To Whom It May Concern:

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Filing for Marketing Approval of SGLT2 Inhibitor
Luseogliflozin Hydrate (TS-071) in Japan

Taisho Pharmaceutical Holdings Co., Ltd. has announced that its consolidated subsidiary Taisho Pharmaceutical Co., Ltd. ("Taisho Pharmaceutical") [Head Office: Toshima-ku, Tokyo; President: Shigeru Uehara] today filed for marketing approval of the SGLT2 inhibitor luseogliflozin hydrate (Development Code: TS-071) with the Ministry of Health, Labour and Welfare for the indication of Type 2 diabetes mellitus. TS-071 was created by Taisho Pharmaceutical.

Luseogliflozin hydrate is a drug with a new mechanism of action that selectively inhibits sodium-glucose cotransporter 2 (SGLT2). It lowers blood glucose levels by inhibiting reabsorption of glucose in the renal tubule, thus increasing urinary glucose excretion. Phase 3 clinical trials in Japan have confirmed the blood glucose-lowering effect of luseogliflozin hydrate on HbA1c, an indicator used to control blood glucose levels, both monotherapy and in combined administration with other oral hypoglycemic agents. At the same time, the trials confirmed that there were no safety issues. Since luseogliflozin hydrate has a different mechanism of action than traditional oral hypoglycemic agents, luseogliflozin hydrate is set to become a Type 2 diabetes mellitus treatment that can be administered in combination with a broad range of other drugs.

The number of people strongly suspected to have diabetes in Japan is currently estimated to be around 9 million. Treatment is needed to lower high blood glucose levels because the long-term
neglect of diabetes can increase the risk of complications such as diabetic retinopathy and diabetic nephropathy. There are high hopes for luseogliflozin hydrate to become a novel diabetes drug that improves both postprandial blood glucose levels and fasting blood glucose, in addition to having a low risk of inducing hypoglycemia (low blood glucose), which can be a concern with diabetes drugs, as well as a body weight reduction effect.

Luseogliflozin hydrate will be manufactured by Taisho Pharmaceutical, and co-marketed by Taisho Pharmaceutical Holdings Co., Ltd.’s consolidated subsidiary Taisho Toyama Pharmaceutical Co., Ltd. ("Taisho Toyama Pharmaceutical") [Head Office: Toshima-ku, Tokyo; President: Akira Ohira] and Novartis Pharma K.K. ("Novartis Pharma") [Head Office: Minato-ku, Tokyo; President: Yoshiyasu Ninomiya] in Japan.

Through the marketing of luseogliflozin hydrate, an oral hypoglycemic agent with a new mechanism of action, by Taisho Pharmaceutical, Taisho Toyama Pharmaceutical and Novartis Pharma, we intend to provide a new diabetes treatment option to many more patients.