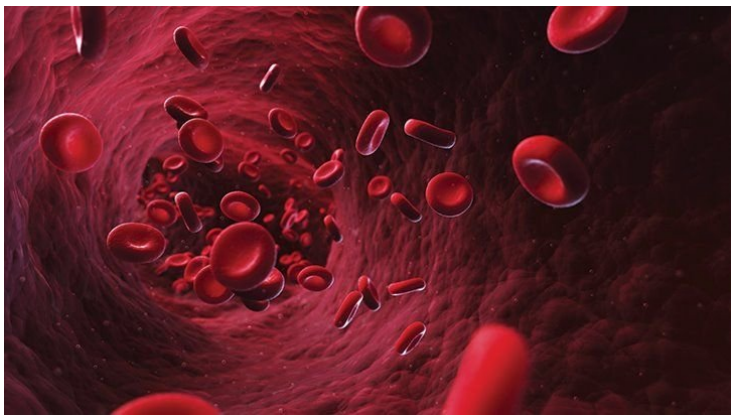
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Genexine and KGbio receive market approval for novel long-acting Erythropoietin in Indonesia

October 23, 2023 | News

A long-acting erythropoietin (EPO) for the treatment of chronic kidney disease induced anaemia



Genexine, a publicly-listed clinical-staged Korean biopharmaceutical company, together with PT Kalbe Genexine Biologics (KGbio), a joint venture clinical-stage biotechnology company between Genexine and Indonesia-based PT Kalbe Farma, have announced the approval of its long-acting erythropoietin, Efepoetin alfa (GX-E4), by the Indonesian Ministry of Food and Drug Safety (BPOM) for the treatment of chronic kidney disease (CKD) induced anaemia in non-dialysis patients. This milestone marks the first market approval for a drug originating from Genexine's research and development with KGbio.

Genexine, in collaboration with KGbio, has been co-developing Efepoetin alfa for CKD patients in both non-dialysis and dialysis settings. While this BPOM approval specifically pertains to the treatment of CKD-induced anaemia in non-dialysis patients, it is anticipated that further approvals for dialysis patients with CKD-induced anaemia will be secured in due course.

Furthermore, a multinational Phase 3 clinical trial targeting dialysis patients is set to commence in the Q4 of 2023, spearheaded by Genexine and KGbio. This study will be conducted across 11 countries in Europe and Asia to facilitate a label expansion including both dialysis and non-dialysis patient populations.