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Lunsumio Provides First Test For Korea's Breakthrough Therapy Program

GIFT Designed To Speed Reviews

by Jung Won Shin

South Korea's breakthrough therapy system, Global Innovative Products Fast Track, kicks off with Roche's follicular lymphoma drug becoming the first to test the new system. Meanwhile, a state-run group is linking with pharma firms to rapidly bring in global new drugs.

South Korea's regulatory authorities are making diverse efforts to enable the more rapid introduction of novel therapies to the country, as part of a broad goal of improving patients' access to medical innovation.

As part of this, the Ministry of Food and Drug Safety (MFDS) has now selected [Roche Holding AG's](#) Lunsumio (mosunetuzumab) as the first product to be reviewed under its new Global Innovative Products Fast Track (GIFT) program, introduced earlier this year to prioritize and speed up regulatory reviews of innovative medicines.

Lunsumio, a CD20xCD3 T-cell engaging bispecific antibody which received EU approval in June, is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies. It was selected for the GIFT initiative amid a lack of existing treatments for the disease, as well as the urgency of bringing in the drug for an unmet need, the ministry said.

The GIFT program, launched in September, aims to provide similar benefits to the Breakthrough Therapy program in the US, in terms of accelerated reviews and speeding up the commercialization of innovative products. The MFDS will designate eligible projects started from the early stages of clinical development and aims to allow some data not directly relevant to

safety to be submitted after launch.

The new initiative is part of the Korean government's ongoing efforts for regulatory innovation, and expediting processed to match global standards and support new technologies and patient access.

Eligibility Criteria

The medicines that can benefit from the GIFT program should meet the following general criteria:

- be for life-threatening or rare diseases with no existing treatments or which have shown meaningful improvements in efficacy versus existing treatments;
- prevent or treat infectious diseases which can seriously harm public health (including bioweapons) and which lack existing treatments or which have shown meaningful improvements in efficacy versus existing treatments or be of a novel concept or mechanisms of action;
- be developed by entities officially designated as "innovative" by the health ministry;
- be "onvergence products" that combine a standard product with drug and/or medical device subject to accelerated review.

Products processed under the GIFT system will have a standard shorter review period of as little as 90 days (from 120 days) and will receive various other forms of support including preparation of approval documents, allowance of rolling reviews, and close regulatory consultations/briefings between developers and reviewers.

Global review standards, such as International Conference on Harmonisation guidelines, will also be applied to prevent clashes with foreign regulators' approaches and to support the rapid entry into global markets of Korean innovative products.

KoNECT Links With Pharma For Global Drugs

In a separate effort, the Korea National Enterprise For Clinical Trials (KoNECT), which is

Korea's Regulatory Innovation Steps Focus On Investment, New Technologies

By [Jung Won Shin](#)

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South Korean ministries release comprehensive broad steps under new government aimed at accelerating investment to deal with infectious diseases and supporting regulatory innovation, including speeding up processes, to match global standards, support new technologies and improve access.

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affiliated with the country's health ministry, and two major domestic pharma firms have also joined hands to bring in new drugs from abroad.

According to a KoNECT report, 617 new drugs were developed and launched worldwide from 2011 to 2020, but only 36.5%, or 225, of these have been launched in South Korea so far - about half of the 415 within the group that were launched in the US.

The report noted that this "drug lag" between Korea and the US is about 21.8 months on average, the biggest reasons being related to marketability and business issues.

Of the 244 new global drugs that didn't launch in Korea, 34 have now been selected by authorities as needing to be introduced in the country, including with the highest priority Beleodaq (belinostat), Palynziq (pegvaliase), Zinplava (bezlotoxumab), artesunate and Xerava (eravacycline).

In the past couple of months, KoNECT has reached agreements with Dong-A ST, an affiliate of [Dong-A Socio Holdings](#), and Boryung Corp., formerly known as [Boryung Pharmaceutical Co., Ltd.](#), to address unmet medical needs in the country and expand treatment options for rare and intractable diseases.

KoNECT will share information on 244 new medicines that have been developed and launched overseas and cooperate with the two firms to bring these into the country.

"The latest agreement is a new cooperation way between public and private companies to bring in new foreign drugs," KoNECT president Byoungjun Bae said.