



Dova Pharmaceuticals Announces FDA Approval of Supplemental New Drug Application for DOPTelet® (avatrombopag) for Treatment of Chronic Immune Thrombocytopenia (ITP)

June 27, 2019

Company Strengthens Thrombocytopenia Portfolio with ITP Approval and Expanded Partnership with Salix for Chronic Liver Disease (CLD) Indication

Company to Host Conference Call at 9am EST

DURHAM, N.C., June 27, 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 the U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application (sNDA) that expands the use of DOPTelet (avatrombopag) to include the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

DOPTelet is also FDA-approved for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. Earlier this week, Dova announced the marketing authorization granted by the European Commission for DOPTelet for the treatment of severe thrombocytopenia in adult patients with CLD who are scheduled to undergo an invasive procedure.

"Dova is pleased to provide DOPTelet to patients and physicians in the United States for the treatment of chronic ITP in adult patients who have had an insufficient response to a previous treatment," said Dr. David Zaccardelli, president and CEO of Dova. "In addition to offering patients with ITP a new treatment option, we expect DOPTelet will also address an important unmet medical need in the market. We sincerely thank the patients and dedicated researchers who participated in our clinical program as well as FDA for their collaboration during the review of this application."

DOPTelet is an oral, thrombopoietin receptor agonist (TPO-RA) administered with food. In the pivotal Phase 3 study, DOPTelet administration resulted in a platelet count of at least 50,000 per μL at day eight of therapy in the majority of patients, with efficacy superior to placebo in maintaining platelet counts in the target range during the 6-month treatment period. Additional supportive efficacy data for the ITP sNDA were provided by two Phase 2 ITP clinical trials, as well as two Phase 3 trials for the treatment of thrombocytopenia in patients with CLD.

Safety data for 128 patients with ITP, and more than 1,000 subjects treated across 24 studies in the DOPTelet clinical development program across multiple indications, support the safety and tolerability of DOPTelet.

"ITP patients should work with their clinician to choose a therapy that supports their lifestyle and aims to achieve the best possible result to treat their ITP. That's why having additional treatment options are so important," said Caroline Kruse, president and CEO of the Platelet Disorder Support Association, a patient advocacy organization dedicated to ITP patients. "We are thrilled to have a new, oral TPO-RA available for adult patients with ITP. Every new treatment provides more choices and new hope to our community."

Dova is committed to enabling patient access to DOPTelet. DOPTelet will be priced similarly to other TPO-RAs used to treat ITP, and Dova will continue to offer Patient Assistance and Co-Pay programs. The commercial launch of DOPTelet for ITP is anticipated to occur in mid-July 2019.

Dova also entered into an expanded partnership in the United States with Salix. Starting on July 1, 2019, in addition to the gastroenterology, colorectal surgery, and proctology segments, Salix will have the exclusive right to co-promote the CLD indication for DOPTelet to the hepatology and interventional radiology segments. Dova will continue to pay Salix a commission based on a percentage of net sales in these specialties, which will be in the mid-thirties beginning on July 1, 2019. In addition, the co-promotion agreement was extended to September 2023.

Dr. Zaccardelli added, "The expanded partnership with Salix builds additional momentum for DOPTelet and enables the Dova team to focus on a successful launch of the ITP indication. As a growing leader in the treatment of thrombocytopenia, we are committed to realizing DOPTelet's significant market opportunity in CLD, ITP and potentially chemotherapy-induced thrombocytopenia (CIT) for which we expect Phase 3 trial top-line results in the first half of 2020."

Full prescribing information for DOPTelet is available on Dova's website, www.Dova.com.

Company to Host Conference Call

Dova will host a conference call today, June 27, 2019 at 9:00 a.m. ET to discuss the approval. A question-and-answer session will follow Dova's remarks.

To participate on the live call, please dial 866-550-8145 (domestic) or +1-430-775-1344 (international) and provide the conference ID 2498719 five to 10 minutes before the start of the call.

A live audio webcast of the call will also be available via the "Investor Relations" page of the Dova website, www.dova.com. Please log on through Dova's website approximately 10 minutes before the scheduled start time. A replay of the webcast will be archived on Dova's website for 90 days following the call.

About Immune Thrombocytopenia (ITP)

ITP is a rare, autoimmune bleeding disorder that affects approximately 60,000 adults in the United States. It is characterized by low numbers of platelets that lead to excessive bruising and severe bleeding. ITP is considered chronic when symptoms last more than 12 months. Fatigue and depression are often associated with ITP, and the daily fear of severe bleeding can limit a patient's work life as well as social and leisure activities. Finding a treatment that works without side effects or lifestyle disruptions is another challenge for ITP patients. While there is no cure, TPO-RAs are commonly used to manage the disease effectively. However, factors such as weekly subcutaneous administration, potential liver toxicities, and food restrictions can be significant barriers to effective TPO-RA treatment.

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.
- Chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

IMPORTANT SAFETY INFORMATION FOR DOPTELET

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 or chronic immune thrombocytopenia. Portal vein thrombosis has been reported in patients with chronic liver disease, and thromboembolic events (arterial and venous) have been reported in patients with chronic immune thrombocytopenia treated with TPO receptor agonists.

In clinical trials, 0.2% (1/430) of patients with chronic liver disease treated with DOPTELET developed a treatment-emergent event of portal vein thrombosis. In clinical trials in patients with chronic immune thrombocytopenia, 7% (9/128) of patients treated with DOPTELET developed a thromboembolic event.

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 or chronic immune thrombocytopenia in an attempt to normalize platelet counts. Follow the dosing guidelines to achieve target platelet counts. Monitor patients receiving DOPTELET for signs and symptoms of thromboembolic events and institute treatment promptly.

Contraindications: None

Drug Interactions

Dose adjustments are recommended for patients with chronic immune thrombocytopenia taking moderate or strong dual CYP2C9 and CYP3A4 inducers or inhibitors.

Adverse Reactions

The most common adverse reactions ($\geq 3\%$) in patients with chronic liver disease were: pyrexia, abdominal pain, nausea, headache, fatigue, and peripheral edema.

The most common adverse reactions ($\geq 10\%$) in patients with chronic immune thrombocytopenia were: headache, fatigue, contusion, epistaxis, upper respiratory tract infection, arthralgia, gingival bleeding, petechiae, and nasopharyngitis.

Please see Full Prescribing Information for DOPTELET (avatrombopag) at [this link](#).

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 potential opportunities for DOPTELET, which include Salix's ability to continue commercialization capabilities with CLD in the United States, the pricing of DOPTELET, the timing of commercial launch of DOPTELET for ITP, the timing of results from Dova's Phase 3 clinical trial for the treatment of chemotherapy-induced thrombocytopenia and the potential to expand the treatment applications for DOPTELET to CIT and 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 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.