MediciNova Reports First Quarter 2021 Financial Results and Business Update

May 13, 2021

- Completed $20M private placement financing with 3D Investment Partners -

- Entered into partnership with BARDA to evaluate MN-166 for chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) and acute lung injury (ALI) -

- Received $4M in milestone payments from assignment agreement with Genzyme Corporation -

- Strong cash balance of $76M to advance multiple late-stage programs -

LA JOLLA, Calif., May 13, 2021 (GLOBE NEWSWIRE) -- MediciNova, Inc., (Nasdaq: MNOV, JASDAQ:4875), a biopharmaceutical company developing small-molecule therapeutics, today reported financial results for the first quarter ended March 31, 2021 and provided a business update.

“As a late-stage biotech company with two anti-inflammatory platform candidates in development, our main focus over 2021 is execution across our programs that will enable us to not only showcase their therapeutic potential but bring us closer to delivering much-needed treatment options to patients,” commented Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova. “We know from the prior approval in Japan and subsequent treatment in post-stroke dizziness and asthma that our lead product candidate MN-166 is remarkably safe and well-tolerated. We are now working to demonstrate the potential of MN-166, along with MN-001, to drive therapeutic benefit across a range of neurodegenerative, inflammatory, and fibrotic indications, without compromising immunity. Recent among these expansions has been our work in acute respiratory distress syndrome to combat the high rates of hospitalization due to COVID-19, and we are pleased to have partnered with BARDA to further evaluate MN-166 against chlorine gas-induced lung damage. MN-166 is the first candidate to have received BARDA funding under the Division of Research, Innovation, and Ventures’ (DRIVe) Repurposing Drugs in Response to Chemical Threats (ReDIRECT) program, exemplifying its differentiated potential as a safe and well-established anti-inflammatory drug.”

Recent Clinical Highlights

MN-166 (ibudilast)

- **Formed partnership with BARDA to develop MN-166 as treatment for ARDS and ALI:** In March 2021, the Company entered into a partnership with the Biomedical Advanced Research and Development Authority (BARDA) to develop MN-166 as a potential treatment for chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). Under the partnership, BARDA will provide funding for proof-of-concept studies of MN-166. The Company also continues to enroll patients in its Phase 2 clinical trial evaluating MN-166 (ibudilast) in COVID-19 patients at risk of developing ARDS. The Phase 2 trial is a randomized, double-blind parallel group study to evaluate the efficacy and safety of MN-166 in hospitalized COVID-19 patients receiving standard of care who are at risk of developing ARDS.

- **Continued enrollment of Phase 3 trial in ALS:** The Company continues to enroll patients in its Phase 3 clinical trial evaluating MN-166 for the treatment of amyotrophic lateral sclerosis (ALS). The Phase 3 trial is a multi-center randomized, double-blind study to evaluate the efficacy, safety, and tolerability of MN-166 in ALS patients for 12 months of treatment followed by a 6-month open-label extension phase, and the primary endpoint is change from baseline in ALSFRS-R score at month 12 and survival time. Progression into this study follows positive Phase 2 data that demonstrated MN-166 resulted in a higher rate of responders on the ALSFRS-R score, indicating less functional decline compared to the placebo group. The ALSFRS-R responders showed increased overall survival compared to non-responders and MN-166 also demonstrated a favorable safety and tolerability profile.

- **Partnering process ongoing for progressive MS program:** The Company is engaged in a process with potential partners regarding MN-166 that could lead to funding for a Phase 3 trial in progressive multiple sclerosis (PMS). In the Phase 2b trial in PMS, MN-166 achieved both primary endpoints, demonstrating a significant 48% reduction in the rate of progression of whole brain atrophy ($p=0.04$) as well as a favorable safety and tolerability profile. MN-166 also showed a trend of reduced risk of confirmed disability progression, an approvable endpoint for PMS, especially among secondary progressive MS (SPMS) patients without relapse, a subgroup that represents the highest unmet need with no approved long-term treatment options and accounting for approximately 80% of all SPMS patients. Based on this encouraging data and discussions with FDA, the Phase 3 trial plan is to enroll SPMS patients without relapse with 3-month confirmed disability progression as the primary endpoint.

