



Chugai Pharmaceutical Co., Ltd.
Kowa Company, Ltd.
Sanofi K.K.

Changes to Marketing Arrangements of the SGLT2 Inhibitor Tofogliflozin Hydrate in Japan

TOKYO & NAGOYA, February 17, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519), Kowa Company, Ltd. (Kowa), and Sanofi K.K. (Sanofi) announced changes to marketing arrangements of tofogliflozin hydrate (hereinafter, tofogliflozin), a SGLT2 inhibitor created by Chugai in Japan.

Under the license agreements in 2012, tofogliflozin has been marketed by Kowa under the brand name “DEBERZA® Tablets 20 mg” (hereinafter, “DEBERZA”), and by Sanofi under the brand name as “Apleway® Tablets 20 mg” (hereinafter, “Apleway”), following regulatory approvals in 2014.

Chugai and Sanofi agreed to terminate their license agreement. Kowa and Sanofi agreed that the marketing right for Apleway will be transferred from Sanofi to Kowa as of April 1, 2020 and the marketing authorization for the product will be also transferred by around June 2020. With these changes to marketing arrangements, tofogliflozin will be marketed solely by Kowa.

Chugai, Kowa, and Sanofi will continue working on to ensure stable supply of the product, provide appropriate information, and promote proper use so that the changes to marketing arrangements will not cause any inconvenience to patients, healthcare professionals and other stakeholders. They will also cooperate to achieve transfer of marketing right and succession of the marketing authorization to carry out their responsibilities.

The changes will not affect Chugai’s consolidated earnings forecast for the business term ending in December 2020.

About tofogliflozin hydrate, a SGLT2 inhibitor

Tofogliflozin hydrate, a selective inhibitor of sodium-glucose cotransporter 2 (SGLT2) created by Chugai, lowers blood glucose by inhibiting glucose reabsorption in the renal tubule and inducing excretion of excess blood glucose into urine.

Marketing authorization for the product was granted by MHLW on March 24, 2014, for the indication of type 2 diabetes mellitus. The drug is marketed by Kowa and Sanofi, with brand names as “DEBERZA® Tablets 20 mg” and “Apleway® Tablets 20 mg,” respectively. Overseas, Kowa owns the exclusive rights to develop and market “DEBERZA®,” as well as to conduct research, develop, and market its combination drug in the US and EU.

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs.

Additional information is available on the internet at <https://www.chugai-pharm.co.jp/english/>.

About Kowa

Kowa Company, Ltd. (Kowa), is a privately held, multinational company headquartered in Nagoya, Japan. Established in 1894, Kowa is actively engaged in various manufacturing and trading activities in the fields of pharmaceuticals, medical equipment, textiles, machinery, construction materials, energy saving products and various consumer products.

Kowa's pharmaceutical division is focused on research and development for cardiovascular therapeutics (dyslipidemia, type 2 diabetes, and atherosclerosis), ophthalmology and anti-inflammatory agents.

For more information, please see <https://www.kowa.co.jp/eng/>.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Contact information for this press release		
Chugai Pharmaceutical Co., Ltd. Corporate Communications Dept. <Media Relations Group> TEL: +81-(0)3-3273-0881 <Investor Relations Group> TEL: +81-(0)3-3273-0554	Kowa Company, Ltd. Public Relations Department Tel : +81-(0)3-3279-7392	Sanofi K.K. Communications Tel : +81-(0)3-6301-4148