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Fusen Pharmaceutical Company Limited

福森藥業有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1652)

VOLUNTARY ANNOUNCEMENT APPLICATION FOR LAUNCHING “ENZALUTAMIDE SOFT CAPSULES” BEING ACCEPTED

The board of directors (the “**Board**”) of Fusen Pharmaceutical Company Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the application for launching “Enzalutamide Soft Capsule” developed by Jiaheng (Zhuhai Hengqin) Pharmaceutical Technology Company Limited* (嘉亨(珠海橫琴)醫藥科技有限公司), a wholly-owned subsidiary of the Group, has been submitted to and accepted by the National Medical Products Administration of the People’s Republic of China. Enzalutamide Soft Capsule is used for the treatment of the following diseases: this product is suitable for adult patients with non-metastatic castration-resistant prostate cancer (NM-CRPC) with high risk of metastasis; Treatment of adult patients with metastatic castration-resistant prostate cancer (CRPC) who have no symptoms or mild symptoms after the failure of androgen deprivation therapy (ADT) and have not received chemotherapy.

Prostate cancer is a common type of urological malignancy, ranking second in the incidence rate of male cancer and fifth in cancer mortality rate globally. The incidence rate of prostate cancer in our country is lower than that in western countries, but it has shown an upward trend in recent years.

Enzalutamide is an androgen receptor inhibitor used in the androgen receptor signalling pathway, which can competitively inhibit the binding of androgen to androgen receptors, thereby inhibiting the nuclear displacement of androgen receptors and the interaction between androgen receptors and DNA. The in vitro activity of N-desmethyl-Enzalutamide, Njalutamide’s main metabolite, is similar to that of Njalutamide. Enzalutamide can inhibit prostate cancer cell proliferation and induce death in vitro, and can reduce tumour volume in mouse prostate cancer transplant tumour models.

Enzalutamide was launched in the United States in 2012 and the European Union in 2013. It was approved for launch in the PRC in 2019, mainly used for the treatment of castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer.

This product is a Class B drug under the National Reimbursement Drug List, and has no medical insurance indications or disease restrictions. It is a mainstream drug for the treatment of prostate cancer and is recommended by domestic and foreign authorities. It has advantages such as good affinity, good efficacy, small molecule compounds, no cytotoxicity, good safety and long-term administration. The “Enzalutamide Soft Capsule” developed by the Company is declared under class 4 of chemical drugs, and its prescription is basically the same as the original reference listed drug. The quality of the product is strictly controlled, and its quality and efficacy are consistent with the original reference listed drug through pharmaceutical and clinical (BE) research, so as to ensure the medication safety of patients. “Enzalutamide Soft Capsule” provides a very favourable risk-benefit ratio in respect of laboratory examination results and clinical symptoms of the treatment of adult patients with non-metastatic castration-resistant prostate cancer (NM-CRPC) who have high risk of metastasis and adult patients with metastatic castration-resistant prostate cancer (CRPC) who have no symptoms or mild symptoms after the failure of androgen deprivation therapy (ADT) and have not received chemotherapy.

“Enzalutamide Soft Capsule” is another important product of the Group, which further enriches the Group’s product pipeline in the area of anti-tumour therapy. The launch of this product will provide more therapeutic options for adult patients with prostate cancer.

By order of the Board
Fusen Pharmaceutical Company Limited
Mr. Cao Changcheng
Chairman and Executive Director

Hong Kong, 30 May 2024

As at the date of this announcement, the Board of the Company comprises Mr. Cao Changcheng (Chairman), Mr. Hou Taisheng, Mr. Chi Yongsheng, Ms. Meng Qingfen and Mr. Cao Zhiming (formerly known as Mr. Cao Dudu) as executive Directors, and Mr. Sze Wing Chun, Mr. Lee Kwok Tung, Louis and Dr. To Kit Wa as independent non-executive Directors.

* *For identification purposes only*