Dova Pharmaceuticals Reports Second Quarter 2019 Operating and Financial Results

August 6, 2019

- *DOPTELET® (avatrombopag) approved by U.S. Food and Drug Administration (FDA) for treatment of chronic immune thrombocytopenia (ITP); commercial launch occurred mid-July*
- *DOPTELET approved by European Commission (EC) for treatment of severe thrombocytopenia in patients with chronic liver disease (CLD)*
- *Second quarter 2019 net sales from DOPTELET of $3.5 million; channel inventory reduced by approximately $450,000 in Q2; prescription referrals increased approximately 7% compared to Q1*
- *Conference call scheduled for 9:00 a.m. ET today. Dr. James Bussel, a world-renowned expert in ITP, will share his opinions regarding the clinical positioning of DOPTELET for the treatment of ITP*

DURHAM, N.C., Aug. 06, 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 reported its operating and financial results for the second quarter ended June 30, 2019.

“The last few months have been a transformational period in Dova’s history, with FDA approval and launch of our thrombopoietin receptor agonist (TPO-RA) DOPTELET for ITP, European approval of DOPTELET for severe thrombocytopenia in adult patients with CLD, and an expanded co-promotion partnership with Salix for CLD. These accomplishments have strengthened our position as a growing leader in the treatment of thrombocytopenia,” said Dr. David Zaccardelli, President and Chief Executive Officer of Dova. “Beyond ITP, we look forward to results of our further indication expansion activities, with top-line data from our Phase 3 trial of DOPTELET for the treatment of chemotherapy induced thrombocytopenia (CIT) expected in the first half of 2020.”

Second Quarter and Subsequent Highlights

- **DOPTELET ITP Approval–** In late June, the FDA approved a supplemental New Drug Application (sNDA) that expanded the use of DOPTELET to include the treatment of thrombocytopenia in adult patients with ITP who have had an insufficient response to a previous treatment.
- **DOPTELET ITP Launch –** In mid-July, DOPTELET was launched commercially for the ITP indication. A sales force of approximately 60 sales professionals with extensive Hematology/Oncology experience, are now calling on roughly 6,000 HCPs that represent 96% of the ITP patient potential in the United States.
- **DOPTELET Differentiating Characteristics in ITP –**

  º DOPTELET is the only oral TPO-RA approved for use in adult patients with ITP that does not have a boxed warning for hepatotoxicity and does not require routine liver enzyme monitoring.
  º DOPTELET is the only oral TPO approved for use in adult patients with ITP without food-type restrictions.
  º DOPTELET, as an oral tablet, does not require weekly visits to a health care provider’s office for subcutaneous injections.
  º DOPTELET increased platelet counts to >50,000 in 66% of ITP patients by Day 8 of treatment in a Phase 3 trial.

- **DOPTELET ITP Publications -** Dova presented four abstracts on the safety and efficacy of avatrombopag from studies in patients with ITP at the 65th International Society on Thrombosis and Haemostasis (ISTH) Annual Scientific Meeting, held July 6-10, 2019, in Melbourne, Australia. These included efficacy data in patients who had previously received another TPO-RA, and the results of a dosing model study.
- **DOPTELET CLD MAA** – In late June, the EC granted marketing authorization for DOPTELET for the treatment of severe thrombocytopenia in adult patients with CLD who are scheduled to undergo an invasive procedure. Further, Dova continues to advance partnering discussions to commercialize DOPTELET in markets outside the US.

- **Salix Partnership –** Dova strategically expanded its co-promotion partnership for CLD in the United States with Salix. Starting on July 1, 2019, in addition to the gastroenterology, colorectal surgery, and proctology segments, Salix has the exclusive right to co-promote DOPTELET for the CLD indication 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 beginning on July 1, 2019, is expected to be in the mid-thirties. In addition, the co-promotion agreement was extended to September 2023.

- **Phase 3 CIT Clinical Trial** – Dova continues to enroll patients in a Phase 3 trial evaluating the safety and efficacy of DOPTELET for the treatment of CIT and plans to report top-line results in the first half of 2020.

DOPTELET CLD Launch Highlights

- Net product sales for DOPTELET were $3.5 million for the second quarter.

  º Inventory held by specialty pharmacies in Dova's contracted network decreased by approximately $450,000 from March 31, 2019 to June 30, 2019.
  º Prescription referrals increased approximately 7% in the second quarter of 2019 compared to the first quarter of 2019.
  º As expected, sales were negatively affected by competitive pricing pressure and payer restrictions in the second quarter of 2019, which Dova is addressing with the new pricing for DOPTELET implemented mid-July 2019.

