November , 2011

Approval for a Change in Dosage and Administration of Anticancer Drug, "Elplat®" in Adjuvant Chemotherapy for Colon Cancer

Yakult Honsha Co., Ltd. (President: Takashige Negishi) today announced that the Company has obtained approval for a change in dosage and administration of its anticancer platinum compound oxaliplatin in adjuvant chemotherapy for colon cancer from the Ministry of Health, Labour and Welfare on November 25, 2011. The trade names of the anticancer agent include *Elplat® for injection 100 mg*, *Elplat® for injection 50 mg*, *Elplat® for I.V. infusion solution 100 mg*, and *Elplat® for I.V. infusion solution 50 mg* (hereafter referred to as Elplat®).

The approval for the change in Elplat® dosage and administration allows clinicians to prescribe for Japanese patients concomitantly with oral anticancer agent capecitabine (XELOX regimen), which was not authorized to be included in such adjuvant chemotherapy in Japan. The XELOX regimen will reduce the frequency of patient visits for outpatient treatment to once every three weeks, providing high convenience for both patients and medical professionals.

Colorectal cancer is one of the most common cancers. In Japan, the number of new patients diagnosed during 2010 is estimated at 131,000.* Out of them, patients who have undergone radical surgery generally receive adjuvant chemotherapy with the aim of reducing the risk of recurrence.

Currently, the FOLFOX regimen, a combination of Elplat® with the continuous intravenous infusion of levofolinate and fluorouracil, is the universal standard treatment as adjuvant chemotherapy for colon cancer. The XELOX regimen is also used as a standard therapy around the world.

*Akira Oshima, Tetsuo Kuroishi, and Kazuo Tajima,
Gan/Toukeihakusho—Rikan/Shibou/Yogo—2004 (White Paper on Cancer Statistics: Incidence/Death/Prognosis 2004), Shinoharashinsha Inc.

Supplemental information

Information on Elplat®

Elplat® is an anticancer platinum compound, for which Yakult Honsha acquired development and selling rights in Japan from Debiopharm (Switzerland) in 1997. *Elplat® for injection 100 mg* was approved for the indication for the treatment of "advanced/recurrent colorectal cancer" in March 2005, and launched on the market in April of the same year. In August 2008, *Elplat® for injection 50 mg* was also approved for the same indication. In August 2009, *Elplat® for injection 50 mg* and *100 mg* became indicated for "adjuvant chemotherapy for colon cancer", while *Elplat® for I.V. infusion solution 50 mg* and *100 mg* became indicated for both the treatment of "advanced/recurrent colorectal cancer" and "adjuvant chemotherapy for colon cancer." In September 2009, since *Elplat® for injection 50 mg and 100 mg, Elplat® for I.V. infusion solution 50 mg* and *100 mg* were approved for additional dosage and administration as "advanced/recurrent colorectal cancer", Elplat® has been administered with an oral anticancer agent capecitabine, as XELOX regimen in Japan.

Elplat® is widely prescribed as the standard chemotherapy for advanced/recurrent colorectal cancer and adjuvant treatment of colon cancer, in Japan and abroad.