Genentech
A Member of the Roche Group

August 28, 2020

**Update on particles identified in Hemlibra® (emicizumab-kxwh)**

Genentech is pleased to provide an update on measures that are being taken in relation to the translucent particles that were identified in Hemlibra® (emicizumab-kxwh) in 2019 during a routine examination of product batches as part of our quality assurance processes. These silicone oil and protein particles are non toxic and based on our ongoing assessment to date, we have not observed a safety risk to patients or an impact on the efficacy of Hemlibra.

We have been working closely with the FDA to take steps to reduce or eliminate these particles in Hemlibra. Our priority is always to deliver the highest quality medicines to patients. As one of many steps, we've made changes to the manufacturing process. As an additional quality assurance measure to give further confidence to the community, we recently proposed the use of a transfer needle with a filter for Hemlibra, to minimize particles. Filter devices are commonly used with biologics, such as antibody therapies, and other intravenously administered medicines, such as replacement factor VIII, to reduce the presence of these types of particles, which are commonly found in injected solutions. On August 19, 2020, the European Medicines Agency (EMA) approved the use of a transfer needle with a filter for Hemlibra.

Genentech has been communicating with the FDA to bring this transfer needle with a filter to the U.S. hemophilia community at the same time. We've updated and submitted the Hemlibra label to the FDA with a formal approval expected later this year. In the meantime, since we've already informed the FDA of this update, the filter needles are now available for the hemophilia community in the U.S. through their Specialty Pharmacies. Patients and caregivers can work with their healthcare providers and Speciality Pharmacy to receive the new needles. If their Speciality Pharmacy does not carry the filter needle at this time, patients should continue to use the transfer needles without a filter to prepare their Hemlibra dose until the transfer needles with a filter are available through their Specialty Pharmacy. As a reminder, we do not believe that these particles pose a safety risk to patients or impact the efficacy of Hemlibra.

We remain committed to delivering safe and effective medicines of the highest quality to the patients we serve and will continue to keep this community informed of any further updates.

Sincerely,

Gina Truslow
Sr. Manager, Patient Advocacy Relations - OMNI