FDA News Release

FDA approves drug to treat dangerously low blood pressure

For Immediate Release

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Release

The U.S. Food and Drug Administration today approved Giapreza (angiotensin II) injection for intravenous infusion 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, M.D., Ph.D., director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research. "There is a need for treatment options for critically ill hypotensive patients who do not adequately respond to available therapies."

Blood pressure is the force of blood pushing against the walls of the arteries as the heart pumps out blood. 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.

Giapreza can cause dangerous blood clots with serious consequences (clots in arteries and veins, including deep venous thrombosis); prophylactic treatment for blood clots should be used.

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.

The FDA granted the approval of Giapreza to La Jolla Pharmaceutical Company.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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