MediciNova Reports Second Quarter 2021 Financial Results and Business Update

August 12, 2021 at 7:00 PM EDT

Initiated preclinical animal studies for MN-166 as a treatment for chlorine gas-induced induced lung disease under partnership with BARDA

Positive Phase 2 results in alcohol use disorder published in Nature Journal reinforce safety and blockbuster potential of MN-166

Phase 2 results for MN-001 in IPF

Enrollment in Phase 3 trial of MN-166 in ALS ongoing

Strong cash balance of $77M to advance multiple late-stage programs

LA JOLLA, Calif., Aug. 12, 2021 (GLOBE NEWSWIRE) -- MediciNova, Inc., (Nasdaq: MNOV, JASDAQ:4875), a biopharmaceutical company developing small-molecule therapeutics, today reported financial results for the second quarter ended June 30, 2021 and provided a business update including results of a safety review from the ongoing Phase 2 trial of MN-166 (ibudilast) in glioblastoma and results from the completed Phase 2 trial of MN-001 (tipelukast) in idiopathic pulmonary fibrosis (IPF).

"Over the past quarter, we have continued to advance our novel anti-inflammatory candidates across all stages of development. Through our BARDA partnership, we initiated the first animal model study for MN-166 (ibudilast) as a treatment for chlorine gas-induced lung injury and reached agreement on the second animal model study. We received a notice of allowance for a pending patent application which covers MN-166 (ibudilast) for the treatment of ophthalmic disease, showcasing its broad applicability. In addition, our legacy programs remain strong, with positive results from a Phase 2 trial in alcohol use disorder recently published in Nature's *Translational Psychiatry*, which serves as further validation for the underlying mechanism of MN-166 (ibudilast) and its potential to drive powerful neurological results. To that end, we continue to enroll patients in our ongoing Phase 3 trial in ALS, and the European Patent Office recently issued a notice of intention to grant for a pending patent application which covers the combination of MN-166 (ibudilast) and riluzole for the treatment of ALS. In collaboration with our ALS investigators Dr. Brooks and Dr. Oskarsson, we recently hosted a webinar for ALS patients and community members highlighting encouraging data reported to-date and the potential of MN-166 (ibudilast) to bridge a long-standing treatment gap without compromising safety," commented Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova. "Turning to our MN-001 (tipelukast) programs, although our Phase 2 trial in IPF did not demonstrate a clear clinical effect on most of the outcome measures, there were fewer worsening IPF events in the MN-001 group and the drug did demonstrate an effect on reducing LOXL2, a biomarker for IPF. We are currently working with collaborators to finalize the protocol for our next planned Phase 2 trial of MN-001 in NASH. Across our programs, we continue to operate a highly cash-efficient business model and believe we are well-positioned for a successful second half."

Clinical Highlights

MN-166 (ibudilast)

- **New patents cover MN-166 (ibudilast) for treatment of ophthalmic disease (U.S.) and ALS (Europe):** In July 2021, the Company announced that it received a Notice of Allowance from the U.S. Patent and Trademark Office for a pending patent application which covers MN-166 (ibudilast) for the treatment of ophthalmic disease, which, once issued, is expected to expire no earlier than October 2039. The Company also received a Notice of Intention to Grant from the European Patent Office for a pending patent application which covers the combination of MN-166 (ibudilast) and riluzole for the treatment of amyotrophic lateral sclerosis (ALS) which is expected to expire no earlier than November 2035. The Company previously announced results from its Phase 2 ALS trial which showed a higher rate of responders for the MN-166 (ibudilast) plus riluzole group as compared to the riluzole-only group.

- **Positive results from Phase 2 trial in AUD published in Nature journal:** In June 2021, the Company announced that positive results from a Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder (AUD) were published in Nature's *Translational Psychiatry*. The study was a randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the effect of 14 days of MN-166 (ibudilast) treatment on mood, heavy drinking, and neural reward signals in 52 individuals with AUD. Key results reported in the publication showed that MN-166 (ibudilast) did not have a significant effect on negative mood but it reduced the odds of heavy drinking across time by 45% (p=0.04) and reduced alcohol craving on non-drinking days (p=0.02).

- **Initiated preclinical animal study under partnership with BARDA:** In June 2021, the Company announced it initiated a sheep study and reached agreement to conduct a mouse study under its partnership with the Biomedical Advanced Research and Development Authority (BARDA) to investigate the efficacy of MN-166 (ibudilast) as a potential medical countermeasure (MCM) against chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). The sheep study will investigate MN-166 (ibudilast) in an ovine model of chlorine-induced acute lung injury, and will evaluate pulmonary function, lung injury and edema formation, cardiopulmonary hemodynamics, and systemic vascular permeability. The murine model will evaluate survival, clinical outcomes, body weights, lung weights, and upper respiratory tract histopathology after exposing mice to chlorine gas and treating them with MN-166 (ibudilast) or

control.

