July 27, 2012

KAKETSUKEN(The Chemo-Sero-Therapeutic Research Institute)
Astellas Pharma Inc.

# Adsorbed Purified Pertussis Diptheria Tetanus Inactivated Poliomyelitis (Sabin strain) Combined Vaccine
## Notice of Marketing Authorization Approval

The Chemo-Sero-Therapeutic Research Institute (KAKETSUKEN) of Kumamoto, Japan and Astellas Pharma Inc of Tokyo, Japan have announced that its combined vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis (polio) (brand name: "Quattrovac® subcutaneous injection syringe", hereafter "the drug product") has received marketing authorization approval on July 27, 2012.

Polio is an acute viral infectious disease caused by the poliovirus. The traditional polio vaccine used in Japan is a live-attenuated oral vaccine prepared by combining attenuated Sabin types 1, 2, and 3 polioviruses (OPV: Oral Poliomyelitis Vaccine).

OPV has superior efficacy and safety and the number of poliomyelitis patients in Japan has sharply declined since it was introduced in 1961. However, very rare incidences of poliomyelitis-like paralysis in vaccine recipients and their contacts due to the vaccine (vaccine-associated paralytic poliomyelitis (VAPP)) led to the development of an inactivated poliomyelitis vaccine (IPV).

Based on such facts and from the view of convenience due to the number of vaccine inoculations, in 2004 KAKETSUKEN began the development of this tetra-valent combined vaccine which includes the inactivated poliomyelitis vaccine derived from Sabin strains. After confirming the safety and efficacy of this vaccine in human clinical trials that began in 2007, a marketing authorization application was submitted in January 2012 and marketing authorization has now been approved.

The vaccine is manufactured at KAKETSUKEN. Astellas Pharma Inc. will conduct national sales and promotional activities similarly to its other vaccine and blood plasma products. Both companies will conduct joint sales promotion in the Kyushu area (Including Okinawa Prefecture). Marketing timing will be announced at a later date.

KAKETSUKEN and Astellas Pharma Inc. strive for consistent contributions towards the promotion of public health and prevention of infectious diseases.


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■ About “Quattrovac® subcutaneous injection syringe”

The vaccine is made by combining the bulk materials of KAKETSUKEN’s approved Adsorbed Purified Pertussis Diptheria Tetanus Combined Vaccine (DPT vaccine) with the bulk of inactivated poliomyelitis vaccine derived from purified attenuated polio viruses (Sabin type 1, 2, and 3) cultured in Vero cells (a cell-line derived from African Green Monkey kidney cells) made by the Japan Poliomyelitis Research Institute (JPRI).

Results showing efficacy in the prevention of pertussis, diphtheria, tetanus, and poliomyelitis and safety were obtained in clinical trials with 0.5ml subcutaneous injections per dose to children 3 months old or older but under 90 months old under the same vaccination schedule as the existing DPT vaccine.

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| Brand Name | Quattrovac® for subcutaneous injection syringe |
| Generic Name | Minimum requirements for biological products: Adsorbed Purified Pertussis-Diptheria-Tetanus-Inactivated Poliomyelitis (Sabin strain) Combined Vaccine |
| Components/ Content | This vaccine is a 0.5mL (1 syringe) injectable product which contains 4 units or more of pertussis antigens, 16.7 Lf or less of diphtheria toxoid, 6.7 Lf or less of tetanus toxoid, 1.5 DU of type 1 (Sabin strain) inactivated polio virus, 50 DU of type 2 (Sabin strain) inactivated polio virus, and 50 DU of type 3 (Sabin strain) inactivated polio virus as active ingredients. |
| Efficacy/Effects | Prevention of pertussis, diphtheria, tetanus, and poliomyelitis |
| Usage/Dose | Primary series immunization: Three subcutaneous injections of 0.5 mL per injection at intervals of 3 weeks or more<br>Booster: One subcutaneous injection of 0.5 mL at 6 months or more after the primary series immunization |
| Storage | Store at 10 degrees or below without freezing, and away from light |
| Shelf Life | 2 years after production date |
| Regulatory Classification | Biological product, powerful drug, prescription pharmaceutical product |
| Production and Distribution | KAKETSUKEN(The Chemo-Sero-Therapeutic Research Institute) |
| Distribution | Astellas Pharma Inc. |
| Approval Date | July 27, 2012 |
| Availability Date | To be determined (will be announced at a later date pending decision) |