November 21, 2025

Takeda Provides Update on ADZYNMA (ADAMTS13, recombinant-krhn)

Earlier today, the U.S. Food and Drug Administration (FDA) posted an FDA Safety Communication regarding Adzynma (ADAMTS13, recombinant-krhn).

The health and safety of the patients we serve is our top priority and we are saddened by the death of this patient. We reported this event to the FDA and have been providing them with updates since we became aware in July, as part of our standard patient safety processes. We have also conducted a thorough assessment and determined that there was no confirmed causal relationship to the use of Adzynma (ADAMTS13, recombinant-krhn) and the patient death.

Adzynma was approved for use on November 9, 2023 by the FDA, and neutralizing antibodies were not identified in patients taking Adzynma with congenital thrombotic thrombocytopenic purpura (cTTP) in clinical trials.

cTTP is an ultra-rare, chronic blood clotting disorder caused by a deficiency in the ADAMTS13 enzyme. It is associated with acute events and debilitating chronic symptoms or thrombotic thrombocytopenic purpura (TTP) manifestations, which can include thrombocytopenia, microangiopathic hemolytic anemia, headache and abdominal pain. When left untreated, acute TTP events have a mortality rate of more than 90 percent.

There are no changes to the overall risk/benefit profile of Adzynma at this time. Patients with questions or concerns related to Adzynma should contact their health care provider.