November 7, 2023
Sawai Pharmaceutical Co., Ltd.

Launch of Pitavastatin tablets in the United States

– Sawai's First generic ANDA approval and launch for US market under Paragraph IV–

Osaka, Japan – November 7, 2023 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Motohiko Kimura) announced the launch of Pitavastatin tablets, 1mg, 2mg, 4mg (branded product: LIVALO®) on November 2, 2023 (US Central time) through Upsher-Smith Laboratories, LLC (Upsher-Smith, Head office: Maple Grove, MN, President and COO: Rich Fisher), a US subsidiary of our parent company, Sawai Group Holdings Co., Ltd. (Head office: Osaka, Japan, Chairman and President: Mitsuo Sawai). This is the first Abbreviated New Drug Application (ANDA) approval and launch under Paragraph IV*1, and the first generic product developed by Sawai to be marketed in the US.

*1: A filing that asserts that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted.

Sawai received approval of its first ANDA under Paragraph IV from the U.S. Food and Drug Administration (FDA) in February 2017, after the conclusion of a patent infringement lawsuit in the United States District Court for the Southern District of New York. Sawai is one of the first ANDA applicants to launch Pitavastatin tablets, thereby holding 180-day exclusivity according to the Hatch-Waxman Act.

To obtain approval for the product in the United States, Sawai established Sawai USA, Inc. in 2013 and acquired Upsher-Smith in 2017 to establish a base in the United States. The launch was realized through our major R&D advantages, i.e., patent research/analysis and product development capabilities. Sawai will continue to reinforce these capabilities to deliver affordable generic drugs to patients.

About Paragraph IV

In the United States, an applicant can file an ANDA to the FDA for approval of commercial marketing of a generic drug before the expiration of the patent related to its branded product according to the Hatch-Waxman Act. To file an ANDA application, a certification (Paragraphs I to IV) of the opinions regarding the patent related to the original product should be included with the ANDA submission. The statute provides an incentive and a reward to generic drug applicants that expose themselves to the risk of patent litigation. The statute does so by granting a 180-day period of exclusivity to the applicant that is first to file a substantially complete ANDA containing a paragraph IV certification to a listed patent.

◆ Contact Information ◆
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