

September 30, 2008

**Zosyn® to be Launched in Japan on October 1: an Injectable Antibiotic Combination Product Consisting of Semisynthetic Antibiotic and  $\beta$ -lactamase Inhibitor**

Taisho Toyama Pharmaceutical Co., Ltd. (“Taisho Toyama”; Headquarters: Tokyo; President: Akira Ohira) has announced the launch in Japan on October 1 of Zosyn® 2.25 for Intravenous Injection and Zosyn® 4.5 for Intravenous Injection (generic name: tazobactam • piperacillin), an antibiotic combination product consisting of semisynthetic antibiotic and  $\beta$ -lactamase inhibitor.

This product, Zosyn, was co-developed by Taiho Pharmaceutical Co., Ltd. (“Taiho Pharmaceutical”; Headquarters: Tokyo; President: Toru Usami) and Toyama Chemical Co., Ltd. (Headquarters: Tokyo; President: Masuji Sugata), and Taiho Pharmaceutical has obtained approval to manufacture and sell the product. The product consists of the  $\beta$ -lactamase inhibitor tazobactam sodium and the penicillin-derivative antibacterial agent piperacillin sodium in a ratio of 1:8 as value of the force. The product is expected to exhibit a superior clinical efficacy for pneumonia, septicemia, pyelonephritis and complicated cystitis. Zosyn has been marketed outside Japan, in the U.S. and other 93 countries, by the U.S. company Wyeth Pharmaceuticals, and is an injectable antibiotic agent which has been highly recognized as a standard curative medicine worldwide. In Japan, Zosyn will be manufactured by Taiho Pharmaceutical Co., Ltd. and marketed by Taisho Toyama Pharmaceutical Co., Ltd.

Details of Zosyn® 2.25 for Intravenous Injection and Zosyn® 4.5 for Intravenous Injection are as follows:

**Product specifications**

Date of manufacturing and marketing approval:

July 16, 2008

Brand name:

Zosyn® 2.25 for Intravenous Injection ; Zosyn® 4.5 for Intravenous Injection

Generic name:

Tazobactam • piperacillin

Indication:

-Indicated bacteria-

Zosyn-susceptible bacteria: *Staphylococcus* spp., *Streptococcus* spp., *Streptococcus pneumoniae*, *Enterococcus* spp., *Moraxella (Branhamella) catarrhalis*, *Escherichia coli*, *Citrobacter* spp., *Klebsiella* spp., *Enterobacter* spp., *Serratia* spp., *Proteus* spp., *Providencia* spp., *Haemophilus influenzae*, *Pseudomonas aeruginosa*, *Acinetobacter* spp.

-Indications-

Septicemia, pneumonia, pyelonephritis, complicated cystitis

Dosage and administration:

For septicemia and pneumonia:

The usual adult dosage of Zosyn for intravenous infusion is a 4.5 g single dose three times daily. In the case of pneumonia, the dosage may be increased to four times daily according to the symptoms and clinical condition. If necessary, the drug may be injected as an intravenous bolus infusion.

The usual pediatric dosage for intravenous infusion is a 112.5 mg/kg single dose three times daily. If necessary, the Zosyn may be injected intravenously. The single-dose amount may be adequately decreased according to the symptoms and clinical condition. However, the upper limit of the dosage is equal to the one for adults: 4.5 g.

When administered by intravenous infusion, the Zosyn is administered after being dissolved in a compatible reconstitution diluent . When administered by injection, the Zosyn should be slowly injected after being dissolved in water for injection, saline or 5% glucose injection.

For pyelonephritis and complex inflammation of the bladder:

The usual adult dosage of Zosyn for drip infusion is a 4.5 g single dose twice daily. The dosage may be increased to three times daily according to the symptoms and clinical condition. If necessary, the Zosyn may be injected as an intravenous bolus infusion.

The usual pediatric dosage for intravenous infusion is a 112.5 mg/kg single dose three times daily. If necessary, the Zosyn may be injected as an intravenous bolus infusion. The dosage may be adequately decreased according to the symptoms and clinical condition. However, the upper limit of the dosage is equal to the one for adults: 4.5 g.

When administered by intravenous infusion, the Zosyn is administered after being dissolved in a compatible reconstitution diluent. When administered by bolus infusion, the drug is slowly injected after being dissolved in water for injection, saline or 5% glucose injection.

#### Special features:

1. Zosyn contains the  $\beta$ -lactamase inhibitor tazobactam and the penicillin-derivative antibacterial agent piperacillin in a ratio of 1:8.
2. Zosyn possesses a wide antibacterial spectrum and superior antibacterial activity against the most causative bacteria for pneumonia, septicemia, pyelonephritis and complicated cystitis (*in vitro*).
3. Zosyn shows superior clinical efficacy for pneumonia, septicemia, pyelonephritis and complicated cystitis with adult dosages of a 4.5 g single dose administered 2-4 times\* daily. \*Pneumonia (3-4 times daily), septicemia (3 times daily), pyelonephritis and complicated cystitis (2-3 times daily).
4. When used for *Pseudomonas aeruginosa*, Zosyn appears to induce less resistant mutants (from studies in rats).

#### Approval holder:

Taiho Pharmaceutical Co., Ltd.

#### Packaging:

Zosyn® 2.25 for Intravenous Injection (2.25 g) single dose vial: 10-vial package; Zosyn® 4.5 for Intravenous Injection (4.5 g) single dose vial: 10-vial package

#### NHI reimbursement prices:

Zosyn® 2.25 for Intravenous Injection (2.25 g) : ¥1,792 per vial; Zosyn® 4.5 for Intravenous Injection (4.5 g): ¥2,668 per vial

Date of NHI price listing:

September 12, 2008

Launch date:

October 1, 2008