BioSpectrum the business of Bio & Health Sciences

DCGI approves Zydus to market biologic for rabies

03 September 2019 | News

Twinrab is the first-of-its-kind, next-gen therapy for treating rabies

Zydus has announced that it has received marketing authorization for TwinrabTM (RabiMabs) from the Drug Controller General of India (DCGI). The novel biologic which will be marketed under the brand name, Twinrab, is indicated in combination with rabies vaccine for rabies post-exposure prophylaxis. The United States Food and Drug Administration (USFDA) has granted an orphan drug status to this candidate.

In 2008, Zydus had entered into an agreement with the World Health Organization (WHO) to explore opportunities in the development of a cocktail of monoclonal antibodies for the treatment of rabies. The use of rabies monoclonal antibodies could emerge as an innovative therapy and form a potent alternative to current blood derived rabies immunoglobulins (RIG's) produced by vaccinating horses (ERIG) or humans (HRIG).

WHO encourages the use of monoclonal antibodies over blood derived RIG where available and has identified the development of products containing two or more antibodies that bind to two different sites on the rabies virus as a research priority. Zydus' Twinrab is the only therapy that meets this requirement.

Speaking on the development, Mr. Pankaj R. Patel, Chairman, Zydus Group said, "After the successful launch of Lipaglyn, our first NCE, we are now ready to launch our Novel Biological Entity, TwinrabTM. Our journey of discovery and the ability to take NCEs and NBEs from lab to market, is in line with our commitment to innovate and bridge unmet healthcare needs. This approval marks a transformational next-gen therapy for rabies treatment as we take a step forward from RIG to Twinrab ."

Zydus currently also manufactures and markets the rabies vaccine – VaxiRab N which is a WHO pre-qualified vaccine.