# Dova Pharmaceuticals Announces European Union Marketing Authorization for DOPTELET® (avatrombopag) for the Treatment of Thrombocytopenia in Patients with Chronic Liver Disease

June 25, 2019

*-Approval Based on Positive Efficacy and Safety Data from Two Phase 3 Clinical Trials-*

*-Company Intends to Partner for the European Commercialization of DOPTELET-*

DURHAM, N.C., June 25, 2019 (GLOBE NEWSWIRE) -- Dova Pharmaceuticals, Inc. (NASDAQ: DOVA), a pharmaceutical company focused on acquiring, developing and commercializing drug candidates for diseases where there is a high unmet need, today announced that the European Commission (EC) has granted marketing authorization for DOPTELET® (avatrombopag) for the treatment of severe thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo an invasive procedure.

“Receiving the European marketing authorization for DOPTELET marks another significant milestone for Dova and our growing leadership in the treatment of thrombocytopenia,” said Dr. David Zaccardelli, president and chief executive officer of Dova. “As an oral thrombopoietin receptor agonist that can raise platelet levels in CLD patients with thrombocytopenia ahead of an invasive procedure, DOPTELET offers a safe and effective alternative to platelet transfusions. Conversations with potential commercial partners are ongoing to make DOPTELET available in Europe.”

Safety and efficacy data from two global Phase 3, double-blind, placebo-controlled trials, conducted in adults with thrombocytopenia (platelet count of less than 50,000/µL) and CLD, supported the EC marketing authorization. DOPTELET was shown to be superior to placebo in increasing the proportion of patients not requiring platelet transfusions or rescue procedures for bleeding up to 7 days following a scheduled procedure in both trials and both the 40 mg and 60 mg treatment groups. DOPTELET was also superior to placebo at the two secondary efficacy endpoints in each trial, i.e., the proportion of patients achieving a platelet count equal to or greater than 50,000/µL and the magnitude of the change in platelet counts from baseline to procedure day.

The marketing authorization applies to all 28 European Union member states plus Iceland, Norway, and Liechtenstein.

For DOPTELET EU product information, please see this link.

DOPTELET was approved by the U.S. Food and Drug Administration for the treatment of thrombocytopenia in adult patients with CLD who are scheduled to undergo a procedure in May 2018.

**Indications and Important Safety Information**
**(Based on FDA-Approved Labeling)**

**INDICATIONS**

DOPTELET (avatrombopag) is approved for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

DOPTELET is a thrombopoietin (TPO) receptor agonist and TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. Portal vein thrombosis has been reported in patients with chronic liver disease treated with TPO receptor agonists. In the ADAPT-1 and ADAPT-2 clinical trials, there was 1 treatment-emergent event of portal vein thrombosis in a patient (n=1/430) with chronic liver disease and thrombocytopenia treated with DOPTELET.

Consider the potential increased thrombotic risk when administering DOPTELET to patients with known risk factors for thromboembolism, including genetic prothrombotic conditions (Factor V Leiden, Prothrombin 20210A, Antithrombin deficiency or Protein C or S deficiency).

DOPTELET should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.

**CONTRAINDICATIONS:**

None.

**ADVERSE REACTIONS**

Most common adverse reactions (≥ 3%) are: pyrexia, abdominal pain, nausea, headache, fatigue, and edema peripheral.

Please see full US Prescribing Information for DOPTELET (avatrombopag) www.doptelet.com.

**About Dova Pharmaceuticals, Inc.**

Dova is a pharmaceutical company focused on acquiring, developing, and commercializing drug candidates for diseases where there is a high unmet need, with an initial focus on addressing thrombocytopenia. Dova's proprietary pipeline includes one commercial product, DOPTELET, for the treatment of thrombocytopenia in adult patients with chronic liver disease scheduled to undergo a procedure and the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. For more information, visit www.Dova.com.

**Cautionary Notes 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 commercial launch of DOPTELET within the European Union for the treatment of severe thrombocytopenia in adult patients with CLD who are scheduled to undergo an invasive procedure, and Dova's ability to develop commercialization capabilities with a partner within the European Union. 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 Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission (SEC) on March 5, 2019, Dova's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC on May 7, 2019, 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.

**Media Relations Contact**
LDR Communications
Lori Rosen
(917) 553-6808
Lori@ldrcommunications.com

**Investor Relations Contact**
Westwicke Partners
John Woolford
(443) 213-0506
john.woolford@westwicke.com

Source: Dova Pharmaceuticals, Inc.