FDA approves cablivi for rare blood-clotting disorder

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(HealthDay)—Cablivi (caplacizumab-yhdp) injection has been approved

by the U.S. Food and Drug Administration to treat adults with acquired thrombotic thrombocytopenic purpura (aTTP).

"Patients with aTTP endure hours of treatment with daily plasma exchange, which requires being attached to a machine that takes blood out of the body and mixes it with donated plasma and then returns it to the body," Richard Pazdur, M.D., director of the FDA Oncology Center of Excellence, said in a statement. "Even after days or weeks of this treatment, as well as taking drugs that suppress the immune system, many patients will have a recurrence of aTTP."

Cablivi is the first targeted treatment that inhibits blood clot formation and provides a new treatment option for patients that may reduce recurrences. Cablivi was evaluated in clinical studies involving 145 people. Those treated with Cablivi had fewer instances of aTTP-related death, the FDA said.

Common side effects include headache and bleeding of the nose or gums. Cablivi's prescribing information includes a warning about the risk for severe bleeding. Health care providers should closely monitor patients who also take anticoagulants, the FDA said.

The drug is produced by Ablynx, based in Belgium.

More information: More Information