# Dova Pharmaceuticals Announces New Drug Application Submission to FDA for Avatrombopag, a Second Generation Thrombopoietin Receptor Agonist

September 22, 2017

DURHAM, N.C., Sept. 22, 2017 (GLOBE NEWSWIRE) -- Dova Pharmaceuticals, Inc. (NASDAQ:DOVA), a specialty pharmaceutical company, today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for avatrombopag, a second generation orally administered thrombopoietin receptor agonist (TPO-RA) for the treatment of thrombocytopenia in patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

"Submission of the NDA for avatrombopag represents a significant milestone and a major advancement towards potentially bringing this novel therapy to patients, including the approximately 1.1 million CLD patients in the United States affected by thrombocytopenia, of whom approximately 70,000 have severe thrombocytopenia," said Alex Sapir, President and CEO of Dova. "The treatment of thrombocytopenia represents an important unmet need in this patient population, as significant limitations impact the use of platelet transfusions, the current standard of care." Risks associated with platelet transfusions include antibody development, bacterial infections, short duration of effect, limited supply, and inconvenience of administration. Currently there is no drug treatment approved by FDA or the European Medicines Agency (EMA) for the treatment of thrombocytopenia in patients with CLD who are scheduled to undergo a procedure.

Primary safety and efficacy data supporting the NDA submission were provided by the results of two pivotal Phase 3 clinical trials, ADAPT-1 and ADAPT-2, that evaluated the efficacy and safety of avatrombopag for the treatment of severe thrombocytopenia (defined as <50,000 platelets per microliter of circulating blood) in patients with CLD. In both trials, avatrombopag met the primary and secondary efficacy endpoints with high statistical significance. Avatrombopag treatment was well tolerated with a safety profile that was generally comparable to that of placebo, with the frequency, severity, and types of adverse events reported being consistent with those expected in patients with CLD. There will be an oral presentation of these two pivotal Phase 3 trials at the upcoming American Association for the Study of Liver Diseases (AASLD) Meeting in Washington, DC on October 23rd at 3PM (EDT).

**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 now been submitted to 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 "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 regulatory development of avatrombopag. 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, 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 June 30th, 2017, filed with the U.S. Securities and Exchange Commission (SEC) on August 14, 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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