

# Valeant Pharmaceuticals Announces Regulatory Approval of Onsolis(TM) in Canada

May 10, 2010

ALISO VIEJO, Calif., May 10, 2010 /PRNewswire via COMTEX/ --Valeant Pharmaceuticals International (NYSE: VRX) today announced that its wholly owned subsidiary, Valeant Canada Limited, has received notice that the New Drug Submission for Onsolis (fentanyl buccal soluble film) has been approved from the Canadian regulatory authority Health Canada. Onsolis is an opioid analgesic indicated only for the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their persistent baseline cancer pain. Onsolis will be the first available fentanyl product with rapid onset of action approved in Canada and is expected to be available for patients in the third quarter of 2010. The product will be commercialized by the joint venture between Meda AB and Valeant Canada Limited (Meda Valeant Pharma Canada Inc.).

"We are excited to receive approval for our first product to come out of our joint venture with Meda," said J. Michael Pearson, chairman and chief executive officer. "Breakthrough pain is an unmet medical need in cancer patients in Canada and currently no drug is approved in Canada for this indication. Onsolis uses a patented delivery system designed to provide rapid and reliable delivery of fentanyl for the treatment of breakthrough pain in adult cancer patients."

Canada represents an important market for Onsolis. It is estimated that there are over 700,000 people diagnosed with cancer in Canada(1), with 30% suffering from pain(2), and that 65% of these sufferers will also have breakthrough cancer pain(3).

## **Indication**

Onsolis (fentanyl citrate) buccal soluble film is indicated only for the management of breakthrough pain in adult cancer patients, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain.

Patients considered opioid tolerant are those who are taking at least 60 mg/day morphine equivalents for a week or longer. All patients starting treatment with Onsolis must begin with titration from the 200 mcg dose.

This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression could occur in patients not taking chronic opiates. For this reason, Onsolis is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room.

Onsolis is intended to be used only by healthcare professionals who are knowledgeable of, and skilled in the use of opioids to treat cancer pain.

## **About Valeant**

Valeant Pharmaceuticals International (NYSE: VRX) is a multinational specialty pharmaceutical company that develops and markets a broad range of pharmaceutical products primarily in the areas of neurology and dermatology. More information about Valeant can be found at

## Forward-looking Statements

This press release may contain forward-looking statements, including, but not limited to, statements regarding the timing of when Onsolis is expected to be available for patients and its potential to aid patients who have breakthrough cancer pain. Forward-looking statements may be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," 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 filed with the Securities and Exchange Commission, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. 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.

(1) Canadian Cancer Society: Canadian Cancer Statistics 2009

(2) Management of Cancer Pain. Levy M., & Samuel, T Semin Oncol 32: 179-193, 2005

(3) Breakthrough Cancer Pain Characteristics and Syndromes in Patients with Cancer Pain. An International Survey. Caraceni et al, Palliative Medicine 2004; 18: 177 et seq

### Contact:

Laurie W. Little  
Valeant Pharmaceuticals  
949-461-6002  
[laurie.little@valeant.com](mailto:laurie.little@valeant.com)



### Investor Inquiries

[ir@bauschhealth.com](mailto:ir@bauschhealth.com)  
877-281-6642  
514-856-3855 (Canada)

### Media inquiries

[Corporate.communications@bauschhealth.com](mailto:Corporate.communications@bauschhealth.com)  
908-569-3692

[LEGAL NOTICE](#)

[PRIVACY POLICY](#)

[EMAIL ALERTS](#)

[EMAIL PAGE](#)

[RSS FEED](#)

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.  
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.U.S.A.18 V2.0

**CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION**