



<div></div> <div> Ministry of Food and Drug Safety</div>	<div>보 도 자 료</div>	배 포	2020. 12. 31.(목)
		담 당 과	의약품안전국 임상정책과 식품의약품안전평가원 생물제제과
		과 장	김정미 (☎043-719-1856) 김재욱 (☎043-719-3461)
		사 무 관 연 구 관	김희선 (☎043-719-1862) 김도근 (☎043-719-3463)

COVID-19 vaccine developed in Korea approved for clinical trial (Phase I/II)

21 COVID-19 therapeutics and vaccines in clinical trials in Korea

□ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) granted approval, on Dec. 31, for the clinical trial of GBP510, a vaccine developed by SK Bioscience in Korea.

○ A total of 15 drugs (13 APIs) and 6 vaccines, approved for COVID-19-related clinical trials, are currently under development in Korea.

□ The clinical trial of SK Bioscience's vaccine is conducted in healthy adults to evaluate the safety and immunogenicity* of GBP510. Phase II clinical trial will follow after the completion of Phase I.

* immunogenicity : the increase rate of neutralizing antibody titer, which will eliminate or reduce virus infectivity

○ GBP510 is a recombinant vaccine that contains coronavirus' surface antigen produced through recombinant technology.

- The infection prevention mechanism is that the surface antigen of the vaccine triggers immune response by stimulating the immune cells to produce neutralizing antibodies. The antibodies, in turn, destroy the coronavirus when it enters the human body.

- SK Bioscience also received MFDS approval for Phase I trial of a recombinant vaccine, NBP2001, on Nov. 23. NBP2001 induces immune

response using the coronavirus's surface antigen, whereas GBP510 uses the surface antigen that binds to a specific protein that forms a nanostructure (icosahedron).

< Vaccines approved for clinical trials in Korea >

Vaccine Types	Sponsor (product name)	Clinical Trial Phase
DNA vaccine (3)	International Vaccine Institute (INO-4800)	I/II
	Genexine (GX-19N)	I/II
	GeneOne Life Science (GLS-5310)	I/II
Recombinant vaccine (2)	SK Bioscience (NBP2001)	I
	SK Bioscience (GBP510)	I/II
Viral vector vaccine (1)	Cellid (AdCLD-CoV19)	I/II

- Pharmaceutical companies across the world are also conducting clinical trials of COVID-19 vaccines that use recombinant technology. (e.g. Novavax in the U.S.: Phase III)
- Mindful of the heightened public interest in the development of COVID-19 treatments and vaccines, MFDS will continue to promptly provide updates on the clinical trials of such products.
- The Ministry will also make every effort to ensure appropriate access to treatment options for the Korean people by providing necessary assistance to accelerate the development of safe and effective COVID-19 treatments and vaccines.