Genentech
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An update from Genentech on Hemlibra® post-approval data communication process and site update

To the hemophilia community,

At Genentech, we recognize and appreciate the ongoing conversation within the hemophilia community around the long-term efficacy and safety of Hemlibra® (emicizumab-kxwh). We understand that the subject of long-term safety for hemophilia treatments is an important topic for this community and we remain committed to listening to you and providing information that leads to informed clinical decision making and patient care.

Genentech's first U.S. medical websites for Hemlibra were originally launched in 2018 to provide updated, verified safety information to the hemophilia community, specifically related to adverse events of interest, whether or not such events were related to Hemlibra. Today, Hemlibra is approved and available for people with hemophilia A in more than 90 countries and more than 7,200 patients around the world have been treated with Hemlibra. We now have much broader availability of information from databases and individual experiences, and the source of safety information has expanded from controlled clinical trial reporting to ongoing voluntary adverse event reporting by healthcare professionals, patients and their caregivers. That's why we've launched updated versions of our medical websites and we've evolved our process for reporting post-approval information on Hemlibra to ensure transparency and meet the community's expectations for information.

The updated U.S. Hemlibra medical sites — www.emipatientinfo.com for patients and www.emicizumabinfo.com for physicians — now provide broader clinical information on the efficacy and safety of Hemlibra. On these sites, we will report data from ongoing studies and real-world use of Hemlibra that are presented at scientific meetings and published in medical journals, as these data are available. Importantly, any future updates on Hemlibra will be appropriately benchmarked, peer reviewed and medically relevant.

We made this decision after actively engaging and working closely with the hemophilia medical and patient communities to understand what would be most impactful. This means that, together with members of the scientific community, we can provide a broader body of data in place of the quarterly data updates previously reported. In addition, Hemlibra's label, as approved by the U.S. Food and Drug Administration (FDA), should always be the primary source of information on the safety and efficacy of the medicine.

Our commitment to providing timely and transparent updates on Hemlibra to the hemophilia community remains unchanged. We will continue to listen, respond and partner with you, so that together we can lead this collective effort for a continued dialogue allowing us to protect patient safety and put this community first.

Respectfully,

Gina Marie Dalferro Truslow, MA
Sr. Manager, Patient Advocacy Relations - OMNI