MediciNova CEO Yuichi Iwaki Provides Corporate Update in Letter to Stockholders

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NIH-funded Phase 2-3 ALS Expanded Access study expands reach of MediciNova's ongoing COMBAT-ALS trial and provides illustration of Company's development strategy

LA JOLLA, Calif., Nov. 19, 2024 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (Nasdaq:MNOV) and the Standard Market of the Tokyo Stock Exchange (Code Number: 4875) focused on development of novel anti-inflammatory treatments for neurodegenerative diseases, malignant brain cancers, and metabolic diseases, provides shareholders a corporate update in the following Letter to Stockholders from CEO Yuichi Iwaki, M.D., Ph.D.:

To our esteemed stockholders,

Since its founding, MediciNova has been clear in its mission to deliver new treatment options to the patients suffering with unmet medical needs. In service of that mission, we have been steadfast in our commitment to both further our science in partnership with some of the greatest minds across the United States, and to do so in a way that preserves capital and provides optimal value to shareholders.

Our recently announced collaboration to supply our compound MN166 (ibudilast) as part of an NIH-funded expanded access clinical trial is illustrative of this commitment, as it provides the Company with non-dilutive funding as we collaborate to continue to develop MN166 for ALS without incurring the expenses associated with an additional clinical trial. The six-month trial is being conducted with 17 institutions, all under the aegis of the lead institution and funded entirely by the NIH and without the added expenses of contract research organizations (CROs). Concurrently, we are conducting the COMBAT-ALS trial, our Company-sponsored Phase 2/3 trial of MN166 for ALS, which is a sponsored 12-month trial. We believe that the combination of the two trials allow us to more completely investigate MN166 in a significantly larger patient population, while maintaining a prudent hold on cash.

Importantly, the NIH-funded trial is also very much in line with our corporate strategy, which is to choose a small number of trials on which to focus our resources and identify partners and other funding sources to ensure that additional programs are conducted, our pipeline is robust, and yet our cash reserves are minimally impacted. Another current example of this strategy is an ongoing clinical trial of MN-166 in Long COVID, which is being funded and conducted under the aegis of Health Canada. Much like the ALS program, MediciNova is providing study drug and some administrative support. However, the Canadian government is largely responsible for most other aspects of the trial. Once the trial is complete, Health Canada will turn the results over to the Company at which time it will be in a position to then apply for approval under that indication to Health Canada. We anticipate that there may be advantages in the regulatory process in Canada resulting from the partnership.

We have several additional programs that are being overseen by both U.S. government agencies (NIH, BARDA) and outside the U.S. that follow this model of partnering with prestigious institutions and government agencies to conduct and sponsor clinical trials. Our responsibilities are usually limited to providing study drug in most of these cases, along with administrative and trial design support. Ultimately, for the sake of clarity, we consider our core programs those for which we have direct fiscal responsibility, such as with our COMBAT-ALS trial, as well as the emerging glioblastoma program. However, our non-core programs, such as the above mentioned Long COVID and others for which we only provide study drug and guidance – but almost never cash – are easy ways for us to create revenue over time, and significant shareholder value.

Our cash and cash equivalents position remains strong, with $42.3 million as of September 30, 2024. As discussed, we are extremely careful in the way we use our cash, and we look forward to an additional non-dilutive cash payout as a result of our recently announced award in connection with the Sanofi/Novartis settlement. We will provide additional information on that award in the coming weeks.

The global landscape is in a state of perpetual flux, encompassing the natural environment, economy, and technological advancements. In the midst of these dynamic changes, our aspiration is to cultivate a society where every individual can attain lifelong health and enjoy a prosperous and fulfilling life. In pursuit of this vision, we are committed to fostering sustainable growth, and we believe that this approach is essential to manage cash while driving multiple programs through a complicated global development and regulatory landscape.

We also understand that our story may be perceived as complex. I hope that laying out this approach has gone some distance to help clarify our story. In the meantime, we also recently announced that our Chief Business Officer, Dr. David Crean, has also assumed the role of managing our communications. We believe it is essential that current and future investors understand the nuances of our company, and have open, two-way communications to ensure clarity and transparency. Transparency is all the more important as we are the only dual-listed biopharmaceutical company, listed both at NASDAQ market and Tokyo Stock Exchange, which presents the challenge of ensuring that all of our shareholders from both markets are up to date, and in the know.

We are very excited about the future at MediciNova and anticipate providing status updates regularly beginning in the coming weeks. In the meantime, we remain grateful to those shareholders who have shown their loyalty over the years and look forward to welcoming new shareholders to the fold.

Sincerely,

Dr. Yuichi Iwaki

MediciNova Founder, CEO and President

About MediciNova

MediciNova, Inc. is a clinical-stage biopharmaceutical company developing a broad late-stage pipeline of novel small molecule therapies for inflammatory, fibrotic, and neurodegenerative diseases. Based on two compounds, MN-166 (ibudilast) and MN-001 (tipelukast), with multiple mechanisms of action and strong safety profiles, MediciNova has 11 programs in clinical development, two of which are the Company's primary focus.

MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS), and Phase 2 in glioblastoma.

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, 2023 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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