To the Media

July 4, 2011

GlaxoSmithKline K.K.
Daiichi Sankyo Co., Ltd.

Announcement of Basic Agreement Concerning Co-promotion in Japan of Vaccine for Prevention of Rotavirus Gastroenteritis

GlaxoSmithKline K.K. (President: Philippe Fauchet; Head Office: Shibuya-ku, Tokyo; hereinafter referred to as GSK) and Daiichi Sankyo Co., Ltd. (President: Joji Nakayama; Head Office: Chuo-ku, Tokyo; hereinafter referred to as Daiichi Sankyo) announce that the companies have reached an agreement for the co-promotion in Japan of Rotarix®, GSK’s vaccine to prevent rotavirus gastroenteritis in infants (hereinafter referred to as “agreement”).

GSK received approval from the MHLW to market Rotarix in Japan on July 1, 2011. Rotarix oral liquid formulation is the first vaccine to be approved in Japan for infants to prevent gastroenteritis caused by rotavirus, for which only symptomatic treatment was available until now. Vaccination with Rotarix completes with 2 oral doses only.

Awareness in Japan on the importance of preventive healthcare is increasing. Both companies wish that by joining hands, Daiichi Sankyo, one of the established players in the Japanese vaccines field with ample know-how and experience, and GSK, a global leader in the creation of innovative vaccines, can help alleviate the concern and burden of parents by delivering the vaccine for prevention of rotavirus gastroenteritis for which only symptomatic treatment was available.

Through this agreement, both companies aim to increase the awareness for the prevention of rotavirus gastroenteritis by use of the vaccine.

About Rotavirus gastroenteritis

Rotavirus gastroenteritis is a form of infectious gastroenteritis most common among severe gastroenteritis in infants. In Japan, about 790,000 children visit doctors every year with this disease and about 10% are hospitalised. Almost 100% of children are said to develop rotavirus gastroenteritis by the age of 5 and symptoms tend to be more severe in babies who become infected for the first time after 3 months of age. Dehydration may occur in some cases due to repeated vomiting and diarrhoea and inadequate fluid replacement.
Most children develop rotavirus gastroenteritis before the age of 3 when they need close supervision, posing a great burden not only on the patient but on the family.

There is no effective medicine known against rotavirus. Thus, treatment of rotavirus gastroenteritis is centred on symptomatic treatment, such as quick and proper fluid replacement. Rotavirus is highly contagious and it is said that only 10 particles of the virus can cause gastroenteritis in infants. WHO recommends that a rotavirus vaccine be included in all national vaccination programmes in all regions including both developing and developed countries.

**About Rotarix® oral liquid formulation**

- First oral live human rotavirus vaccine in Japan to prevent rotavirus gastroenteritis
- Prevented 92% of severe rotavirus gastroenteritis (Japanese clinical trials)
- Vaccination can start from 6 weeks of age and be completed before the age of 24 weeks with at least 4 weeks interval between 2 doses.
- 2 doses of vaccination have shown to provide strong protection against rotavirus gastroenteritis. Clinical trials conducted in Japan and overseas have confirmed that Rotarix prevents severe rotavirus gastroenteritis and all rotavirus gastroenteritis.
- In Japanese clinical trials, major adverse reactions reported within 30 days after vaccination were 37 cases of irritability (7.3%), 18 cases of diarrhea (3.5%), and 17 cases of cough/rhinorrhea (3.3%) (at the time of approval) in 508 vaccinated subjects.