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First-ever Indian drug to get direct US FDA approval to enter ph 3 trials in US & EU

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Centhaquine set to enter US FDA approved phase 3 clinical trial in US and Europe

Pharmazz India, a majority-owned subsidiary of US-based Pharmazz, Inc.'s first-in-class drug developed in India, Centhaquine has become the first-ever Indian drug to get direct approval from the US Food and Drug Administration (FDA) to enter phase 3 clinical trials in the United States and the European Union (EU).

Pharmazz India obtained marketing authorisation for Lyfaquin® (Centhaquine) to manage hypovolemic shock in India in May 2020. Centhaquine citrate, a resuscitative agent for managing hypovolemic shock, was found to be effective without causing arterial constriction or an increase in blood pressure by enhancing the output from the heart.

It is a compound that acts via a unique mechanism of action. Since more than half of our blood is pooled on the venous side of circulation and is not supplying oxygen and nutrition to the tissues, centhaquine can divert that blood to the heart and on the arterial side of circulation to increase tissue blood perfusion and increase the supply of oxygen and nutrition to the tissues and hence save organ from failure.

In clinical studies already conducted in India, Centhaquine has been found to be safe and effective in improving blood pressure and reducing mortality having been administered to approximately 6000 patients across 250+ hospitals throughout the country. An ongoing phase IV clinical study has enrolled 139 patients until now across many leading Indian hospitals.

With the successful completion of this trial, Centhaquine will become a first-in-class new chemical entity that originated from India to become a drug that is needed for unmet medical need to save lives across the globe. Centhaquine can be of particular help in saving lives of patients with massive blood loss in civilian or military population.