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News Release

August 10, 2011

Astellas: Additional Indication Application for Synthesized Penicillin "Sawacillin®"

Tokyo, August 10, 2011 – Astellas Pharma Inc. (Tokyo:4503, "Astellas") announced that it has submitted today an additional indication application based on the evidence in the public domain* within Japan for changes in the maximum dosages (Refer to "Product Overview and Application Details") of its synthetic penicillin "Sawacillin® Capsules 125," "Sawacillin® Capsules 250," "Sawacillin® Fine Granules 10%," and "Sawacillin® Tablets 250" (Generic name: amoxicillin hydrate, "Sawacillin") for a treatment of pediatric infectious diseases.

As a result of a review by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs**" conducted in October 2010 for the uses of Sawacillin in pediatric applications, the Ministry of Health, Labor and Welfare submitted a request to Astellas for development of new dosages of Sawacillin in December 2010. In light of this request, Astellas submitted an official indication of its desire to submit an application in the public domain on January 24, 2011 for an additional indication of Sawacillin. Thereafter, the indication was evaluated as an application in the public domain by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs" in June 2011. Furthermore, on August 1, 2011 the Second Committee of the "New Drugs of the Pharmaceutical Affairs and Food Sanitation Council" determined that an application in the public domain would be allowed based on its own preliminary evaluations.

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.

* 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.

** 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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Product Overview and Application Details

Product Name:	Sawacillin® Capsules 125 Sawacillin® Capsules 250 Sawacillin® Fine Granules 10% Sawacillin® Tablets 250
Generic Name:	Amoxicillin hydrate
Efficacy, Impact:	No changes
Usages, Dosages (abstract):	(For infections excluding helicobacter pylori infection) Adults: Use as amoxicillin hydrate, normally one dosage of 250mg (titer) should be administered orally 3 to 4 times per day. Moveover dosages should be varied in accordance with age and symptoms of the patient. Children: Use as amoxicillin hydrate, one dosage of between 20mg to 40mg (titer) for each kilogram of body weight should be administered orally 3 to 4 times per day. Moveover 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. (Reference: Current registration) (For infections excluding helicobacter pylori infection) Used as amoxicillin hydrate, normal adults should take one dosage of 250mg (titer) orally 3 to 4 times per day. Moreover, the dosage should vary depending upon the age and symptoms of the patient.

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For inquiries or additional information

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