Discontinuation of Commercialization of Gatiflo® (gatifloxacin) Tablets, a broad-spectrum antibacterial agent, in Japan

Kyorin Pharmaceutical Co., Ltd. (Tokyo, President: Itaru Kojo), a wholly owned subsidiary of Kyorin Co., Ltd., and Dainippon Sumitomo Pharma Co., Ltd. (Osaka, President: Masayo Tada) announce that they have decided to voluntarily discontinue commercialization of Gatiflo® (gatifloxacin) Tablets, a broad-spectrum antibacterial agent, in Japan as of September 30, 2008.

[Profile of Gatiflo® Tablets]
Generic Name: gatifloxacin hydrate
Brand Name: Gatiflo® Tablets (Approved on April 11, 2002, Launched in June 2002)
Therapeutic Category: Synthetic antimicrobial
Marketing Companies: Manufactured by Kyorin Pharmaceutical Co., Ltd.
Marketed by Kyorin and Dainippon Sumitomo Pharma Co., Ltd.
Sales Performance: About 3.5 billion yen (Fiscal year ending in March 2008, NHI price basis)
Indications: Respiratory tract infection, urologic tract infection, otologic tract infection etc.

[Background behind Discontinuation]
Gatiflo® Tablets was launched in June 2002 as a broad-spectrum antibacterial agent, having a high degree of usefulness for various infection diseases, such as respiratory tract and urologic tract infections. After the launch, serious hyperglycemia and hypoglycemia of which the relationship with the product could not be denied were reported. In response to such reports, we warned of possible serious hyper/hypoglycemia and changed the product label to contraindicate use in patients with diabetic mellitus in addition to the issuance of “Dear Dr. Letter” in March 2003. As the result of such our efforts, incidence of dysglycemia has been decreased.

On the other hand, Kyorin’s licensee in the US, Bristol-Myers Squibb Company (New York) has discontinued commercialization of Tequin® (gatifloxacin tablets, injection and oral suspension) for commercial reason in June 2006. The Food and Drug Administration (FDA) recently announced on the Federal Register its decision that
Tequin® was delisted from the Orange Book for the reason of safety, etc. This was the measure not to accept any abbreviated new drug application (ANDA) for Tequin®.

Under the circumstances, we have discussed the handling of Gatiflo® Tablets in Japan seeking opinions from various sectors. As the result of such discussion and investigation, while the necessity of Gatiflo® Tablets is recognized by a number of expert physicians even now when new drugs having similar antibacterial spectrum are available, taking into the consideration future risk-benefit of patients for the use of Gatiflo® Tablets, which includes the difficulty in eradicating administration to diabetic patients, only by familiarizing physicians with the contraindication of the product in diabetic patients, we have decided to voluntarily discontinue commercialization of Gatiflo® Tablets.

We will carefully investigate how the discontinuation impacts on the forecast of our financial performance of this fiscal year. If the revision of the current forecast is necessary after our investigation, we will disclose immediately.

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