Dova Pharmaceuticals Reports Third Quarter 2018 Operating and Financial Results

November 8, 2018

Third quarter net product sales of $2.9 million from DOPTELET® (avatrombopag); 335 cumulative unique prescribers from launch through September 30, 2018

sNDA accepted for review by FDA for DOPTELET for the treatment of chronic immune thrombocytopenia (ITP)

Entered into exclusive co-promotion agreement with Salix Pharmaceuticals to promote DOPTELET to gastroenterologists

Conference call scheduled for 4:30 p.m. ET today

DURHAM, N.C., Nov. 08, 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 reported its operating and financial results for the third quarter ended September 30, 2018.

"We continued to make steady progress in the third quarter with both our launch efforts for DOPTELET for patients with thrombocytopenia associated with chronic liver disease as well as the potential expansion of DOPTELET for additional indications," said Alex C. Sapir, President and Chief Executive Officer of Dova. "We were also delighted to have finalized an agreement with Salix Pharmaceuticals, one of the world's premier gastrointestinal pharmaceutical companies, in order to expand our reach to target gastroenterologists. We continue to hear very positive feedback from the market on how DOPTELET is performing in patients and because of that experience, we are consistently adding more new prescribers. In addition, we are also excited that FDA accepted the avatrombopag supplemental New Drug Application (sNDA) for review for the treatment of chronic ITP, which provides additional long-term growth potential for DOPTELET."

DOPTELET Launch Highlights

- From launch through September 30, 2018, a total of 335 health care professionals have prescribed DOPTELET to their patients with an increasing number using DOPTELET for multiple patients within their practice.
- During the third quarter, for prescriptions that completed the adjudication process with payers, Dova has seen 81% of those prescriptions approved by the payer with an average approval time of 7.9 days.
- Dova has made significant progress in its outreach efforts having reached 67% of target prescribers an average of 2.8 times from launch through September 30, 2018.
- Inventory held by specialty pharmacies increased by approximately 65% from July 1, 2018 to September 30, 2018 as certain specialty pharmacies increased their inventory levels and stocking locations based on increased patient shipments.
- In September, Dova entered into an exclusive co-promotion agreement with Salix Pharmaceuticals to co-promote DOPTELET in the United States. Salix is deploying approximately 100 sales specialists who will promote DOPTELET to gastroenterology healthcare professionals. Dova will continue its commercial efforts targeting primarily hepatologists and interventional radiologists and certain other specialties.

Other Important Highlights for the Quarter

- The U.S. FDA accepted for review Dova's sNDA for DOPTELET for the treatment of thrombocytopenia in adult patients with chronic ITP who have had an insufficient response to a previous treatment. The sNDA for ITP is supported by safety and efficacy data from two Phase 2 clinical trials and one randomized, placebo-controlled Phase 3 clinical trial that met its primary and secondary efficacy endpoints with high statistical significance. The Prescription Drug User Fee Act (PDUFA) goal date for an FDA decision is June 30, 2019.
- Following the submission in April of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for DOPTELET for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure, the Company expects a target decision date for approval in Europe in the second or third quarter of 2019.

- Enrollment remains ongoing for the Company's Phase 3 clinical trial for the treatment of patients with chemotherapy-induced thrombocytopenia (CIT), the pre-surgery study treating thrombocytopenia, and the CLD registry study.

Third Quarter and Financial Results

Dova reported a net loss of $19.5 million for the third quarter of 2018, compared to a net loss of $9.7 million for the same period in 2017.

For the third quarter of 2018, Dova reported net product sales from DOPTELET of $2.9 million. The Company recognizes revenue when products are delivered to its specialty pharmacy partners.

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

Research and development expenses were $4.8 million in the third quarter of 2018, compared to $5.4 million for the same period in 2017. The decrease was primarily driven by the $1.0 million milestone payment that Dova became obligated to pay Astellas upon submission of the NDA and the completion of the clinical trials in 2017 of DOPTELET, partially offset by the initiation of clinical trials to evaluate DOPTELET for the treatment of a broader population of surgical patients as well as for CIT.

Selling, general and administrative expenses were $17.0 million in the third quarter of 2018, compared to $4.2 million for the same period in 2017. The increase was primarily driven by increased headcount and sales and marketing activities to support the commercial launch of DOPTELET, increased corporate infrastructure, and additional costs associated with operating as a public entity.

As of September 30, 2018, Dova had $122.0 million in cash and equivalents compared to $94.8 million as of December 31, 2017.

Company to Host Conference Call

Dova will host a conference call today, November 8, 2018 at 4:30 p.m. ET to discuss third quarter 2018 financial results and 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 2574148 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.

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 by FDA of DOPTELET for the treatment of adult patients with ITP who have had an insufficient response to a previous treatment, , the potential timing of approval by the EMA of DOPTELET for the treatment of thrombocytopenia in adult patients with CLD who are scheduled to undergo a procedure 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 September 30, 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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Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue				
Product sales, net	$ 2,929	$ —	$ 4,886	$ —
Other revenue	—	—	2,627	—
Total revenue, net	2,929	—	7,513	—
Operating expenses:				
Cost of product sales	370	—	889	—
Research and development	4,847	5,426	12,771	12,995
Selling, general and administrative	17,031	4,185	45,856	7,045
Total operating expenses	22,248	9,611	59,516	20,040
Loss from operations	**(19,319)**	**(9,611)**	**(52,003)**	**(20,040)**
Interest income and other income (expense), net	342	224	369	243
Interest expense	(546)	(336)	(1,315)	(857)
Total other expenses, net	(204)	(112)	(946)	(614)
Net loss	**$ (19,523)**	**$ (9,723)**	**$ (52,949)**	**$ (20,654)**
Net loss per share, basic and diluted	$ (0.69)	$ (0.38)	$ (1.91)	$ (1.03)
Weighted average common shares outstanding, basic and diluted	28,203,222	25,290,709	27,668,066	20,014,226

Summary Balance Sheet Data

(In thousands)

	September 30, 2018 (unaudited)	**December 31, 2017**
Cash and equivalents	$ 122,027	$ 94,846
Total assets	**$ 130,089**	**$ 96,379**
Debt/Note, short-term and long-term	$ 20,378	$ 30,212
Total liabilities	**$ 35,891**	**$ 35,197**
Total stockholders' equity	$ 94,198	$ 61,182

Source: Dova Pharmaceuticals, Inc.