March, 2015

Anticancer drug "*Elplat®*" Approval for the Additional Indication of Unresectable Advanced or Recurrent Gastric Cancer

Tokyo, Japan, March 20, 2015 - Yakult Honsha Co., Ltd. (hereafter, Yakult) (President & COO: Takashige Negishi) announced today that it obtained approval for the additional indication of "unresectable advanced or recurrent gastric cancer", with respect to its products, *Elplat® (50mg, 100mg and 200mg)*, from the Japanese Ministry of Health, Labor and Welfare (hereafter, MHLW).

On December 13, 2010, Yakult officially received a request from the MHLW to pursue development of *Elplat®* for such additional indication, as a result of evaluation by the 5th "Review Committee for Unapproved or Off-Label Use of Drugs with High Medical Needs" (hereafter, Review Committee) held on October 6, 2010. Furthermore, the 20th Review Committee held on July 11, 2014, determined that such additional indication was eligible for an "Application with Public Knowledge". On September 5, 2014, the Second Committee on New Drugs of Pharmaceutical Affairs and Food Sanitation Council subsequently concluded that the Application with Public Knowledge could be allowed for such additional indication. Accordingly, Yakult had submitted such application.

Gastric cancer is the most common cancer in Japan and the number of newly diagnosed gastric cancer patients during 2010 is estimated at 125,730*1. Oxaliplatin-containing therapy is positioned as one of the standard therapies for gastric cancer in European and U.S. guidelines.

Yakult will sincerely work for promoting proper use of *Elplat®*, and continuously attempt to provide cancer patients and medical staffs with new treatment options.

*1 Center for Cancer Control and Information Services, National Cancer Center, Japan

1. *Elplat®*

Elplat® is an anticancer platinum drug, for which Yakult acquired development and commercialization rights in Japan from Debiopharm International (Switherland) in 1997. *Elplat®* was approved for the indication for the treatment of "curatively unresectable advanced/recurrent colorectal cancer" in March 2005, and launched on the market in April of the same year. In August 2009, *Elplat®* became indicated for "postoperative adjuvant chemotherapy for colon cancer".

An additional dosage and administration for "curatively unresectable advanced/recurrent colorectal cancer" was approved in September 2009, and an additional dosage and administration for "postoperative adjuvant chemotherapy for colon cancer" was approved in November 2011. In December 2013, *Elplat®* was approved for the indication for the treatment of "curatively unresectable pancreatic carcinoma". In December 2014, a supplemental new drug application for "postoperative adjuvant chemotherapy for gastric cancer" was submitted.

2. Review Committee

The Review Committee is a working group organized by the MHLW aiming to accelerate the development for drugs and indications which are not yet approved in Japan but already available in Europe and U.S. by means of evaluating medical needs as well as confirming the applicability of Application with Public Knowledge and the necessity of conducting any additional studies for marketing authorization of such drugs and indications.

3. Application with Public Knowledge

Application with Public Knowledge is a kind of marketing authorization applications for a drug commonly known to be medically and pharmaceutically effective and safe without performing clinical trials in whole or in part.