November 21, 2011

To the Media

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

# Launch of Rotarix® oral liquid formulation

## First vaccine to prevent rotavirus gastroenteritis in Japan

## -Protecting babies from 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) announced that Rotarix® oral liquid formulation, the rotavirus vaccine for infants for prevention of gastroenteritis caused by rotavirus for which GSK obtained approval in July, will be launched on 21st November 2011.

Rotarix® is the only attenuated human rotavirus vaccine for effective vaccination of infants between 6 weeks and 24 weeks of age with only two doses. Since obtaining first global approval in 2004, Rotarix® has been approved in over 120 countries and given to more than 50 million infants worldwide. Several hundred types of strains of rotavirus are thought to exist and clinical trials have confirmed Rotarix® to be effective through cross protection against gastroenteritis caused by multiple rotavirus strains, so it can be expected to be effective against many strains not included in the vaccine.

GSK, the Japanese subsidiary of the GlaxoSmithKline Group, a global leader in the creation of innovative vaccines, and Daiichi Sankyo, one of the established players in the Japanese vaccines field with ample know-how and experience, will jointly promote the product to facilitate its usage by the population of Japan.

**About Rotarix® oral liquid formulation**

- First oral live attenuated human rotavirus vaccine in Japan to prevent rotavirus gastroenteritis.
- Achieved 92% prevention of severe rotavirus gastroenteritis in Japanese clinical trials.

- The preventive double dose vaccination can start from 6 weeks of age and must be completed by 24 weeks of age. However, following there first dose there must be a 4 week resting period before the second dose is administered.
- 2 doses have shown to provide strong protection against rotavirus gastroenteritis. Clinical trials conducted in Japan and overseas have confirmed prevention of both overall and severe rotavirus gastroenteritis
- In Japanese clinical trials, main 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/rhino rhea (3.3%) (at the time of approval) in 508 vaccinated subjects

**Product summary**

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| Product name | *Rotarix® oral liquid formulation* |
| Generic name | Oral live attenuated human rotavirus vaccine |
| Date of approval | 1 July 2011 |
| Indication | Prevention of gastroenteritis caused by rotavirus |
| Dosage and administration | The usual infant dose is two oral doses of 1.5 mL. There should be an interval of at least 4 weeks between doses. |
| Manufacturing and Marketing | GlaxoSmithKline K.K. |
| Co-promotion | Daiichi Sankyo Co., Ltd. |

**About rotavirus gastroenteritis**

Rotavirus gastroenteritis is a form of infectious gastroenteritis and is most common among severe gastroenteritis in infants. In Japan, about 790,000 children visit doctors every year with this disease and about 10% are hospitalized. Almost 100% of children are said to develop rotavirus gastroenteritis by the age of 5 and it is known that 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 diarrhea and inadequate fluid replacement. Also because most children develop rotavirus gastroenteritis before the age of 3 when they need close supervision, most families need to nurse them constantly, posing a great burden not only on the patient but on the family, so there are expectations toward the role a vaccine would play.

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 as total prevention is difficult even in a sanitary environment, the WHO recommends that a rotavirus vaccine be included in all national vaccination programmes in all regions, including both developing and developed countries.

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