For Immediate Release

May 25, 2018
Sawai Pharmaceutical Co., Ltd.

Sawai Pharmaceutical Submits Public Knowledge-Based Application for Anti-Cancer Agent OXALIPLATIN I.V. Infusion Solution for Additional Indication

Osaka, Japan –May 25, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today submitted public knowledge-based applications[1] for the anti-cancer agent, OXALIPLATIN I.V. Infusion Solution 50mg [SAWAI] / 100mg [SAWAI] / 200mg [SAWAI]) (brand products ELPLAT® I.V. Infusion Solution 50mg / 100mg / 200mg) for the additional indication of small intestinal cancer to the Ministry of Health, Labour and Welfare (MHLW).

The public knowledge-based application for the additional indication of ELPLAT® is evaluated as applicable by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs[2]".

In addition, during a meeting held April 25, 2018, the Second Committee of the "New Drugs of the Pharmaceutical Affairs and Food Sanitation Council" conducted preliminary evaluations of ELPLAT®'s additional indication for small intestinal cancer and concluded that a public knowledge-based application would be allowed.

Based on these decisions, Sawai submitted public knowledge-based applications for generic drug, OXALIPLATIN I.V. Infusion Solution 50mg [SAWAI] / 100mg [SAWAI] / 200mg [SAWAI] for the additional indication on May 25, 2018.

Even though the addition of indications and usage, and dosage and administration of public knowledge-based applications of generic drugs results in a significant increase in the application review fees compared with the one of partial change applications, the Company decided to submit the application to offer benefits to patients who need its generic drugs.

1 “Public Knowledge-Based Application” is a marketing authorization application that seeks supplemental indication approval for an existing drug. In this system, an application is submitted based on medical and pharmacological public knowledge of a drug’s safety and efficacy and does not require additional clinical studies to be conducted, in whole or in part.

2 The “Review Committee on Unapproved Drugs and Indications with High Medical Needs” was established to promote the development by pharmaceutical companies of drugs and indications that have been approved in Europe and the United States but not yet approved in Japan by evaluating the medical needs, as well as confirming the applicability of public knowledge-based application, and the validity of studies that should be conducted additionally for the applications.

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