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Korea's New Fast Track Scheme A GIFT For High-Need Drugs

Nefecon, Pegcetacoplan Selected

by Jung Won Shin

South Korea designates two more global innovative products for support under a new fast track system, in a move set to speed up patient access to novel therapies.

South Korea's Ministry of Food and Drug Safety (MFDS) has designated two orphan drugs - *Calliditas Therapeutics AB*'s budesonide and *Apellis Pharmaceuticals, Inc.*'s pegcetacoplan - as the second and third products to be accepted into the newly established Global Innovative Products on Fast Track (GIFT) scheme, meaning they will receive support from early-stage clinical trials to enable more rapid commercialization.

The ministry had been operating a fast track system since August 2020 amid the COVID-19 pandemic and designated 23 products under this system. The products that went on to approval included *Celltrion, Inc.*'s COVID-19 antibody treatment Regkirona (regdanvimab), as well as COVID-19 vaccines from *AstraZeneca PLC*, *Pfizer Inc.*, *Moderna, Inc.*, *Janssen Pharmaceutical Cos.*, *Novavax, Inc.* and *SK Bioscience*.

In September last year, the ministry newly established the GIFT system to reinvigorate the fast track pathway, as part of which it selected *Roche Holding AG*'s follicular lymphoma drug Lunsumio (mosunetuzumab) as the first product to be reviewed. GIFT aims to provide similar benefits to the Breakthrough Therapy program in the US, in terms of accelerated reviews and speeding up the commercialization process for important new innovative products.

The MFDS intends to designate eligible projects from the early stages of clinical development and to allow some data not directly relevant to safety to be submitted after launch.

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Rationale For New Selections

Budesonide, used for the treatment of igA nephropathy, was selected for GIFT as there are current no treatments for the disease in Korea. Notably, the fast track system does allow additional indications for already approved drugs (as in this case) to be designated.

Calliditas's lead product was granted accelerated approval by the US Food and Drug Administration under the trade name Tarpeyo and conditional marketing authorization by the European Commission as Kinpeygo, becoming the first and only approved treatment for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need. More than 50% of patients potentially progress to end-stage renal disease and there are about 9,000 patients in Korea.

Lunsumio Provides First Test For Korea's Breakthrough Therapy Program

By Jung Won Shin

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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.

Read the full article here

Apellis's pegsetacoplan, a targeted C3 complement inhibitor, is used to treat geographic atrophy (GA) and was selected for GIFT because it has improved efficacy versus existing treatments, the regulatory authorities noted. There are currently no treatments to slow the progression of GA, a leading cause of vision loss and blindness that impacts more than five million people globally; Korea has about 500 patients.

The drug is the only treatment to demonstrate increased effects over 24 months across a broad patient population, and in December Apellis submitted a marketing authorization application to the European Medicines Agency for an intravitreal formulation for GA secondary to age-related macular degeneration. A US filing is under review with a Prescription Drug User Fee Act target action date of 26 February.

Daewoong Shares GIFT Experience

During a recent briefing to showcase the impact of the new fast track system, *Daewoong Pharmaceutical Company Ltd.* - officially designated as "an innovative pharma company" in the country this year - shared its experience of GIFT treatment for its newly approved diabetes drug Envlo (enavogliflozin).

Envlo, a SGLT2 inhibitor, was originally designated to the previous fast track system in 2020 and then moved over to the GIFT scheme. It was approved last November, with a launch planned in the first half of 2023, and the process was shortened by two months using the program's rolling

review system.

“For a company, this is really helpful as a shorter approval process can lead to earlier exports. In fact, we could progress exports to Brazil, Mexico and Saudi Arabia one step faster,” said Jong Won Choi, head of development at Daewoong. “After being designated to undergo GIFT, we could frequently communicate with the reviewer through ways such as briefings and technology consultations. This clarified directions for preparation and allowed prompt preparation of documents.”

Going forward, the MFDS said it plans actively to communicate with innovative pharma firms to understand their challenges in the development of new drugs, and to encourage the rapid approval and export of outstanding Korean products.

The ministry stressed it will be highly receptive to the views of developers, which it notes need official support to rapidly commercialize medicines using innovative technologies.