

Translation

May, 2013

## Submission of Supplemental New Drug Applications for Pancreatic Cancer

Tokyo, Japan, May 31, 2013 - Yakult Honsha Co., Ltd. (hereafter, Yakult) (President & COO: Takashige Negishi) announced today that it submitted supplemental new drug applications relating to an additional indication for pancreatic cancer, with respect to its products, *Campto®* (40mg and 100mg), *Elplat®* (50mg, 100mg and 200mg), and *Levofolinate [Yakult]* (25mg and 100mg), to 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.

These supplemental new drug applications were submitted 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, Yakult's licensor and supplier of *Elplat®* in Japan, was involved in the design of the Japanese FOLFIRINOX clinical study and in the data review.

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 the early approvals for these supplemental new drug applications to provide the new treatment option for patients with pancreatic cancer and medical staffs engaged in the treatment thereof in Japan.

Note:

1. FOLFIRINOX regimen

The FOLFIRINOX regimen is a combination therapy of 4 drugs; oxaliplatin, irinotecan hydrochloride, 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.