MN-001 (tipelukast)

- **Completed enrollment of Phase 2 trial in IPF:** The Company has completed enrollment in its Phase 2 trial of MN-001 in idiopathic pulmonary fibrosis (IPF). The Phase 2 randomized, placebo-controlled, double-blind trial is evaluating the efficacy and safety of MN-001 in patients with IPF over the course of a 26-week treatment period followed by at 26-week open label extension. The co-primary endpoints of the trial are change from baseline of forced vital capacity (FVC) and semiannual rate of decline of disease activity based on FVC.

- **Preparing second Phase 2 trial in NASH:** Following the early completion of its Phase 2 trial evaluating MN-001 in nonalcoholic steatohepatitis (NASH) and nonalcoholic fatty liver disease (NAFLD) due to positive interim data, the Company is now preparing to initiate a larger Phase 2 trial in NASH. In the first Phase 2 trial, MN-001 demonstrated a statistically significant reduction in the primary endpoint, mean serum triglycerides (p=.02). The Company will provide an update on this program as the new trial is initiated.

Recent Business Updates

- **Established MedACT (MediciNova Ancillary Clinical Trial Support):** As part of its ongoing patient support and engagement, the Company has established MedACT, a patient support program that grants financial and other support as needed across its ongoing clinical trials.

- **Received $4 million in gene therapy milestone payments:** In April 2021, the Company announced it received two milestone payments under its agreement with Genzyme Corporation, a subsidiary of Sanofi, as a result of the successful achievement of two clinical development milestones for a gene therapy product based on adeno-associated virus (AAV) vector technology.

- **Discontinued development of COVID-19 vaccine:** In March 2021, the Company announced its plans to discontinue development of a SARS-CoV-2 vaccine for COVID-19 to focus its resources on its later-stage development programs with larger unmet medical needs and market opportunities.

- **Raised $20 million through private placement:** In January 2021, the Company raised $20 million through a private placement of common stock sold to 3D Opportunity Master Fund, a fund managed by 3D Investment Partners Pte. Ltd.

First Quarter 2021 Financial Results

- **Cash Position:** As of March 31, 2021, cash and cash equivalents were $76.3 million, as compared to cash and cash equivalents of $61.3 million as of March 31, 2020. This increase was primarily due to approximately $20 million received in a private placement transaction which closed in January 2021. The Company expects current cash and cash equivalent to fund operations at least through the end of 2022.

- **Revenues:** Revenues were $4.0 million for the three months ended March 31, 2021, compared to $0.0 million for the three months ended March 31, 2020. The $4.0 million increase was due to the receipt of two milestone payments under MediciNova's assignment agreement with Genzyme Corporation, a subsidiary of Sanofi.

- **Research, Development and Patents Expenses:** R&D and patents expenses were $2.1 million for the three months ended March 31, 2021, compared to $1.3 million for the three months ended March 31, 2020. The increase of $0.8 million was primarily due to higher clinical trial expenses from the ongoing clinical trial of MN-166 (ibudilast) in ALS and higher stock compensation expense resulting from an increase in our stock price.

- **General and Administrative Expenses:** G&A expenses were $2.1 million for the three months ended March 31, 2021, compared to $1.7 million for the three months ended March 31, 2020. The increase of $0.4 million was primarily due to higher stock compensation expense resulting from an increase in our stock price.

- **Net Loss:** Net loss was $0.2 million for the three months ended March 31, 2021, or $(0.00) per basic and diluted share, as compared to a net loss of $2.7 million for the three months ended March 31, 2020, or $(0.06) per basic and diluted share.

About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company founded upon 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 amyotrophic lateral sclerosis (ALS), degenerative cervical myelopathy (DCM), progressive multiple sclerosis (MS), substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence) and glioblastoma (GBM), 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) and MN-029 (denibulin). For more information on MediciNova, Inc., please visit www.medicinova.com.

Forward-Looking Statements

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 to the development of formulations as well as the initiation and conduct of 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, 2020 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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