

**FOR IMMEDIATE DISTRIBUTION**

**FIGHTING CANCER OFTEN INVOLVES BATTLING TREATMENT SIDE EFFECTS**

*New study shows EMEND® significantly improved prevention of chemotherapy-induced nausea and vomiting, when added to standard therapy*

**Kirkland, Quebec – June 25, 2009** – Presented today in Rome during the Multinational Association of Supportive Care in Cancer (MASCC) meeting, a new study showed that EMEND® (aprepitant) in combination with a standard antiemetic regimen of ondansetron and dexamethasone significantly improved the prevention of chemotherapy-induced nausea and vomiting (CINV) in both men and women with various cancer types – breast, lung, colorectal and ovarian – who received a first cycle of a broad range of moderately emetogenic (vomit-inducing) chemotherapy. In fact, this study included the broadest range of patients, tumour types and chemotherapy regimens to date in a clinical trial of an NK1 (neurokinin 1) inhibitor like aprepitant.

"These research findings are important," said Dr. David Warr, a Toronto-based oncologist. "Before this study was carried out, the drugs to combat nausea and vomiting had only been tested in patients who received a couple of common chemotherapy treatments for breast cancer or high dose cisplatin. We didn't have a clear idea of how common these problems were with other very widely used chemotherapy programs or whether aprepitant was necessary in addition to the usually administered antiemetics. We now have confirmation that the nausea and vomiting are more common than what many physicians believe and that aprepitant can significantly benefit these patients."

"I've been cancer free for over five years now, but when I went through chemotherapy my best friend and ally was my chemo nurse," said Montreal resident Jean Stutsman. "Cancer changes your life and affects everyone around you. Our minds and bodies are involved in a fight against cancer and that often means battling against treatment side effects too."

"Chemotherapy induced nausea and vomiting (CINV) remains an important issue for people dealing with cancer," states Kim Chapman, president of the Canadian Association of Nurses in Oncology (CANO). "Key to the prevention or management of CINV is the understanding of the patient's experience. Oncology Nurses have the ability to consistently and in a standardized way identify a patient's experience with CINV. People on chemotherapy need to tell their nurse or doctor if they experience nausea and vomiting even if they currently are taking anti-nausea medication so that changes can be made to get even better control. There are many ways to manage nausea and vomiting without the need for dose reduction or other changes to the chemotherapy."

“This news is most welcome,” said Barry Stein, cancer survivor, activist and president of the Colorectal Cancer Association of Canada (CCAC). “Who can forget those first few days after commencing treatment and wondering how we will get through the side effects! EMEND® in combination with other medications may go a long way to help colorectal and other cancer patients who are undergoing chemotherapy get through their treatment so they can maximize its benefit. When faced with the challenge of completing difficult treatments at any stage of the disease, minimization of the side effects will also enhance the quality of life of patients.”

### **More patients reported no vomiting**

The study’s primary efficacy endpoint was met when 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,  $p < 0.01$ ).

In addition, the study’s secondary efficacy endpoint was met when 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,  $p < 0.01$ ).

This randomized, double-blind, gender-stratified, parallel-group study involved 848 male and female patients with a variety of tumour types--breast, lung, colorectal and ovarian. Patients scheduled to receive a single dose of moderately emetogenic chemotherapy with one or more of a broad range of agents (carboplatin, oxaliplatin, epirubicin, idarubicin, ifosfamide, irinotecan, daunorubicin, doxorubicin, cyclophosphamide or cytarabine) were randomized into:

- Those taking aprepitant 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).
- Those in the control group who received the standard regimen consisting of 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).

### **Aprepitant well tolerated**

The overall incidence and types of adverse events were similar between the two treatment groups. The number of patients with drug-related adverse events, serious adverse events (including deaths), and adverse events resulting in discontinuation were similar 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<sup>®</sup>**

EMEND<sup>®</sup> (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 for the prevention of nausea and vomiting in women due to treatment with moderately emetogenic cancer chemotherapy consisting of cyclophosphamide and anthracycline. The intravenous formulation of EMEND<sup>®</sup> was approved in April 2009 as EMEND<sup>®</sup> IV (fosaprepitant).

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.

## **About Merck Frosst**

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company discovering, developing and marketing a broad range of innovative medicines and vaccines to improve human health. Merck Frosst is one of the top 25 R&D investors in Canada, with an investment of close to \$110 million in 2007. More information about Merck Frosst is available at <http://www.merckfrosst.com>.

## **Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

EMEND<sup>®</sup> is a trademark of Merck & Co., Inc., Used under license

- 30 -

**FOR MORE INFORMATION PLEASE CONTACT:**

Sheila Murphy  
Manager, Public Affairs  
Merck Frosst Canada Ltd.  
514-241-8550

Roch Landriault / Stephanie Lyttle  
NATIONAL Public Relations  
514-843-2345 / 514-843-2365  
[rlandriault@national.ca](mailto:rlandriault@national.ca)  
[slyttle@national.ca](mailto:slyttle@national.ca)