Hemlibra® (emicizumab) Update

March 28, 2018

Given the recent dialogue, we are reaching out to clarify the facts surrounding five people with haemophilia A with inhibitors to factor VIII who have passed away while receiving Hemlibra® (emicizumab).

In 2015, Hemlibra pivotal clinical trials were initiated in people with haemophilia A with inhibitors. It was also made available through requests to Roche for compassionate use[1] as well as through expanded access protocols[2] in the US and other countries. Data from the pivotal trials have demonstrated the positive benefit/risk profile of Hemlibra and have led to regulatory approvals for people with haemophilia A with inhibitors in the US[3], EU[4], and other countries.

Since 2016, five adults with haemophilia A with inhibitors taking Hemlibra have passed away. One of the patients was enrolled in the HAVEN 1 clinical trial; one was in the US expanded access programme and three were receiving treatment through compassionate use requests. In each of these cases, the assessment of the treating physician or investigator was that the cause of death was unrelated to Hemlibra. Based on these assessments and the available information, these events do not change the currently known benefit/risk profile.

Upon learning of adverse events, rigorous assessment and reporting protocols are followed. If any adverse event in a person taking Hemlibra impacts the overall benefit/risk profile of the medicine, we will share this information as quickly as possible. Hemlibra's prescribing information, in countries where it is approved, remains the primary source of information on the safety and efficacy of the medicine. We are committed to providing timely and transparent updates on the safety profile of Hemlibra to health authorities, healthcare professionals and the haemophilia community.

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[1] The Genentech expanded access protocol, reviewed by the FDA, allowed U.S. patients who were not participating in a Hemlibra clinical trial but who met eligibility criteria similar to our key studies to have access to Hemlibra prior to approval.

[2] Compassionate use of Hemlibra is available on a case-by-case basis to eligible patients, following a request to Roche from their treating physician, if they have a serious or life-threatening condition, have exhausted all other treatment options and are unable to participate in a clinical trial.

[3] Hemlibra® (emicizumab-kxwh) is approved in the US for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with haemophilia A with factor VIII inhibitors.

[4] Hemlibra® (emicizumab) is approved in the EU for routine prophylaxis of bleeding episodes in people with haemophilia A with factor VIII inhibitors. Hemlibra can be used in all age groups Emicizumab is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the prescribing information for how to report adverse reactions.