- **Continued enrollment of Phase 3 trial in ALS:** The Company continues to enroll patients in the Phase 3 clinical trial, COMBAT-ALS, which is evaluating MN-166 (ibudilast) for the treatment of amyotrophic lateral sclerosis (ALS). The Phase 3 trial is a multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of MN-166 (ibudilast) in ALS patients after 12 months of treatment followed by a 6-month open-label extension phase. The primary endpoint is change from baseline in ALSFRS-R score at month 12 and survival time. To provide further education on the potential of MN-166 (ibudilast) to treat patients with ALS, the Company hosted an informational webinar in June 2021. The webinar, which included presentations from Dr. Björn Oskarsson, lead clinical investigator of COMBAT-ALS, and Dr. Benjamin Rix Brooks, who led the first clinical study of MN-166 (ibudilast) in patients with ALS, provided an overview of the drug's mechanism of action, the COMBAT-ALS study design, and findings from the Phase 2 trial in ALS. A replay of the webinar can be viewed here.

- **Partnering process ongoing for progressive MS program:** The Company is engaged in a process with potential partners regarding MN-166 (ibudilast) that could lead to funding for a Phase 3 trial in progressive multiple sclerosis (PMS). Based on encouraging Phase 2b data, especially among secondary progressive MS (SPMS) patients without relapse, 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.

- **Completed Glioblastoma safety review:** The Company has completed a safety review of Part 1 of the Phase 2 trial of MN-166 (ibudilast) in combination with temozolomide, which enrolled 15 subjects with recurrent glioblastoma. This is an open-label clinical trial at Dana-Farber Cancer Institute which includes a dose-escalation portion (Part 1) followed by a fixed-dose treatment period (Part 2). There were no concerning safety signals observed in Part 1 and there were no serious adverse events related to MN-166 (ibudilast). 5 out of 15 subjects completed cycle 6 without disease progression, i.e. 33% of subjects were progression-free at 6 months.

- **Enrolling subjects in COVID-19 ARDS Phase 2 trial:** The Company has completed 75% of planned enrollment in the Phase 2 trial of MN-166 (ibudilast) in COVID-19 at risk for ARDS. This is a randomized, double-blind, placebo-controlled study in hospitalized COVID-19 subjects at risk for developing ARDS and receiving standard of care including anticoagulation. The primary endpoints include the proportion of subjects free from respiratory failure at Day 7, mean change from baseline in clinical status using the NIAID 8-point ordinal scale at Day 7, the percentage of patients with improvement in clinical status at Day 7, and mean change in cytokine levels from baseline to Day 7.

MN-001 (tipelukast)

- **Phase 2 trial results in IPF:** The Phase 2 trial of MN-001 (tipelukast) in idiopathic pulmonary fibrosis (IPF) completed enrollment of 15 subjects including 10 subjects in the MN-001 (tipelukast) group and 5 subjects in the placebo group. This Phase 2 randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of MN-001 (tipelukast) in IPF over a 26-week treatment period. Although there were no clinically meaningful trends in favor of MN-001 (tipelukast) for the majority of the clinical outcome measures in this small study, there were no worsening IPF events (acute IPF exacerbation or hospitalization due to respiratory symptoms) in the MN-001 (tipelukast) group compared to one worsening IPF event in the placebo group. MN-001 (tipelukast) demonstrated a substantial reduction in LOXL2, a biomarker for IPF, whereas LOXL2 increased in the placebo group. MN-001 (tipelukast) was safe and well tolerated.

- **Preparing for second Phase 2 trial in NASH:** Following the early completion of its Phase 2 trial evaluating MN-001 (tipelukast) in nonalcoholic steatohepatitis (NASH) and nonalcoholic fatty liver disease (NAFLD) due to positive interim data, the Company is now working to finalize a protocol for a larger Phase 2 trial in NASH. In the first Phase 2 trial, MN-001 (tipelukast) demonstrated a statistically significant reduction in the primary endpoint of mean serum triglycerides (p=.02). The Company will provide further updates upon initiation of the next trial.

Second Quarter 2021 Financial Results

- **Cash Position:** As of June 30, 2021, cash and cash equivalents were $77.8 million, as compared to cash and cash equivalents of $60.4 million as of June 30, 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 equivalents to fund operations at least through the end of 2022.

- **Research, Development and Patents Expenses:** R&D and patents expenses were $2.5 million for the three months ended June 30, 2021, compared to $2.2 million for the three months ended June 30, 2020. The increase of $0.3 million was primarily due to higher clinical trial expenses from the ongoing clinical trial of MN-166 (ibudilast) in ALS.

- **General and Administrative Expenses:** G&A expenses were $1.8 million for the three months ended June 30, 2021, compared to $2.3 million for the three months ended June 30, 2020. The decrease of $0.5 million was primarily due to lower stock compensation expense for performance-based stock options resulting from a decrease in our stock price and decreased consultant fees.

- **Net Loss:** Net loss was $4.3 million for the three months ended June 30, 2021, or ($0.09) per basic and diluted share, as compared to a net loss of $4.5 million for the three months ended June 30, 2020, or ($0.10) per basic and diluted share.

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. MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM), and is Phase 3-ready for progressive multiple sclerosis (MS). MN-166 (ibudilast) is also being evaluated in Phase 2 trials in glioblastoma, patients at risk of developing acute respiratory distress syndrome (ARDS), and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in nonalcoholic steatohepatitis (NASH). MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants. 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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