MediciNova Given Notice of Monetary Damages Due Under Patent Settlement of Sanofi-Novartis

November 11, 2024

LA JOLLA, Calif., Nov. 11, 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), today announced that it was notified by Sanofi that the Sanofi/Novartis litigation was settled. Accordingly, MediciNova is entitled to receive a certain amount of monetary damages through this settlement. Further details will be provided as they become available.

Yuichi Iwaki, M.D., Ph.D., MediciNova CEO commented, “The successful resolution of the Sanofi-Novartis litigation and the resulting monetary damages due to MediciNova both validates the value of our intellectual property and provides an additional source of non-dilutive funding, which we plan to apply to supporting our ongoing clinical development programs, particularly our late-stage pipeline targeting inflammatory, metabolic, and neurodegenerative diseases. This outcome further reinforces our commitment to developing unique assets with long-term value. We remain dedicated to preserving our financial position as we continue to prudently advance our novel small molecule therapies towards commercialization."

About Sanofi/Novartis litigation

On March 30,2022, MediciNova, Inc. was notified that Genzyme Corporation, a subsidiary of Sanofi, filed its First Amended Complaint, which included a claim for infringement of U.S. Patent No. 9,051,542, on February 23, 2022 in a lawsuit previously filed against Novartis Gene Therapies, Inc., Novartis Pharmaceutical Corporation, and Novartis AG in the U.S. District Court for the District of Delaware. This patent, among others was included in the assignment Agreement dated December 19, 2005, between MediciNova, Inc., as successor in interest to Avigen, Inc. and Genzyme Corporation. The plaintiffs allege that the defendants infringe certain U.S. patents through the unauthorized manufacture, use, and sale of recombinant adeno-associated virus vectors (“rAAV vectors”) for their gene therapy drug Zolgensma. If Genzyme recovers any monetary damages, by way of settlement or otherwise, as a result of this litigation, then MediciNova is entitled to receive a certain portion of such monetary damages from Genzyme as per the terms of assignment agreement.

About Zolgensma

The U.S. Food and Drug Administration (FDA) approved Zolgensma (onasemnogene abeparvovec-xioi) on May 24, 2019. Zolgensma is a gene therapy that treats children under two years old with spinal muscular atrophy (SMA). It was the first gene therapy approved by the FDA to treat a disease. Novartis priced an infusion at $2.1 million, making it one of the priciest medicines on the market. Zolgensma has become one of Novartis’ top-sellers, generating more than $1.3 billion in annual sales in 2023. The company expects it to eventually earn between $1.5 billion and $2 billion annually. Approved in 45 countries, Zolgensma replaces the faulty gene responsible for causing spinal muscular atrophy, a condition that in its severe form robs infants of the ability to stand, sit and, eventually, breathe. Untreated, it’s typically fatal by a very young age. Zolgensma can deliver dramatic benefits, keeping children alive and in some cases helping them achieve motor and developmental milestones they otherwise wouldn’t. In the U.S, its use is limited to babies under the age of two, where it’s seen as having the greatest benefit.

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 Long COVID and substance dependence. MN 001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and a second Phase 2 trial in non-alcoholic fatty liver disease (NAFLD) is ongoing. MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

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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