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Korea gives fast track approval to promising DNA vaccine for advanced cervical cancer

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Genexine receives fast track designation from Korean Health Authority

Genexine, a clinical-staged Korean biopharmaceutical company committed to the discovery and development of novel biologics for the treatment of unmet medical needs, has received Fast Track Designation (FTD) from the Korean Ministry of Food and Drug Safety (MFDS) for GX-188E (tirvalimogene teraplasmid), its first-in-class proprietary therapeutic DNA vaccine.

Following an evaluation of the full set of Phase 2 data from the recently completed clinical trial in advanced cervical cancer, Korea's Health Authority (MFDS) concluded that GX-188E met the criteria for fast-track designation.

Under MFDS regulations, FTD is given to a drug that is intended to treat a serious condition and the nonclinical or clinical data demonstrate the potential to address an unmet medical need. Having such a designation can mean that a drug can move more quickly through the development and regulatory process in an expedited manner.

Neil Warma, Genexine's President and CEO said, "We are committed to the cancer patients in which this therapy could be effective and appreciate that FTD could help to possibly speed our time to market to deliver the drug to patients more rapidly. We are in the process of designing the optimal Phase 3 study with GX-188E and expect to initiate that study this year."