MediciNova Announces SARS-CoV-2 Vaccine Joint Development with BioComo and Mie University Japan

July 27, 2020

LA JOLLA, Calif., July 27, 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 an agreement with BioComo (President: Masayuki Fukumura, Mie prefecture, Japan; http://www.biocomo.jp/) and Mie University (Mie prefecture, Japan) for joint development of a SARS-CoV-2 vaccine using BC-PIV, a human parainfluenza virus type 2 vector developed by BioComo and Tetsuya Nosaka, M.D., Ph.D., professor of the Department of Microbiology and Molecular Genetics, Mie University Graduate School of Medicine. MediciNova has been granted exclusive worldwide development rights to use BC-PIV for SARS-CoV-2 vaccine development from BioComo and Mie University.

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 SARS-CoV-2 vaccine prototype has been developed to include the specific SARS-CoV-2 antigen protein in order to express maximum antigenicity. 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vaccine (https://www.nature.com/articles/s41598-019-49579-y) and a Respiratory Syncytial virus prefusion F vaccine (unpublished data) using this BC-PIV platform technology.

Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, "Given the current global pandemic of COVID-19, we appreciate this very important opportunity to jointly develop a vaccine against SARS-CoV-2 with BC-PIV in collaboration with BioComo and Mie University. Previously, BioComo has been successful in developing vaccines against Ebola virus and RS virus with their BC-PIV technology, which made us confident that their technology will be successful for SARS-CoV-2 vaccines. Moreover, it is very attractive that a BC-PIV SARS-CoV-2 vaccine can be developed as an intra-nasal formulation, in addition to an intra-muscular injection, because of its high affinity for nasal mucosa or upper respiratory tract mucosa that could induce local mucosal immunity. We feel a great sense of mission to initiate this SARS-CoV-2 vaccine project in addition to our MN-166 project targeting ARDS, which is a very serious and potentially fatal disease that can be caused by COVID-19."

Masayuki Fukumura, President of BioComo, commented, “We are very pleased to proceed with the co-development of a SARS-CoV-2 vaccine with MediciNova which has a proven track record of international clinical development for unmet medical needs. We initiated the development of a novel BC-PIV SARS-CoV-2 vaccine with Dr. Tetsuya Nosaka in March of this year (http://www.biocomo.jp/20200319.pdf). Multiple stabilized Spike protein mutants of SARS-CoV-2 were devised and the respective genes and proteins were loaded onto BC-PIV. We have already completed core characterization studies with mice models. BC-PIV is characterized by its ability to load a large antigenic protein retaining the three-dimensional structure of the vector envelope and its high affinity for the nasal mucosa and upper respiratory tract mucosa. BC-PIV SARS-COV-2 vaccine can be developed as an intra-nasal vaccine in addition to an intra-muscular 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 intra-nasal vaccine is expected to induce local mucosal immunity. GMP manufacturing has been one of the barriers for us until now, but through our joint development with MediciNova, we will proceed with further non-clinical and clinical trial development as quickly as possible globally and not only in Japan. We are thrilled with the challenge to develop a vaccine that has potential clinical application to limit the spread of SARS-CoV-2.”

Tetsuya Nosaka, Professor at Mie University Graduate School of Medicine, commented, “I am very excited about the outcome of the long-standing development of the vector and genetically modified vaccines with BioComo that can be applied to prevent COVID-19, a major global health threat. We believe BC-PIV is effective, safe, convenient, and cost efficient as a vaccine vector, and have been seeking an opportunity for the clinical application for long time. However, the academic research environment has been less encouraging lately. Therefore, it is a great encouragement for us as member of the academic community to achieve this international joint development with MediciNova, which has an abundant track record of manufacturing and clinical development. We are confident that the BC-PIV SARS-CoV-2 vaccine will be successful and hope that this vaccine will be available in a clinical setting as soon as possible and will be the “gospel” for the people in the world.”

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 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 cost-effective production of those vaccines. BC-PIV is the core platform technology which was named after the corporate name, BioComo, and the leading vaccine carrier which 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 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 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 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.

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Source: MediciNova, Inc.