

Media contacts:

Julie Wu
Manager, Public Affairs
Merck
514-428-3765
julie.wu@spcorp.com

Sophie Côté Laplante
Associate
NATIONAL Public Relations
514-843-2376
scotelaplante@national.ca

MORE WOMEN CAN PREVENT CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING

EMEND[®] indication updated by Health Canada includes broader group of women patients

Montreal, Canada, May 26, 2010 – More women fighting cancers such as breast, lung, colorectal and ovarian can now help prevent the nausea and vomiting associated with their treatment of moderately emetogenic (vomit-inducing) cancer chemotherapy (MEC). Although new treatment entities have been developed in the past 10 years for control of chemically-induced nausea and vomiting (CINV), CINV remains a significant problem in the context of current practice.¹

Today Merck announced that Health Canada has updated the indication for EMEND[®] (aprepitant) in combination with a 5-HT₃ antagonist class of antiemetics and dexamethasone for the prevention of nausea and vomiting in women due to treatment with moderately emetogenic cancer chemotherapy (MEC). This new indication replaces the former indication "for the prevention of nausea and vomiting in women due to moderately emetogenic cancer chemotherapy consisting of cyclophosphamide and anthracycline". The indication in prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy remains unchanged.²

Consequences of chemotherapy-induced nausea and vomiting

Up to 75 per cent of cancer patients can experience CINV.^{3,4,5} Patients who are beginning cancer treatment consistently list CINV as one of their greatest fears.⁶ Uncontrolled nausea and vomiting might even influence patients to discontinue their treatment early.⁵

The burden that CINV places on patients with cancer and the healthcare system can be considerable. In observational studies:

- 90 per cent of patients affected with CINV reported an impact on their quality of life⁷
- Over one in eight patients had a follow-up hospital visit associated with CINV defined as outpatient hospital visit, emergency room visit or hospitalization. Hospitalization was the most common type of visit for uncontrolled CINV.

(more)

More patients reported no vomiting

A randomized, double-blind, gender-stratified, parallel-group study involved 848 patients with a variety of tumour types – breast, lung, colorectal and ovarian.⁸ Patients scheduled to receive a single dose of one or more of a broad range of moderately emetogenic chemotherapy agents (any IV dose of carboplatin, oxaliplatin, epirubicin, idarubicin, ifosfamide, irinotecan, daunorubicin, doxorubicin; cyclophosphamide IV < 1500 mg /m² ; or cytarabine IV > 1 g/m²) were randomized into the:

- Aprepitant group who received an antiemetic regimen consisting of 125 mg aprepitant, ondansetron 8 mg twice daily and dexamethasone 12 mg on Day 1, and aprepitant 80 mg once daily on Days 2 and 3 (N=430).
- Control group or standard therapy group who received ondansetron 8 mg twice daily and dexamethasone 20 mg on Day 1 and ondansetron 8 mg twice daily on Days 2 and 3 (N=418).

The study's primary efficacy endpoint was met as significantly more patients taking aprepitant in combination with standard therapy reported no vomiting during the 120 hours following initiation of the first cycle of chemotherapy compared to the control group (76.2 per cent vs. 62.1 per cent, p<0.0001).⁸

In addition, the study's key secondary efficacy endpoint was met as significantly more patients achieved a complete response (defined as no vomiting and no use of rescue medications) up to 120 hours post-chemotherapy compared to the control group (68.7 per cent vs. 56.3 per cent, p=0.0003).⁸

Aprepitant generally well tolerated

In this study, the overall incidence and types of adverse events were generally similar between the two treatment groups. The percentage of patients with drug-related adverse events, serious adverse events (including deaths), and adverse events resulting in discontinuation were comparable in the two treatment groups. The most frequently reported drug-related clinical adverse events in both treatment groups were constipation, fatigue, headache and diarrhea.

Information about EMEND®

EMEND® (aprepitant), Merck's neurokinin 1 (NK1) receptor antagonist, obtained Canadian approval in October 2007 and is indicated in combination with a 5-HT₃ antagonist class of antiemetics and dexamethasone for the prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting in women due to treatment with moderately emetogenic cancer chemotherapy.

The intravenous formulation of EMEND® was approved in April 2009 as EMEND® IV (fosaprepitant dimeglumine).

(more)

Aprepitant is believed to work through a novel mechanism, which primarily blocks nausea and vomiting signals in the brain by targeting substance P, a key neurotransmitter involved in the emetic pathway. By blocking the actions of multiple signals, a combination of aprepitant with other anti-emetic medicines works to provide more complete protection against the nausea and vomiting caused by chemotherapy.

Recommended dosing is 125 mg of oral aprepitant one hour prior to chemotherapy treatment or 115 mg of fosaprepitant intravenously 30 minutes prior to chemotherapy (day 1) and 80 mg of oral aprepitant once daily in the morning on days 2 and 3; in addition to a corticosteroid and a 5-HT3 antagonist. Aprepitant may be taken with or without food.

The overall safety of aprepitant was evaluated in approximately 4300 individuals. The most common adverse experiences, regardless of causality, occurring in patients receiving highly emetogenic chemotherapy who were treated with oral aprepitant in clinical studies (cycle 1) were: asthenia/fatigue (17.8 per cent), nausea (12.7 per cent), hiccups (10.8 per cent), diarrhea (10.3 per cent), constipation (10.3%), anorexia (10.1 per cent). The most common adverse experiences, regardless of causality, occurring in patients receiving moderately emetogenic chemotherapy who were treated with aprepitant in clinical studies (cycle 1) were: fatigue (15.4 per cent), alopecia (12.4 per cent), headache (13.2 per cent), and constipation (10.3 per cent).

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our medicines, vaccines, biologic therapies, and consumer and animal products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching programs that donate and deliver our products to the people who need them. Merck. Be Well. For more information, visit www.merck.com.

Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the proposed merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's and Schering-Plough's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

(more)

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period, due to, among other things, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2008 Annual Report on Form 10-K, Schering-Plough's Quarterly Report on Form 10-Q for the quarterly period ended Sept. 30, 2009, the proxy statement filed by Merck on June 25, 2009 and each company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

###

EMEND® is a Registered Trademark of Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**, Used under license.

¹ Lachaine J, Yelle L, Kaizer L, Dufour A, et al. Chemotherapy-induced emesis : quality of life and economic impact in the context of current practice in Canada. *Supportive Cancer Therapy* 2005;2:181-7.

² EMEND® Product Monograph February 2010.

³ Wisner W, Berger A. Practical management of chemotherapy-induced nausea and vomiting. *Oncology* (Williston Park) 2005; 19:637-45.

⁴ Erazo Valle A, Wisniewski T, Figueroa Vadillo JI, et al. Incidence of chemotherapy-induced nausea and vomiting in Mexico; healthcare provider predictions versus observed. *Curr Med Res Opin* 2006; 22:2403-10.

⁵ NCCN Clinical Practice Guidelines in Oncology; Antiemesis, Version 2.2010.

⁶ Viale PH. Integrating aprepitant and palonosetron into clinical practice: a role for the new antiemetics. *Clin J Oncol Nurs* 2005; 9:77-84.

⁷ Ballatori E, Roila F, Ruggeri B, et al. The impact of chemotherapy-induced nausea and vomiting on health-related quality of life. *Support Care Cancer* 2007; 15:179-85

⁸ Rapoport BL, Jordan K, Boice JA, Taylor A, Brown C, et al. Aprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with a broad range of moderately emetogenic chemotherapies and tumor types: a randomized, double-blind study. *Support Care Cancer* 2010;18:423-431.