

Valeant Pharmaceuticals Announces Licensing Agreement With Norgine B.V. For NER1006 In U.S. And Canada

August 08, 2016

LAVAL, Quebec, Aug. 8, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant" or the "Company") today announced that it has entered into a licensing agreement with Norgine B.V. ("Norgine"); under which Valeant has obtained the rights to develop and commercialize NER1006 Powder for Oral Solution in the U.S. and Canada. NER1006 is a novel, low-volume (1L) polyethylene glycol-based bowel preparation for cleansing of the colon in preparation of colonoscopy, whose U.S. regulatory filing is anticipated in 2016.

Norgine is a European specialist pharmaceutical company focused on developing, manufacturing, and marketing its products in various therapeutic areas, including: gastroenterology, hepatology, and critical and supportive care.

NER1006 has been developed to provide overall bowel cleansing, with an additional focus on the ascending colon in adults. The NER1006 Phase III clinical trial program is now completed and includes three multicenter randomized parallel group studies: NOCT, MORA, and DAYB. The NOCT and MORA studies support efficacy, whereas the DAYB study contributes to the safety evaluation.

"We are excited to partner with Norgine to bring an innovative treatment to the patients that need it most," said Joseph C. Papa, chairman and chief executive officer of Valeant. "To date, NER1006's clinical results have been positive and it is an excellent strategic fit with the Salix portfolio that will enhance our gastrointestinal business. This agreement reflects our commitment to bolstering R&D and our commercial offerings as we continue to shape Valeant for the future."

Peter Stein, CEO at Norgine said, "We are extremely pleased to enter into this agreement with Valeant and build upon our successful partnership for MOVIPREP®. Valeant has an established presence in gastroenterology in the U.S. and Canada and a strong portfolio of products in this therapy area. As a European specialist pharma company, Norgine is entirely focused upon the development and commercialization of products in Europe. Valeant is therefore an excellent choice as our partner for the launch of NER1006 in the U.S. and Canada."

Norgine will manufacture and supply NER1006 for Valeant. Financial terms of the agreement have not been disclosed.

About NER1006

NER1006 is a novel, low-volume (1L) polyethylene glycol based bowel preparation that has been developed to provide whole bowel cleansing, with an additional focus on the ascending colon. This low-volume solution is developed not only to support improved patient acceptability and compliance but also to contribute to effectiveness of colonoscopy procedures at detecting colon cancer and for optimized bowel surveillance, through effective bowel cleansing.

About NOCT, MORA and DAYB studies

- NOCT study. A U.S. study that compares NER1006 versus a trisulfate bowel cleansing solution (SUPREP[®]) using a 2-day split-dosing regimen in adults. Both primary endpoints were met, achieving non-inferior overall bowel cleansing success and 'Excellent plus Good' cleansing of the colon ascendens using the Harefield Cleansing Scale (HCS).
- MORA study. A European study that compares NER1006 versus a 2L PEG (MOVIPREP[®]) with ascorbate bowel cleansing solution using a 2-day split-dosing regimen and a 1-day morning split-dosing regimen in adults. The study met both primary endpoints showing that when administered as either a 2-day overnight or 1-day morning split-dosing regimen, and compared to 2L PEG, NER1006 was non-inferior in achieving overall bowel cleansing, and non-inferior and superior in achieving 'Excellent plus Good' cleansing of the colon ascendens.
- DAYB study. A European study that compares NER1006 versus a sodium picosulfate and magnesium salt solution (CITRAFLEET[®]) using a day before only split-dosing regimen in adults. Although the study met both primary endpoints, demonstrating non inferiority, the data will contribute to safety evaluation only. The study used a dosing schedule for the comparator that is not relevant to current medical practice in U.S.

About MOVIPREP[®]

MOVIPREP[®] is a polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid for oral solution, indicated for colon cleansing as preparation for colonoscopy in adults.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorders, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com.

About Norgine

Norgine is a European specialist pharmaceutical company that has been established for over 100 years. Norgine provides expertise and 'know how' in Europe to develop, manufacture and market products that offer real value to healthcare professionals, payers and patients. Norgine's approach and infrastructure is integrated and focused upon ensuring that Norgine wins partnership opportunities for growth. Norgine is headquartered in the Netherlands and its global operations are based in Amsterdam and in Harefield, UK. Norgine owns a R&D site in Hengoed, Wales and two manufacturing sites, one in Hengoed, Wales, and one in Dreux, France. For more information, please visit www.norgine.com

Forward-looking Statements

This press release may contain forward-looking statements, including, but not limited to, statements regarding expected regulatory filings. Forward-looking statements 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 Company's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which

factors are incorporated herein by reference. 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. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes, unless required by law.

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