Information on neutralising anti-drug antibody to Hemlibra

We recently learned that a patient in our phase III HAVEN 2 clinical trial developed a neutralising anti-drug antibody to Hemlibra. As with all therapeutic proteins, there is a potential for the development of anti-drug antibodies with Hemlibra, as indicated in the US and EU Hemlibra product labels. For this patient, the anti-drug antibody resulted in reduced efficacy of Hemlibra. The patient and his family have decided to discontinue treatment with Hemlibra, and he will resume treatment with his previous medicine.

To date, more than 600 people with haemophilia A have been treated with Hemlibra worldwide, including in clinical trials. This is the first confirmed report of a detectable anti-drug antibody that has impacted the efficacy of Hemlibra in a person with haemophilia A. We continue to monitor for the development of anti-drug antibodies to Hemlibra in ongoing studies globally.

The development of anti-drug antibodies to Hemlibra is distinct from the development of inhibitors to factor VIII. Anti-drug antibodies to Hemlibra may affect whether the medicine works, but they do not change the severity of the underlying disorder. On the other hand, for the nearly one in five people with haemophilia A who develop inhibitors to factor VIII[1], the inhibitors not only affect the efficacy of factor VIII replacement therapies, but they can also affect any natural factor VIII in the body. Inhibitors to factor VIII put people with haemophilia A at greater risk for life-threatening bleeds or repeated bleeds that can cause long-term joint damage.

We are committed to providing timely and transparent updates about Hemlibra to health authorities, healthcare professionals and the haemophilia community. Should patients or caregivers have any questions about Hemlibra, we encourage them to speak with their treating physician.

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[1] https://www.cdc.gov/ncbddd/hemophilia/inhibitors.html