BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Daewoong Pharmaceutical submits NDA for global new drug Fexuclue Tablets to the Philippines

March 29, 2022 | News

Daewoong Pharmaceutical expects to strengthen its global business in key markets of ASEAN countries by obtaining marketing authorization in foreign countries with its branch offices



South Korea's Daewoong Pharmaceutical has submitted the New Drug Application (NDA) for a new drug Fexuclue 40 mg Film-coated Tablets (ingredient name: Fexuprazan) to the Philippines, Thailand, and Indonesia among countries where Daewoong has overseas corporations and branch offices (hereafter countries with Daewoong's branch offices).

Daewoong prepared additional research data locally required by each country and submitted NDA sequentially to three countries in the Association of Southeast Asian Nations (ASEAN) region from last February to mid-March. This is the first case of applying for marketing authorization to countries with Daewoong's branch offices for a chemical new drug developed by Daewoong since its entry into overseas business, and Daewoong holds the marketing authorization.

The total pharmaceutical market size of the three major ASEAN countries, namely the Philippines, Thailand, and Indonesia, is valued at $13.5 billion, according to the Global IMS in 2020. In particular, Indonesia is the fourth most populous country in the world with a population of about 280 million and a high market potential. The estimated market size of the three countries reaches $452 million.

Fexuclue Tablets is the best-in-class new drug in the class of gastroesophageal reflux disease developed by Daewoong. It is a potassium-competitive acid blocker (P-CAB) that reversibly blocks the proton pump that secretes gastric acid from the stomach wall.

Meanwhile, Fexuclue Tablets obtained approval from the Ministry of Food and Drug Safety in Korea last December, aiming to launch in Korea in this summer.