October 24, 2023

Transfer of Marketing Authorization of Anticancer Drug Elplat® to Takata Pharmaceutical

Debiopharm International SA (headquarters: Lausanne, Switzerland; CEO: Bertrand Ducrey; hereinafter "Debiopharm"), Yakult Honsha Co., Ltd.(headquarters: Minato-ku, Tokyo; President and Representative Director: Hiroshi Narita; hereinafter "Yakult Honsha") and Takata Pharmaceutical Co., Ltd. (headquarters: Saitama City, Saitama; Representative Director and President: Hiroki Takada; hereinafter "Takata Pharmaceutical") today announced that they have agreed that Yakult Honsha will transfer the marketing authorization in Japan of anticancer drug Elplat® (generic name: oxaliplatin, trade name: Elplat® I.V. Infusion Solution 50 mg, 100 mg, 200 mg; hereinafter "Elplat®") that Yakult Honsha licensed from Debiopharm and that was manufactured and marketed in Japan, to Takata Pharmaceutical in phases.

To achieve a smooth transfer of the marketing authorization of Elplat® as well as stable supply and drug information activities of Elplat® to Takata Pharmaceutical, the transfer will be performed in 2-phased plan consisting of the transfer of sales and distribution activities and subsequent transfer of the marketing authorization as described below.

- Transfer of sales and distribution: April 2024 (tentative)
- Transfer of the marketing authorization: April 2025 (tentative)

About Elplat®.

Elplat® is an anticancer platinum drug, for which Yakult Honsha acquired development and commercialization rights in Japan from Debiopharm 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. Subsequently, Elplat® was approved for the indication for the treatment of “curatively unresectable pancreatic carcinoma” in December 2013. And furthermore, Elplat® was approved for the indication for “unresectable advanced or recurrent gastric cancer” in March 2015 and then “gastric cancer” in November 2015, integrating “unresectable advanced or recurrent gastric cancer” and “postoperative adjuvant chemotherapy for gastric cancer”. And in September 2018, the indication for "small intestinal cancer" was approved.

About Yakult Honsha

Yakult Honsha is a Japanese company that develops, manufactures and markets beverages, foods, pharmaceuticals and cosmetics under the corporate philosophy of "We contribute to the health and happiness of people around the world through pursuit of excellence in life science in general and our research and experience in microorganisms in particular."

About Takata Pharmaceutical

Takata Pharmaceutical is a research and development-oriented company that is primarily engaged in the research, development, manufacturing and marketing of pharmaceutical products under the corporate philosophy of " Contributing to the health of people by developing innovative products and supplying high-quality products" including value-added generic drugs with strength in the field of pediatrics.

About Debiopharm

Debiopharm’s commitment to patients

Debiopharm develops innovative therapies that target high unmet medical needs in oncology and infectious diseases. Bridging the gap between disruptive discovery products and real-world

patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally.

For more information, please visit www.debiopharm.com

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