Dova Pharmaceuticals Announces FDA Acceptance of Supplemental New Drug Application for DOPTELET® (avatrombopag) for the Treatment of Chronic Immune Thrombocytopenia (ITP)

November 5, 2018

DURHAM, N.C., Nov. 05, 2018 (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 the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for DOPTELET (avatrombopag) for a new indication, the treatment of chronic immune thrombocytopenia (ITP) in patients who have had an insufficient response to a previous treatment. ITP is an autoimmune bleeding disorder characterized by thrombocytopenia, i.e., an abnormally low level of platelets. The Prescription Drug User Fee Act (PDUFA) goal date for an FDA decision on the sNDA is June 30, 2019.

DOPTELET, a second generation, orally administered thrombopoietin receptor agonist (TPO-RA), was approved by FDA in May 2018 for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

“Chronic ITP affects approximately 60,000 adults in the United States and despite the currently available therapies, which include two other TPO-RAs, there remains an important unmet need,” said Lee F. Allen, MD, PhD and Chief Medical Officer of Dova. “Acceptance of this sNDA is another significant milestone for Dova, and an important step towards addressing this underserved patient population and expanding the applications for DOPTELET as a treatment for thrombocytopenia. We look forward to working closely with the FDA as they review this sNDA.”

The ITP sNDA is supported by safety and efficacy data from one pivotal randomized, placebo-controlled Phase 3 clinical trial in the target indication that met its primary (number of weeks with a platelet count ≥$50x10^9$/L in the absence of rescue therapy) and first secondary (proportion of subjects with platelet counts ≥50×10^9/L on Day 8) efficacy endpoints with high statistical significance ($P<0.0001$). Data from the Phase 3 clinical trial has been recently published online (Br J Haematol. 2018 Sep 7. doi: 10.1111/bjh.15573. [Epub ahead of print]), and will be included in an upcoming volume of the British Journal of Haematology. Additional supportive efficacy data for the ITP sNDA are provided by two Phase 2 ITP clinical trials, as well as the two Phase 3 trials for the treatment of thrombocytopenia in patients with CLD. Data from all 24 studies in the avatrombopag clinical development program support the safety and tolerability of avatrombopag across multiple indications.

Indication and Important Safety Information

INDICATION

DOPTELET (avatrombopag) is indicated 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%) were: pyrexia, abdominal pain, nausea, headache, fatigue, and edema peripheral.

Please see full 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.

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 the potential timing of FDA review, the potential market of avatrombopag in patients with ITP, and Dova’s expectations regarding the possible approval of the sNDA. 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, 2017, filed with the U.S. Securities and Exchange Commission (SEC) on February 16, 2018, 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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