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News Release

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Astellas: New Maximum Pediatric Dosages of Synthesized Penicillin "Sawacillin®" Approved

Tokyo, February 22, 2012 – Astellas Pharma Inc. (Tokyo:4503, "Astellas") announced today that it was granted approval of an additional indication application within Japan for changes in the maximum pediatric dosages of its synthetic penicillin "Sawacillin Capsules 125," "Sawacillin Capsules 250," "Sawacillin Fine Granules 10%," and "Sawacillin Tablets 250" (generic name: amoxicillin hydrate, "Sawacillin") as a treatment of pediatric infectious diseases.

For the uses of Sawacillin in pediatric applications, the Second Committee of the "New Drugs of the Pharmaceutical Affairs and Food Sanitation Council" determined that an application in the public domain[1] would be allowed based on its own preliminary evaluations on August 1, 2011, and Astellas submitted the additional indication application for the changes on August 10, 2011. This application was a result of changes in the maximum pediatric dosages[2] of amoxicillin that were sought by the Japanese Society of Chemotherapy, and after a review by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs[3]" conducted in October 2010, the Ministry of Health, Labor and Welfare reqested Astellas to apply these changes to its synthetic penicillin "Sawacillin®" (for infections excluding helicobacter pylori infection).

In keeping with its corporate philosophy, Astellas endeavors to contribute to the advancement of medicine and to improvements in the health of patients around the world by conducting activities designed to acquire approval for yet-to-be approved and off-label drugs.

[1] Application (based on the evidence) in the public domain: clinical trials may be partially or completely omitted in the drug (additional efficacy, impact) approval application process for drugs that are commonly known to be effective in widely accepted medical and pharmaceutical realms.

[2] Usages, Dosages (abstract; updated portion is underlined): "Children: Use as amoxicillin hydrate, normally one dosage of between 20mg to 40mg (titer) for each kilogram of body weight should be administered orally 3 to 4 times per day. Moreover, dosages should be varied in accordance with age and symptoms of the patient, with the maximum dosage of 90mg (titer) not to be exceeded per day."

[3] Review Committee on Unapproved Drugs and Indications with High Medical Needs: a committee convened by the Ministry of Health, Labor and Welfare with the goal of promoting new development and applications of drugs which have yet to be approved for use within Japan but that have already been approved for use in the United States and Europe.

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For inquiries or additional information
Astellas Pharma Inc. Corporate Communications Tel: +81-3-3244-3201 Fax: +81-3-5201-7473 http://www.astellas.com/en