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Daewoong Pharmaceuticals gets CFDA nod to start Nabota clinical trials in China

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Nabota was launched in Korea in 2014, followed by successive launches in Thailand, the Philippines, South America, Mexico, and Vietnam.



Korea's Daewoong Pharmaceutical recently announced that it has received China's regulatory nod for running clinical trials of its botulinum toxin treatment (BTX) type A product, Nabota. With this product, Daewoong is making inroads into China, hoping to launch the product by 2020.

Nabota was launched in Korea in 2014, followed by successive launches in Thailand, the Philippines, South America, Mexico, and Vietnam. Daewoong manufactured a total of 19.52 billion won ($18.21 million) worth of Nabota in 2016, and 19.37 billion won in 2015, reported a leading Korean news portal.

The announcement comes as the China Food and Drug Administration approved the company's Clinical Trial Application (CTA) for Nabota filed in 2016, Daewoong said.

Lee Jong-wook, CEO, Daewoong Pharma, said, "The Chinese approval is noteworthy in that it took Nabota only 18 months from product filing to approval, whereas it takes an average of 30 months for existing, competing products. We expect the next steps to proceed just as quickly."

Daewoong Pharmaceutical's Chinese unit will begin phase 3 clinical studies on Nabota for the treatment of glabellar lines between the eyebrows this year and complete it by 2019.

Deawoong Pharmaceutical, said in a statement that it holds export contracts with major Middle Eastern countries such as Saudi Arabia and the United Arab Emirates, as well as India, and expects an expansive global market launch this year.

Daewoong has also applied for marketing rights to the U.S. FDA and the European EMA last year, and is undergoing a review with health regulators to ensure its manufacturing facilities meet the standards of Good Manufacturing Practice, it said.