Dova Pharmaceuticals Announces FDA Acceptance of the Avatrombopag New Drug Application (NDA) with Priority Review

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PDUFA date of May 21, 2018

DURHAM, N.C., Nov. 27, 2017 (GLOBE NEWSWIRE) -- Dova Pharmaceuticals, Inc. (NASDAQ:DOVA) today announced the New Drug Application (NDA) for avatrombopag has been accepted for filing and has been granted Priority Review by the United States Food and Drug Administration (FDA). Dova is seeking FDA approval of avatrombopag for the treatment of thrombocytopenia in patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. The submission is based on two identically-designed Phase 3 clinical trials, ADAPT 1 and ADAPT 2, in which avatrombopag met all primary and secondary endpoints with high statistical significance. The Prescription Drug User Fee Act (PDUFA) goal date for an FDA decision is May 21, 2018.

Alex Sapir, President and Chief Executive Officer of Dova, commented, “We are extremely pleased that FDA has accepted our NDA submission with Priority Review. We believe that avatrombopag represents a novel treatment option with robust efficacy as well as an improved safety profile when compared to platelet transfusions, today’s current standard of care. We look forward to working closely with FDA through the review process.”

The FDA’s Priority Review status accelerates the review time from ten months to a goal of six months from the date of acceptance of filing and is granted to applications for drugs that, if approved, would provide significant improvements in safety or effectiveness in the treatment of a serious condition over available therapies.

About Avatrombopag

Avatrombopag is a second generation orally administered TPO-RA which is intended to address the limitations of other existing treatments for thrombocytopenia. In two identically-designed Phase 3 clinical trials, ADAPT 1 and ADAPT 2, avatrombopag met all primary and secondary endpoints with high statistical significance. Avatrombopag is initially being studied for its potential for the acute treatment of thrombocytopenia in patients with CLD scheduled to undergo a procedure. Dova is also planning to explore the potential use of avatrombopag in a broader population of patients with thrombocytopenia, including in patients undergoing surgical procedures associated with a high risk of bleeding, and patients who develop thrombocytopenia after receiving chemotherapy. In addition, Dova is exploring a potential regulatory approval pathway for avatrombopag for the treatment of adults with chronic immune thrombocytopenic purpura (ITP) based on results from a completed Phase 3 trial in this patient population. Dova holds the worldwide rights to avatrombopag for all current and future indications.

About Dova Pharmaceuticals, Inc.

Dova is a pharmaceutical company focused on acquiring, developing, and commercializing drug candidates for rare diseases where there is a high unmet need, with an initial focus on addressing thrombocytopenia. Dova’s lead drug candidate, avatrombopag, has successfully completed two pivotal Phase 3 clinical trials for the treatment of thrombocytopenia in patients with CLD scheduled to undergo a procedure and an NDA has been submitted to the FDA for this initial indication.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “anticipated”, “believe”, “expect”, “may”, “plan”, “potential”, “will”, and similar expressions, and are based on Dova’s current beliefs and expectations. These forward-looking statements include expectations regarding the potential U.S. launch for avatrombopag in patients with CLD who are scheduled to undergo a procedure and the clinical development of avatrombopag for other indications. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, increased regulatory requirements, Dova’s reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in Dova’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed with the U.S. Securities and Exchange Commission (SEC) on November 9, 2017, and Dova’s other periodic reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Dova as of the date of this release, and Dova assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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