

FDA approves drug to treat dangerously low blood pressure

22 December 2017 | News

La Jolla Pharmaceutical Company Announces FDA Approval of Giapreza™ (angiotensin II)



La Jolla Pharmaceutical Company announced that the U.S. Food and Drug Administration (FDA) have approved GiaprezaTM (angiotensin II) to increase blood pressure in adults with septic or other distributive shock.

"Shock, the inability to maintain blood flow to vital tissues, can result in organ failure and death," said Norman Stockbridge, director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research.

According to Norman, There is a need for treatment options for critically ill hypotensive patients who do not adequately respond to available therapies.

Hypotension is abnormally low blood pressure. Shock is a critical condition in which blood pressure drops so low that the brain, kidneys and other vital organs can't receive enough blood flow to function properly.

In a clinical trial of 321 patients with shock and a critically low blood pressure, significantly more patients responded to treatment with Giapreza compared to those treated with placebo.

Giapreza effectively increased blood pressure when added to conventional treatments used to raise blood pressure.

This application received a Priority Review, under which the FDA's goal is to take action on an application within six months when the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

La Jolla plans to make Giapreza available in the U.S. market in March 2018.