

July 23, 2010

Press Release

TOYAMA CHEMICAL CO., LTD.
Mitsubishi Tanabe Pharma Corporation

**Approval for Partial Changes in Indications, Dosage and Usage,
as well as New 1000 mg Dosage Formulation, for Injectable New Quinolone
Antibacterial Agents, Pasil® and Pazucross®**

Toyama Chemical Co., Ltd. (President: Masuji Sugata, hereinafter: Toyama Chemical) and Mitsubishi Tanabe Pharma Corporation (President & CEO: Michihiro Tsuchiya, hereinafter: Mitsubishi Tanabe Pharma) announced that they received, as of July 23, approval for partial changes of indications, dosage and usage for Pasil® (manufactured and marketed by Toyama Chemical) and Pazucross® (manufactured and marketed by Mitsubishi Tanabe Pharma) (generic name: pazufloxacin mesilate), an injectable new quinolone antibacterial agent jointly developed by the two companies in Japan, as well as approval for the manufacture and marketing of new 1000 mg dosage formulation, Pasil® Injection 1000 mg (to be manufactured and marketed by Toyama Chemical) and Pazucross® Injection 1000 mg (to be manufactured and marketed by Mitsubishi Tanabe Pharma).

With regard to the changes in the indications, *Streptococcus pneumoniae* was added to the list of indicated bacterial species and an additional indication for septicemia was approved. As for dosage and usage, an addition was approved: "For septicemia, pneumonia caused by *Streptococcus pneumoniae*, and severe or intractable respiratory tract infections (limited to pneumonia and secondary infections with chronic respiratory diseases), a daily dose of 2000 mg is administered to adults twice daily by intravenous infusion." The approved dosage was increased in response to demand from the Japanese Society of Chemotherapy. Physicians had requested increased dosage of the agent to obtain greater efficacy, while securing safety, in the treatment of severe or intractable infectious diseases, a major challenge among medical professionals in recent years.

In connection with the dosage escalation, 1000 mg dosage formulations were developed to meet the needs on the medical front for convenient administration. Upon NHI price listing, as with conventional 300 mg and 500 mg products, new Pasil® 1000 mg and Pazucross® 1000 mg will be manufactured by Toyama Chemical and Mitsubishi Tanabe Pharma, respectively, and will be distributed by Taisho Toyama Pharmaceutical Co., Ltd. (President: Akira Ohira) and Mitsubishi Tanabe Pharma, respectively.

<Media enquiry>
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