BAUSCH Health

Dova Pharmaceuticals and Salix Enter Into Exclusive Co-Promotion Agreement For DOPTELET® (Avatrombopag)

September 27, 2018

Salix Sales Force to Promote First FDA-Approved Drug for Thrombocytopenia in Chronic Liver Disease Patients Scheduled to Undergo a Procedure

DURHAM, N.C. and BRIDGEWATER, N.J., Sept. 27, 2018 (GLOBE NEWSWIRE) -- Dova Pharmaceuticals, Inc. (“Dova”) (NASDAQ: DOVA), a specialty pharmaceutical company focused on acquiring, developing, and commercializing drug candidates for diseases where there is a high unmet need, and Salix Pharmaceuticals (“Salix”), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases and its parent company, Bausch Health Companies Inc. (NYSE/TSX: BHC), today announced that they have entered into an exclusive agreement to co-promote Dova’s DOPTELET (avatrombopag) in the United States (U.S.). The U.S. Food and Drug Administration ("FDA") approved DOPTELET on May 21, 2018 for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. DOPTELET represents the first thrombopoietin (TPO) receptor agonist approved in the United States for this indication.

Salix PHARMACEUTICALS

Thrombocytopenia, a condition in which patients have a low platelet count, is the most common hematological abnormality in patients with CLD that often worsens with the severity of liver disease. It is estimated that approximately 15 percent of the 7.5 million patients with CLD have some form of thrombocytopenia. In a study published in 2010, patients with severe thrombocytopenia (<75,000/µL) had a 31 percent incidence of procedure-related bleeding. As a result of the associated increased rate of bleeding, there is an increased risk for the CLD patient when undergoing common scheduled medical procedures such as liver biopsy, colonoscopy, endoscopy, and routine dental procedures.

As part of the co-promotion arrangement, Salix intends to deploy approximately 100 sales specialists who will promote DOPTELET to gastroenterology healthcare professionals. The Salix sales force will begin selling DOPTELET in mid-October 2018. Dova will continue its commercial efforts targeting primarily hepatologists and interventional radiologists and certain other specialties. Pursuant to the agreement, Dova will pay Salix a quarterly fee based on net sales (as defined in the agreement) of DOPTELET prescribed by gastroenterologists in the U.S.

“We are delighted to be working with Salix, a company considered by many to have the preeminent gastroenterology sales force in the United States,” said Alex C. Sapir, president and chief executive officer, Dova Pharmaceuticals. “Given Salix’s presence and strong reputation

within large gastroenterology group practices coupled with the early interest we are seeing among the gastroenterology community, we are excited to see the impact this partnership will bring to DOPTELET and to patients."

"Salix considers liver disease a strategic therapeutic area of focus, given our history and knowledge with XIFAXAN® (rifaximin), an innovative medicine indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults, a condition that is often a consequence of chronic liver disease," said Mark McKenna, president, Salix Pharmaceuticals. "Adding DOPTELET to our portfolio will enable our sales force to promote yet another innovative product that addresses a true unmet need in the marketplace."

About DOPTELET
DOPTELET (avatrombopag) is a second generation, once daily, orally administered TPO receptor agonist approved for the treatment of thrombocytopenia in adult patients with CLD who are scheduled to undergo a procedure. DOPTELET is designed to mimic the effects of TPO, the primary regulator of normal platelet production.

Two global Phase 3, double-blind, placebo-controlled trials (ADAPT-1 [N=231] and ADAPT-2 [N=204]), conducted in adults with thrombocytopenia (platelet count of less than 50,000/μL) and CLD, supported the FDA approval. Patients were assigned to either 40 mg or 60 mg of avatrombopag daily for five days based on their Baseline platelet counts (40 to <50,000/μmL or <40,000/μmL, respectively). Avatrombopag was shown to be superior to placebo in increasing the proportion of patients not requiring platelet transfusions or rescue procedures for bleeding up to seven days following a scheduled procedure in both trials in both the 40 mg (ADAPT-1, 88% vs. 38%, p <0.0001; ADAPT-2, 88% vs. 33%; p<0.0001), and 60 mg (ADAPT-1, 66% vs. 23%, p <0.0001; ADAPT-2, 69% vs. 35%; p=0.0006) treatment groups. Avatrombopag was also superior to placebo at the two secondary efficacy endpoints in each trial. In the avatrombopag treatment groups, there was an increased proportion of patients achieving the target platelet count of ≥50,000/μmL on procedure day, and a greater magnitude of the change in mean platelet count from baseline to procedure day; all treatment differences between the avatrombopag and placebo treatment groups for each secondary endpoint were highly statistically significant with p values <0.0001. The most common adverse reactions with avatrombopag included pyrexia, abdominal pain, nausea, headache, fatigue and edema peripheral. Portal vein thromboses have been reported in patients with CLD and in patients receiving TPO receptor agonists. One treatment-emergent event of portal vein thrombosis was reported in the ADAPT trials in an avatrombopag-treated patient.

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 one 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 XIFAXAN
XIFAXAN is a nonsystemic* antibiotic that slows the growth of bacteria in the gut that are believed to be linked to symptoms of overt hepatic encephalopathy (HE). It has been proven to reduce the risk of overt HE recurrence and HE-related hospitalizations in adults.

*There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.

INDICATION
XIFAXAN (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is not for everyone. Do not take XIFAXAN if you have a known hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in XIFAXAN.
- If you take antibiotics, like XIFAXAN, there is a chance you could experience diarrhea caused by an overgrowth of bacteria (*C. difficile*). This can cause symptoms ranging in severity from mild diarrhea to life-threatening colitis. Contact your healthcare provider if your diarrhea does not improve or worsens.
- Talk to your healthcare provider before taking XIFAXAN if you have severe hepatic (liver) impairment, as this may cause increased effects of the medicine.
- Tell your healthcare provider if you are taking drugs called P-glycoprotein and/or OATPs inhibitors (such as cyclosporine) because using these drugs with XIFAXAN may lead to an increase in the amount of XIFAXAN absorbed by your body.
- In clinical studies, the most common side effects of XIFAXAN were:

HE: Peripheral edema (swelling, usually in the ankles or lower limbs), nausea (feeling sick to your stomach), dizziness, fatigue (feeling tired), and ascites (a buildup of fluid in the abdomen)
IBS-D: Nausea (feeling sick to your stomach) and an increase in liver enzymes

- XIFAXAN may affect warfarin activity when taken together. Tell your healthcare provider if you are taking warfarin because the dose of warfarin may need to be adjusted to maintain proper blood-thinning effect.
- If you are pregnant, planning to become pregnant, or nursing, talk to your healthcare provider before taking XIFAXAN because XIFAXAN may cause harm to an unborn baby or nursing infant.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit
www.fda.gov/medwatch
or call 1-800-FDA-1088.

For product information, adverse event reports, and product complaint reports, please contact:
Salix Product Information Call Center
Phone: 1-800-321-4576
Fax: 1-510-595-8183
Email:
salixmc@dlss.com

Please click
here
for full Prescribing Information.

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 CLD scheduled to undergo a procedure.

About Salix
Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm health care providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, New Jersey.

About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at
www.bauschhealth.com
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Dova Pharmaceuticals 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 benefits of the collaboration, the timing of the Salix sales force beginning to sell DOPTELET and other information relating to the transaction between Dova and Salix. 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.

Bausch Health Forward-looking Statements This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health and Salix undertake no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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The Xifaxan 550 mg product and the Xifaxan trademark are licensed by Alfasigma S.p.A. to Salix Pharmaceuticals or its affiliates.

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