August 15, 2023
Fuji Pharma Co., Ltd.

Marketing Approval for generic lenalidomide, the first collaboration product with Lotus

Tokyo, Japan - Fuji Pharma Co., Ltd. ("Fuji") has announced that it has received marketing approval for a new generic drug containing lenalidomide as active pharmaceutical ingredient and 2 strengths. The newly approved drug, Lenalidomide capsules 2.5mg/5mg「F」, has been indicated for the treatment of multiple myeloma and other medical conditions.

Lenalidomide capsules 2.5mg/5mg「F」is the first collaboration product with Lotus Pharmaceutical Co., Ltd. (Head Office: Taiwan, TPEX ticker:1795, "Lotus"), based on the capital and business alliance agreement signed by Fuji and Lotus. Lotus is responsible for the formulation development, whereas Fuji takes responsibility for the local BE study as Lotus will be supplying the finished product to Fuji for commercialization in Japan.

In Fuji's Mid-Term Business Plan (FY9/2020-9/2024), Fuji has set " Men's hormones, anti-cancer, and other products " as our target at the end of FY9/2029. The launch of Lenalidomide capsules 2.5mg/5mg「F」will lead to a stronger lineup of anti-cancer drugs in this target and Fuji will provide new treatment options to patients and medical professionals through the supply of this product. Fuji will continue our efforts to expand our product lineup and make further contributions in the healthcare field and the healthcare economy.

Therapeutic category	Product name	Original drug
Antihematopoietic malignancy agent	Lenalidomide capsules 2.5mg/5mg「F」	Revlimid Capsules 2.5mg / 5mg

[About Lotus]
Founded in 1966, Lotus (1795: TT) is an international pharmaceutical company with global presence, focused on commercializing novel and generic pharmaceuticals, offering patients better, safer and more accessible medicines. The Company has a recognized best-in-class R&D and manufacturing platform in Asia and has established partnerships in nearly every global market including the U.S., Europe, Japan, China, and Brazil. Lotus runs over 100 strategically selected pharmaceutical projects in development and registrations across Asia and the US, with over 250 commercial products. The Company invests in diversified best portfolio consisting of high-barrier oncology, complex generics as well as 505(b)2 and NCE via internal R&D investment and licensing-in partnership, and also strengthens its portfolio competitiveness by adding biosimilar products with support from strategic partners. Its industry-leading infrastructure certified by most of the advanced regulatory authorities around the world, including US FDA, EU EMA, Japan PMDA, China FDA, and Brazil ANVISA.

Note

The financial forecasts and other projections provided in this release are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks. Actual results may differ significantly from these forecasts for a number of reasons. It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification. Information in this release about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

For further information, contact

Fuji Pharma Co., Ltd.

Corporate Communication Section, Corporate Planning Department, Corporate Strategy Division

fsks@fujipharma.jp