

FOR IMMEDIATE RELEASE

**MERCK'S INVESTIGATIONAL SHINGLES VACCINE REDUCED THE INCIDENCE,
SEVERITY AND DURATION OF SHINGLES PAIN IN NEW STUDY PUBLISHED
IN *THE NEW ENGLAND JOURNAL OF MEDICINE***

MONTREAL, Quebec – June 2, 2005 – An investigational live attenuated Oka/Merck VZV vaccine (“investigational shingles vaccine”) developed by Merck & Co., Inc. reduced the total burden of pain and discomfort associated with shingles by 61 per cent compared to placebo, according to a new study published in today’s issue of *The New England Journal of Medicine*. The Phase III Shingles Prevention Study was conducted by Merck in collaboration with the US Department of Veterans Affairs and the National Institute of Allergy and Infectious Diseases over five years in more than 38,500 men and women age 60 and older.

Shingles is a common, frequently painful disease that can occur without warning in anyone who has had varicella (chickenpox) – nearly all adults in Canada are at risk (25 million in 2005).

“The study results are considerable in that they also showed the investigational shingles vaccine reduced by 67 per cent the incidence of persistent nerve pain which is the most frequent complication of shingles known as postherpetic neuralgia (PHN),” said Dr. Aline Boulanger, Director of the Pain and Anaesthesiology Clinic, Hôpital Sacré-Coeur, Montreal, and Director of the Pain Clinic at the Hôtel-Dieu Hospital, part of the Centre Hospitalier de l’Université de Montréal (CHUM). “PHN pain can last for weeks, months or even years, even the touch of a sheet or a piece of clothing against the affected area can be very painful for someone suffering from PHN.”

“Three years ago I noticed an itchy, painful sore on my head that my doctor thought was an allergic reaction to a hair product,” explained Ms. Fernande Dumont who was finally diagnosed with shingles when other sores developed down her cheek and neck. “At the time my pain was constant but every hour and half it increased so that my head felt like it was being drilled into for about 45 seconds. For the past two years I’ve still had to take medicine to try and relieve the pain and I’m also taking an anti-depressant.”

Study design

The randomized, double-blind, placebo-controlled study was conducted to determine whether vaccination with a single dose of the investigational shingles vaccine (n=19,270) would decrease the incidence and/or severity of shingles and PHN in men and women age 60 and older with no previous history of shingles compared to placebo (n=19,276).

The primary endpoint of the study was the burden of illness (BOI) caused by shingles over the first six months after shingles rash onset, a measure affected by the incidence, severity and duration of shingles-associated pain and discomfort. Severity of pain was evaluated according to a “worst pain” score on a 0-to-10 scale using a validated questionnaire (Zoster Brief Pain Inventory) with a zero being no pain and a 10 being worst pain imaginable. Those in the study who did not develop shingles were assigned a score of zero. The BOI score represented the average severity of illness among all subjects in the vaccine or placebo group.

The study also evaluated the incidence of PHN in the group that received the investigational shingles vaccine compared to placebo. PHN was defined as shingles-associated pain (rated as ≥ 3 on a 0-to-10 scale, using the Zoster Brief Pain Inventory) that persisted or appeared more than 90 days after the onset of the shingles rash. The incidence of shingles in the group vaccinated with investigational shingles vaccine compared to placebo recipients was also evaluated in the study.

Reductions seen in burden of illness and incidence of both PHN and shingles

The study showed efficacy with the investigational shingles vaccine on all measured endpoints compared to placebo: Findings of the study showed that the investigational shingles vaccine significantly ($p < 0.001$) reduced the:

- Incidence, severity and duration of pain and discomfort associated with shingles by 61.1 per cent, the overall BOI score was 2.21 for the vaccine group compared to a score of 5.68 in the placebo group;
- Incidence of PHN by two-thirds (66.5 per cent);
- Overall incidence of shingles by 51.3 per cent.

Safety evaluations conducted during the first 42 days following vaccination showed that the number and types of serious adverse events were similar in the investigational shingles vaccine and the placebo groups and the distribution of serious adverse events by organ system were also similar between the groups. Only five subjects had serious adverse events that were assessed by site investigators, two in the vaccine group (exacerbation of asthma and polymyalgia rheumatica) and three in the placebo group (anaphalactoid reaction, polymyalgia rheumatica and Good Pasture's syndrome).

Reactions at the injection site were generally mild. An independent data and safety monitoring board reviewed the safety data and interim results from the study.

About Merck Frosst

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company. Merck Frosst discovers, develops, manufactures and markets a broad range of innovative medicines to improve human health. Merck Frosst is one of the top 20 R&D investors in Canada, with an investment of \$117 million in 2004. The Company is committed to fostering partnerships to deliver the most valuable health outcomes for Canadian patients. More information about Merck Frosst is available at <http://www.merckfrosst.com>.

FOR INTERVIEWS with medical expert and patient, please contact Eva Sogbanmu at 514-843-2373

FOR MORE INFORMATION PLEASE CONTACT:

Sheila Murphy

Manager, Public Affairs
Merck Frosst Canada Ltd.
(514) 428-2748

Eva Sogbanmu

NATIONAL PharmaCom
(514) 843-2373