Health Canada Endorsed Important Safety Information on ROTARIX™ (Human Rotavirus, live, attenuated, oral vaccine)

July 12, 2010

Dear Health Care Professional

Subject: **Presence of Porcine Circovirus, Type 1 (PCV-1) in ROTARIX™ (Human Rotavirus, live, attenuated, oral vaccine)**

ROTARIX™ is an orally administered vaccine that is authorized for the active immunization of infants from the age of 6 weeks for the prevention of gastroenteritis caused by rotavirus types G1P[8], G2P[4], G3P[8], G4P[8] and G9P[8].

GlaxoSmithKline Inc. (GSK), in consultation with Health Canada, would like to inform healthcare professionals of new information on the composition of its Human Rotavirus vaccine, ROTARIX™ (live, attenuated, oral vaccine).

- GSK has identified the presence of material from porcine circovirus, Type 1 (PCV-1) in its ROTARIX™ vaccine.
- According to scientific literature, PCV-1 is a virus commonly found in pigs and pork products. PCV-1 does not replicate in humans and is not known to cause illness in humans or any other animals.[1,2]
- Available evidence, obtained before and after the marketing authorization, supports the safety and effectiveness of ROTARIX™.
- GSK's Vaccine Safety Monitoring Board has reviewed all data and has concluded that the benefit/risk profile of the vaccine remains unchanged to date.

The safety and effectiveness of ROTARIX™ has been extensively studied. The safety profile of ROTARIX™ is based on extensive clinical data from the largest vaccine clinical trial program conducted by GSK, enrolling more than 90,000 participants in Europe, Latin America, Asia, Africa and the US. The discovery of PCV-1 in the vaccine is a new finding which GSK continues to investigate. Since material from PCV-1 has been present in ROTARIX™ since the initial stages of its development, the established safety profile therefore reflects exposure to material from PCV-1. ROTARIX™ was authorized in Canada in October 2007 based on data from 12 clinical studies involving over 76,000 subjects.

Post marketing surveillance data of the product reflects more than 69 million doses which have been distributed globally since its launch five years ago. The Canadian Product Monograph for ROTARIX™ will be updated to reflect the discovery of PCV-1. The benefit/risk profile of the vaccine remains unchanged and GSK will continue to work closely with Health Canada on this issue.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving ROTARIX™ should be reported to your local public health authority, GlaxoSmithKline or the Public Health Agency of Canada as follows:

REPORTING SUSPECTED VACCINE ADVERSE EVENTS

If a patient experiences an adverse event following immunization, please complete the Adverse Events Following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

Contact information for each provincial/territorial public health jurisdiction can be found through the following link:

http://www.phac-aspc.gc.ca/im/ci-rp-eng.php

The national AR Reporting Form and the AEFI Reporting Guidelines can be found on the Public Health Agency of Canada web site: http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

Contact Information:
By toll-free telephone: 1-866-844-0018
By toll-free fax: 1-866-844-5931
Email Address: caefi@phac-aspc.gc.ca
Web Address: http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

Mail:
Vaccine Safety Section
Centre for Immunization and Respiratory Infectious Diseases
Public Health Agency of Canada A/L 6502A
130 Colonnade Road
Ottawa, Ontario
K1A 0K9

or to

GlaxoSmithKline Inc.
7333 Mississauga Road North
Mississauga, Ontario, L5N 6L4
Tel: 1-800-387-7374

For other inquiries related to this communication, please contact Health Canada at:

Biologics and Genetic Therapies Directorate
E-mail: BGTD_ORA_Enquiries@hc-sc.gc.ca
Tel: (613) 957-1722

Sincerely,

original signed by

Dr. Tjark Reblin
Vice President, Medical and Chief Medical Officer
GlaxoSmithKline Canada

References:

1. Linlin Li, Journal of Virology, Feb 2010, p.1674-1682
2. Hatterman, Kim, Xenotransplantation 2004: 11: 284-294.