



Basel, 11 January 2018

An Open Letter to the Haemophilia Community Regarding Patient Access to HEMLIBRA® (emicizumab)

This is an open letter to the haemophilia community to clarify how recent legal actions could impact patient access to HEMLIBRA® (emicizumab, formerly ACE910)¹. As of now, there are no limitations on the ability of physicians to prescribe HEMLIBRA in the U.S., and we assure you that we are doing everything we can to protect patients' rights to access this important new medicine.

At the Roche Group—Genentech in the U.S., Chugai in Japan, and Roche in the rest of the world—we are dedicated to improving the lives of patients through innovation and scientific discoveries. HEMLIBRA represents one of our most important scientific achievements, with over 20 years of research and development invested in bringing this therapy to patients with haemophilia.

We are writing this letter because we value transparency. The haemophilia community has fought hard to preserve access to healthcare and to treatment choice, and deserves more information about recent legal actions and patent infringement claims. We strongly believe that patients should not be put in the middle of these legal disputes, and we are committed to preventing any impact on patients throughout the ongoing litigation. It is understandable that companies may disagree about their intellectual property or patents, but it is never acceptable for a company to try to keep breakthrough medicines from patients.

The most recent legal actions began in May 2017 when Shire sued Genentech and Chugai for alleged patent infringement in the U.S. We do not believe that Shire's patent is valid, nor that HEMLIBRA infringes this patent. We intend to vigorously defend our case in court during a trial, which is scheduled for September 2019. In the meantime, on December 14, 2017, Shire filed a motion for a preliminary injunction against Genentech that attempts to limit patient access to this medicine before the scheduled patent trial. In its motion, Shire asked the court to issue an order that prevents us from providing HEMLIBRA to certain patients in the U.S. We believe the injunction is unfounded and will oppose it. The court would need to grant Shire's request before it can be implemented.

If granted as proposed, Shire's preliminary injunction would prevent certain patients in the U.S. from receiving HEMLIBRA. Specifically, Shire has proposed that the court prohibit Genentech from selling HEMLIBRA to the following patients:

- Haemophilia A patients with inhibitors (defined as those with an inhibitor titre of greater than 5 Bethesda units who cannot be treated effectively with Factor VIII replacement therapy), unless (i) they have already started HEMLIBRA before the injunction is granted by the court, or (ii) they have previous experience with on-demand or prophylactic bypassing agents and their needs are not currently being met, as defined by Shire using criteria that include experiencing certain life- or limb-threatening bleeds or venous access issues.
- Haemophilia A patients who have an inhibitor titre less than or equal to 5 Bethesda units, or who can be effectively treated with Factor VIII replacement therapy, regardless of whether they have already started HEMLIBRA.
- Haemophilia A patients without an inhibitor, regardless of whether they have already started HEMLIBRA.

¹ HEMLIBRA is currently approved in the U.S. for routine prophylaxis for adults and paediatric patients with haemophilia A with inhibitors. It is not currently approved for haemophilia A patients without an inhibitor. It has not yet been approved for use outside of the U.S.

The FDA approved HEMLIBRA for routine prophylaxis for adult and paediatric patients with haemophilia A with inhibitors. The data that supported the FDA approval have also been submitted to the European Medicines Agency and are currently under review for approval consideration. We believe it is inappropriate for Shire to dictate which patients should receive HEMLIBRA. That decision rests with treating physicians and patients. Over the last two years, we have met with Shire to try to come to an agreement in the best interest of patients. It is now up to the court to make a ruling and we are prepared to defend our case. We are disappointed that Shire would attempt to limit patient access to HEMLIBRA in advance of the full trial before the court.

In addition to these legal actions in the U.S., Shire has taken other actions over the last two years that attempt to limit patient access to this medicine worldwide or block scientific exchange about this medicine, including:

1. Shire attempts to block global patient access and manufacturing of HEMLIBRA in Japan: In April 2016, Shire, through its wholly-owned subsidiaries Baxalta Inc. and Baxalta GmbH (“Shire”), filed a lawsuit against Chugai for alleged patent infringement, and asked the Japanese court to stop the global exportation, sale and manufacture of HEMLIBRA. Again, we do not believe that Shire’s patent is valid, nor that HEMLIBRA infringes this patent. In addition, Shire asked the court to order the destruction of the existing inventory of medicine. Chugai is pursuing a vigorous defence through the appropriate legal channels. This lawsuit is ongoing at this time.
2. Shire attempts to block scientific exchange at a key medical congress: On July 9, 2017, Shire obtained a preliminary injunction in Germany against Roche alleging that Roche made “incomplete and misleading statements” about HEMLIBRA in an abstract of the pivotal HAVEN 1 data. This may have been an effort to prevent the data from being presented on July 10, 2017 at the International Society on Thrombosis and Haemostasis (ISTH) Congress in Germany. In September, a German court reviewed the evidence and concluded that Roche had not engaged in any inappropriate promotional activities. Following those comments from the judges, Shire chose to withdraw their injunction. As a result, the case was formally closed and Shire incurred all related court and legal fees for Roche.

While the lawsuits are currently active in Japan and the U.S., similar actions could follow in other geographies where similar patents exist, such as Germany, France, UK, Spain, Italy and Australia.

We hope this letter provides transparency into a matter that has the potential to affect patients. As a reminder, there are currently no limitations on the ability of physicians to prescribe HEMLIBRA in the U.S. We ask you to join us in advocating for access to HEMLIBRA for all appropriate patients so there are no limitations in the future.

Thank you for your consideration of this important matter and for your partnership. We will continue to share as much information as possible.