



## Translation

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

## License Agreement of SGLT2 Inhibitor “CSG452” in Japan

October 26, 2012 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, Chugai)], Kowa Company, Ltd. [Main Office: Nagoya, Aichi. President & CEO: Yoshihiro Miwa (hereafter, Kowa)] and Sanofi K.K. [Main Office: Shinjuku-ku, Tokyo. CEO: Jez Moulding (hereafter, Sanofi)] announced today that they have entered into license agreements for Chugai’s original compound SGLT2 inhibitor “CSG452” for which Chugai is currently conducting clinical development for type 2 diabetes.

Under the agreement, the three companies, Chugai, Kowa and Sanofi will co-develop the compound, and Kowa and Sanofi will file the application for marketing authorization under their own brand names, while Chugai will manufacture the products for supply to the two companies. Under the terms of the agreements, Chugai will receive milestone payments from Kowa and Sanofi.

CSG452 is an inhibitor of sodium-glucose cotransporter 2 (SGLT2), created by Chugai. CSG452 lowers blood glucose by inhibiting glucose reabsorption in the kidney and inducing excretion of excess blood glucose into urine. Currently, Chugai is conducting phase III clinical trial in Japan to evaluate its efficacy and safety for the target indication of type 2 diabetes. This compound has a unique mechanism of action which does not rely on insulin, and in addition to improving both fasting plasma glucose and postprandial glucose, it has low risk of inducing hypoglycemia and has a clear effect of body weight reduction<sup>1</sup>. It is expected that it will become an emerging oral anti-diabetic.

The number of type 2 diabetes patients continues to rise each year in Japan, with an estimated 8.9 million who are “strongly suspicious to have diabetes” and up to 22.1 million who “cannot be denied of the possibility of having diabetes” according to the investigation made on 2007 by the Ministry of Health, Labour and Welfare. If diabetes is left untreated, it may induce microvascular complications such as diabetic nephropathy, diabetic retinopathy and diabetic neuropathy, which will lead to a significant loss of quality of life by events such as dialysis, loss of sights or amputation of limbs, and may also lead to serious diseases that shorten the lives as the risk of inducing arteriosclerosis will rise. In the medical treatments for type 2 diabetes, the patients who have achieved targeted level of blood glucose for a long period of time are still about 30%<sup>2</sup> of all, and a new option for the treatment is in need.

Through the joint effort to develop CSG452, Chugai, Kowa and Sanofi hope to provide a new option of diabetes treatment to as many patients as possible.

There will be no changes to this year’s consolidated business forecasts of Chugai.

<sup>1</sup> Ikeda S, et al.; A novel and selective SGLT2 inhibitor, tofogliflozin improves glycemic control and lowers body weight in patients with type 2 diabetes mellitus. Abstract 768, EASD 2012

<sup>2</sup> Diabetes Treatment Master, Japan Diabetes Clinical Data Management Study Group 5(4): 401-406, 2007

### **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, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and Ukima is conducting research for technology development for industrial production. Overseas, Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2011 of Chugai totaled 373.5 billion yen and the operating income was 62.4 billion yen. We are aiming at the consolidated revenue of 418.5 billion yen and operating income of 80 billion yen in 2012.

Additional information is available on the Internet at <http://www.chugai-pharm.co.jp/>

### **About Kowa**

Since its establishment as a cotton wholesaler in Nagoya in 1894, Kowa Company, Ltd. has grown into an international conglomerate with 80 affiliated companies. Kowa is actively engaged in various business fields with major focuses on the manufacturing and sales of pharmaceutical products, LED lighting equipment and green products, and the trading of textile goods, machinery, building materials and chemical products. Through Kowa Pharmaceutical Co. Ltd., Kowa promotes and sells various pharmaceutical products primarily for the treatment of cardiovascular diseases, such as "Livalo" for hypercholesterolemia and "Olmotec" for hypertension. In addition, Kowa targets its research and development efforts on lifestyle diseases (dyslipidemia, atherosclerosis, and diabetes), immunology and inflammation, and ophthalmology.

Additional information is available on the Internet at <http://www.kowa.co.jp/eng/>

### **About Sanofi**

Sanofi, a global and diversified healthcare leader, locates its headquarters in Paris, France.

Sanofi employs over 110,000 people in 100 nations all over the world, and discovers, develops and distributes therapeutic solutions focused on patients' needs with core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

In Japan, Sanofi K.K. has approximately 3,000 employees nationwide in Japan. The company develops, manufactures, and markets pharmaceutical products under the vision to become the most trusted healthcare leader bringing health and happiness to Japan. Please visit the company's website ([www.sanofi.co.jp](http://www.sanofi.co.jp)) for details.

Contacts		
Chugai Pharmaceutical Corporate Communications Tel : +81-(0)3-3273-0881	Kowa Company, Ltd. Public Relations Department.2 Tel : +81-(0)3-3279-7392	Sanofi K.K. Communications Department Tel : +81-(0)3-6301-4148