

Zydus to launch novel biologic for rabies, Twinrab™

*Twinrab™ (RabiMabs), approved by the DCGI, is the first-of-its-kind,
next-gen therapy for treating rabies
The USFDA has granted orphan drug designation to the product*

Ahmedabad, September 3, 2019

Zydus today announced that it has received marketing authorization for Twinrab™ (RabiMabs) from the Drug Controller General of India. 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, Twinrab™. 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.

About Rabies

Rabies is a fatal disease and is prevalent in 150 countries across the globe. The disease transmits through the bite of a rabid animal and infects the central nervous system, causing encephalopathy (disease of the brain) and could ultimately result in death, if medical treatment is not sought before the symptoms appear. WHO statistics reveal that dog bites claims lives of more than

55,000 people each year and India (~21,000 deaths) accounts for 35% * of the world's deaths. With over 2,000 deaths reported each year, on average, for the past 10 years, China has the second highest number of reported rabies cases in the world. In USA, domestic animals like dogs, cats and wildlife like bats, raccoons, and skunks are the major carriers of rabies. The Centre for Disease Control and Prevention statistics for USA revealed that 30,000 to 60,000 persons are administered rabies post-exposure prophylaxis each year.

About Twinrab™

The blood derived RIGs are in limited supply, expensive and can lead to infections and adverse reactions due to varying purity. As Twinrab™ is cell culture derived, it offers high levels of purity including freedom from risk of infections as compared to the human serum derived products. Twinrab™ will be produced in bioreactors, making it easier to produce in large quantities. While the rabies vaccine induces active immunity, the rabies monoclonal antibodies are to be administered with the vaccine to provide immediate passive neutralizing activity which means more protection for the patient.

Twinrab™ is a prescription drug authorized for sale in India only and can be taken only under the advice and guidance of a registered medical practitioner.

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs over 23,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

**Source : From the latest Rabies TRS : <https://apps.who.int/iris/bitstream/handle/10665/272364/9789241210218-eng.pdf>*