because of its high affinity to nasal and upper

respiratory tract mucosa, which is the same route of the natural infection of SARS-CoV-2. An intranasal vaccine is expected to induce local mucosal immunity. To date, BioComo has succeeded in producing a recombinant Ebola virus vaccine (https://www.nature.com/articles/s41598-019-49579-y) and a Respiratory Syncytial virus prefusion F vaccine (unpublished data) using this BC-PIV platform technology.

About BioComo

BioComo, a biotech company founded at Mie Prefecture Japan in May 2008, is developing cutting-edge technology platforms for creating the novel and predominant vaccine carriers and adjuvants to enhance immunity in collaboration with the Microbiology and Molecular Genetics Department of Mie University. They have already succeeded in the development of a highly efficacious and state-of-the art vaccine carrier and novel adjuvant candidates. Their technology will be applied to the production of the next generation vaccines for the prevention of infections such as RS virus, Ebola virus, Influenza virus, and SARS-CoV-2. It will also enable faster and more cost-effective production of those vaccines. BC-PIV is the core platform technology which carries the corporate namesake, BioComo, and the leading vaccine carrier that is derived from the recombinant human parainfluenza virus 2 (hPIV2) vectors. BioComo is dedicated to inventing new vaccines for both global infection threats as well as malignant tumors.

About MediciNova

MediciNova, Inc. is a publicly traded biopharmaceutical company founded upon acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with unmet medical needs with a primary commercial focus on the U.S. market. MediciNova's current strategy is to focus on BC-PIV SARS-COV-2 vaccine for COVID-19, MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence), as well as prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19, and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). MediciNova's pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers. MediciNova is engaged in strategic partnering and other potential funding discussions to support further development of its programs. For more information on MediciNova, Inc., please visit www.medicinova.com.

Statements in this press release that are not historical in nature constitute forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the future development and efficacy of BC-PIV SARS-COV-2 vaccine, MN-166, MN-001, MN-221, and MN-029. These forward-looking statements may be preceded by, followed by or otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would," "considering," "planning" or similar expressions. These forward-looking statements involve a number of risks and uncertainties that may cause actual results or events to differ materially from those expressed or implied by such forward-looking statements. Factors that may cause actual results or events to differ materially from those expressed or implied by these forward-looking statements include, but are not limited to, risks of obtaining future partner or grant funding for development of BC-PIV SARS-COV-2 vaccine, MN-166, MN-001, MN-221, and MN-029 and risks of raising sufficient capital when needed to fund MediciNova's operations and contribution to clinical development, risks and uncertainties inherent in clinical trials, including the potential cost, expected timing and risks associated with clinical trials designed to meet FDA guidance and the viability of further development considering these factors, product development and commercialization risks, the uncertainty of whether the results of clinical trials will be predictive of results in later stages of product development, the risk of delays or failure to obtain or maintain regulatory approval, risks associated with the reliance on third parties to sponsor and fund clinical trials, risks regarding intellectual property rights in product candidates and the ability to defend and enforce such intellectual property rights, the risk of failure of the third parties upon whom MediciNova relies to conduct its clinical trials and manufacture its product candidates to perform as expected, the risk of increased cost and delays due to delays in the commencement, enrollment, completion or analysis of clinical trials or significant issues regarding the adequacy of clinical trial designs or the execution of clinical trials, and the timing of expected filings with the regulatory authorities, MediciNova's collaborations with third parties, the availability of funds to complete product development plans and MediciNova's ability to obtain third party funding for programs and raise sufficient capital when needed, and the other risks and uncertainties described in MediciNova's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2019 and its subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Undue reliance should not be placed on these forward-looking statements, which speak only as of the date hereof. MediciNova disclaims any intent or obligation to revise or update these forward-looking statements.

INVESTOR CONTACT:
Geoff O'Brien
Vice President
MediciNova, Inc.
info@medicinova.com

MEDICINOVA

Source: MediciNova, Inc.