Dova Pharmaceuticals Submits Supplemental New Drug Application for DOPTELET® (avatrombopag) for the Treatment of Chronic ITP

September 4, 2018

DURHAM, N.C., Sept. 04, 2018 (GLOBE NEWSWIRE) -- Dova Pharmaceuticals, Inc. (NASDAQ: DOVA), a specialty pharmaceutical company focused on acquiring, developing, and commercializing drug candidates for diseases where there is a high unmet need, today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for DOPTELET (avatrombopag), the Company's second generation, orally administered thrombopoietin receptor agonist (TPO-RA), seeking approval for the treatment of adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The FDA previously granted orphan drug designation to avatrombopag for this indication. DOPTELET was recently approved by the FDA in May 2018 for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

"Following the exciting last few months with the approval and launch of DOPTELET for patients with CLD, Dova continues its forward momentum with the submission of our sNDA for DOPTELET for the treatment of patients with ITP," said Alex C. Sapir, President and CEO of Dova. "This represents another significant achievement for Dova that has the potential to expand the treatment applications for DOPTELET and validate its use for an additional indication. Despite the availability of two approved TPO receptor agonists for the treatment of chronic ITP, there remains an important unmet medical need."

"Given DOPTELET's convenient oral route of delivery, combined with its lack of hepatotoxicity or need for strict dietary restrictions with its administration, we believe DOPTELET, if approved by the FDA, is well-differentiated and has the potential to capture a meaningful share of the $1.5 billion global ITP market," Mr. Sapir added.

The ITP sNDA is supported by safety and efficacy data from one completed 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 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 will be published 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 that supported the recent approval of the CLD NDA. Data from all 24 studies in the avatrombopag clinical development plan 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 rare 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 expectations regarding the potential approval of DOPTELET for the treatment of adult patients with ITP who have had an insufficient response to a previous treatment and the potential to expand the treatment applications for DOPTELET. 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, Dova's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the SEC on August 9, 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.

Contacts

Mark W. Hahn
Chief Financial Officer
(919) 338-7936
mhahn@dova.com

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

dova.jpg

Source: Dova Pharmaceuticals, Inc.