December, 2013

Anti Cancer drug; Campto®, Anti cancer drug; Elplat®,
Folinic acid;Levofolinate [Yakult]
Approvals for the Additional Indication of Unresectable Pancreatic Cancer

Tokyo, Japan, December 20, 2013 - Yakult Honsha Co., Ltd. (hereafter, Yakult) (President & COO: Takashige Negishi) announced today that it obtained approvals for the additional indication of "unresectable pancreatic cancer", with respect to its products, *Campto® (40mg and 100mg), Elplat® (50mg, 100mg and 200mg), and Levofolinate [Yakult] (25mg and 100mg)*, from the Japanese Ministry of Health, Labor and Welfare (hereafter, MHLW).

On April 6, 2012, Yakult officially received a request from the MHLW to pursue development of FOLFIRINOX regimen (as described below) for pancreatic cancer, as a result of evaluation by the 11th Review Committee for unapproved or off-label use of drugs with high medical needs (hereafter, Review Committee) held on March 23, 2012, and as of May 31, 2013, Yakult has submitted supplemental new drug applications for pancreatic cancer.

These approvals were based on a Phase Ⅱ/Ⅲ study conducted in France which is known as the ACCORD 11 Study and a Phase Ⅱ study conducted by Yakult in Japan regarding FOLFIRINOX regimen for patients of metastatic pancreatic cancer, which had not been previously treated with chemotherapy. Debiopharm International, a Swiss Biopharmaceutical Company based in Lausanne, the licensor of Elplat® to Yakult for the development and commercialization in Japan, supported Yakult in the data review of ACCORD 11 Study and the design of the Phase Ⅱ study in Japan.

Pancreatic cancer is one of cancers with a few treatment options. In Japan, the number of newly diagnosed pancreatic cancer patients during 2008 was estimated at around 30,000.

Yakult will sincerely work for promoting proper use of these products for this indication, and continuously attempt to provide cancer patients and medical staffs with new treatment options.

Note:

1. FOLFIRINOX regimen
The FOLFIRINOX regimen is a combination therapy of 4 drugs; irinotecan hydrochloride, oxaliplatin, fluorouracil and levofolinate calcium. This regimen is generally used for pancreatic cancer overseas and is already used as a standard therapy for pancreatic cancer in U.S., Canada and EU.

The ACCORD11 Study showed that the median overall survival was 11.1

months, the median progression free survival was 6.4 months and objective response rate was 31.6% in patients with the FOLFIRINOX regimen, which were significantly improved in comparison with patients with another standard chemotherapy, gemcitabine alone. As well, similar efficacy and tolerability to the ACCORD11 Study were confirmed in the domestic Phase Ⅱ study.

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.