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For Immediate Release

Daiichi Sankyo Co., Ltd. Sanofi Pasteur K.K.

# Announcement on obtaining in Japan the marketing and manufacturing license for the 4-valent combination vaccine for the prevention of Pertussis, Diphtheria, Tetanus and Poliomyelitis (Polio) "Squarekids<sup>®</sup>subcutaneous injection syringe"

**Tokyo, Japan (July 04, 2014)** - Daiichi Sankyo Co., Ltd. (hereinafter Daiichi Sankyo) and Sanofi K.K. announce that Kitasato Daiichi Sankyo Vaccine Co., Ltd. (hereinafter Kitasato Daiichi Sankyo Vaccine), a Daiichi Sankyo Group company in Japan, has obtained a manufacturing and marketing licensing in Japan for the 4-valent combination vaccine for the prevention of Pertussis, Diphtheria, Tetanus and Poliomyelitis (Polio) (hereinafter "this vaccine").

This vaccine is a product made of precipitated and purified pertussis, diphtheria, tetanus (DPT vaccine) of Kitasato Daiichi Sankyo and inactivated polio vaccine (Salk vaccine) (eIPV:Enhanced Inactivated Poliomyelitis Vaccine) of Sanofi Pasteur in a prefilled syringe, and is the first 4-valent combination vaccine in Japan that contains inactivated polio vaccine (Salk vaccine).

Daiichi Sankyo Group and Sanofi Pasteur are committed to contributing towards protecting the health of people in Japan by introducing innovative vaccines with high medical needs and by promoting the importance of preventative medicine in Japan.

Commercial Name	Squarekids <sup>®</sup> subcutaneous injection syringe
Generic Name	Precipitated and purified pertussis-diphtheria-tetanus-inactivated polio vaccine (Salk vaccine) vaccine
Regulatory category applicable to this drug	Biological product, drastic medicine, prescription drug (Note – to be used under physician's prescription

## **Product Overview**





Specification-Content	This drug contains in its 0.5ml, the equivalency of 4 units and over of protective antigen of Bordetella pertussis, 23.5 units and over of diphtheria toxoid, 13.5 units and over of tetanus toxoid, 40 D-antigen units 8 D-antigen units and 32 D-antigen units of inactivated polio virus type I, type II and type III respectively.
Effect-Efficacy	Prevention of pertussis, diphtheria, tetanus and poliomyelitis
Dosage-Administration	Primary immunization: Normally, 3-dose administration to children by subcutaneous injection, each dose containing 0.5ml, with an interval of 3 weeks or longer. Booster immunization: Normally, one dose of 0.5ml administration to children by subcutaneous injection, with an interval of 6 months or longer.
Approval date of manufacturing and marketing license	July 4, 2014
Manufacturing and marketing license holder	Kitasato Daiichi Sankyo Vaccine Co., Ltd.
Distributor	Daiichi Sankyo Co., Ltd.
Marketing alliance parties	Sanofi K.K. Japan Vaccine Co., Ltd.

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### About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, dyslipidemia and bacterial infections used by patients around the world, the Group has also launched treatments for thrombotic disorders and is building new product franchises.

Furthermore, Daiichi Sankyo research and development is focused on bringing forth novel therapies in oncology and cardiovascular-metabolic diseases, including biologics.

The Daiichi Sankyo Group has created a "Hybrid Business Model," to respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit: <u>www.daiichisankyo.com</u>.

### About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' need. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT:SAN) and in New York (NYSE:SNY).

In Japan, Sanofi K.K. has approximately 2,700 employees nationwide. The company develops, manufactures, and markets pharmaceutical products under the vision to become the most trusted healthcare leader bringing health and happiness to Japan. Please visit the company's website (www.sanofi.co.jp) for details.

#### **About Sanofi Pasteur**

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers the broadest range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR 1 million in research and development. For more information, please visit: www.sanofipasteur.com or www.sanofipasteur.us