- Early in the second quarter of 2019, a new marketing strategy for the CLD indication was launched, including revised product positioning, messaging, and a new action-oriented brand campaign.
- From launch through June 30, 2019, a total of 1,368 health care professionals have prescribed DOPTELET to their patients, with an increasing number of repeat prescribers.

- More than 9,200 calls were conducted, reaching more than 4,000 unique health care providers during the second quarter of 2019.

- For prescriptions in the second quarter of 2019 that have gone through the adjudication process with payers, 77% of those prescriptions were approved. On average, the time to decision for a referral was 7.4 business days in the second quarter of 2019.

Second Quarter Financial Results

Net product sales for DOPTELET were $3.5 million for the second quarter of 2019. Dova recognizes revenue when products are delivered to its specialty pharmacy partners.

Dova reported a net loss of $17.1 million for the second quarter of 2019, compared to a net loss of $19.7 million for the same period in 2018.

Cost of product sales for the second quarter were $0.4 million, which consisted of the cost of inventory, royalty payments and certain distribution and overhead costs.

Research and development expenses were $4.5 million in the second quarter of 2019, compared to $4.5 million for the same period in 2018.

Selling, general and administrative expenses were $15.5 million in the second quarter of 2019, compared to $18.6 million for the same period in 2018. The second quarter of 2018 saw higher expense levels as a result of the full sales staff being onboard for most of the second quarter of 2018 while in 2019 the full sales staff for the launch of DOPTELET for the ITP indication were hired at the end of the second quarter and early third quarter.

As of June 30, 2019, Dova had $76.8 million in cash and cash equivalents compared to $104.6 million as of December 31, 2018. Additionally, on May 6, 2019, Dova entered into an amended and restated loan agreement with Silicon Valley Bank that extended the interest only period of the existing $20 million loan facility by 12 months and provided additional potential borrowings of $30 million upon achieving certain clinical and revenue milestones. In July 2019, subsequent to the quarter end, Dova drew $10 million on this loan agreement upon approval in ITP.

Company to Host Conference Call

Dova will host a conference call today, August 6, 2019 at 9:00 a.m. ET to discuss second quarter ended June 30, 2019 financial results as well as recent operational highlights. 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 7784728 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.

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 (≥3%) in patients with chronic liver disease were: pyrexia, abdominal pain, nausea, headache, fatigue, and peripheral edema.

The most common adverse reactions (≥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, the timing of results from Dova's Phase 3 clinical trial for the treatment of CIT 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 June 30, 2019, filed with the SEC on August 6, 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.

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Dova Pharmaceuticals, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
	(unaudited)			
Revenue				
Product sales, net	$ 3,516	$ 1,957	$ 7,517	$ 1,957
Other revenue	-	2,627	-	2,627
Total revenue, net	3,516	4,584	7,517	4,584
Operating expenses:				
Cost of product sales (see Note A)	444	519	959	519
Research and development (see Note A)	4,505	4,508	8,589	7,924
Selling, general and administrative (see Note A)	15,496	18,565	31,250	28,826
Total operating expenses	20,445	23,592	40,798	37,269
Loss from operations	**(16,929)**	**(19,008)**	**(33,281)**	**(32,685)**
Other income, net	439	(195)	976	27
Interest expense	(574)	(454)	(1,138)	(769)
Total other expenses, net	(135)	(649)	(162)	(742)
Net loss	**$ (17,064)**	**$ (19,657)**	**$ (33,443)**	**$ (33,427)**
Net loss per share, basic and diluted	$ (0.60)	$ (0.70)	$ (1.18)	$ (1.22)
Weighted average common shares outstanding, basic and diluted	28,291,756	28,194,046	28,256,746	27,396,052

Note A
Stock-based compensation expense included in:

Cost of product sales	$ 57	$ 292	$ 87	$ 292
Research and development	347	582	845	1,012
Selling, general and administrative	2,326	3,318	5,011	5,703
Total stock-based compensation	$ 2,730	$ 4,192	$ 5,943	$ 7,007

	June 30, 2019	**December 31, 2018**
	(Unaudited)	
Cash and equivalents	$ 76,782	$ 104,566
Total assets	$ 87,182	$ 112,169
Debt/Note, short-term and long-term	$ 20,701	$ 20,608
Total liabilities	$ 36,374	$ 35,811
Total stockholders' equity	$ 50,808	$ 76,358

Source: Dova Pharmaceuticals, Inc.