Bayer HealthCare is aware that an article, “Recombinant factor VIII products and inhibitor development in previously untreated boys with severe hemophilia A,” authored by Calvez et al., was recently published in the journal Blood. The article discusses an analysis of inhibitor development in previously untreated patients (PUPs) with hemophilia A in France who are on Factor VIII products, including Bayer's Kogenate® FS/BAYER.

The article suggests that PUPs in France taking Kogenate BAYER experienced a higher risk of inhibitor development than those on another product. Bayer has reviewed the article and considers the results to be in line with the established body of evidence on inhibitor development in PUPs using Kogenate FS/Bayer. The inhibitor development risk found in the study is also in line with the updated Kogenate FS/BAYER label as already implemented or in process.

Bayer will be proactively informing relevant regulatory authorities. In addition, Bayer will inform physicians as appropriate, so they can make informed decisions regarding treatment for their previously untreated patients.