Of those 17 patients, 16 patients were enrolled in the phase 1/2 study (6, 5, and 5 patients in the 0.3, 1, and 3 mg/kg QW groups, respectively). Two patients without inhibitors at baseline tested positive for inhibitors during emicizumab prophylaxis. Of those 17 patients, 16 patients were enrolled in the phase 1/2 study (6, 5, and 5 patients in the 0.3, 1, and 3 mg/kg QW groups, respectively).

No thrombotic events including thrombotic microangiopathy or deaths were reported. ABRs decreased or remained zero in most patients. Robust evaluation of the long-term effect on ABRs is difficult since ABRs can be affected by amounts of FVIII for breakthrough bleeds.

In November 2016, following the occurrence of thrombotic events and thrombotic microangiopathy in the WARFARIN 1 study [2], the FDA advised investigators to discontinue prophylaxis in patients with inhibitors to BPA, preferably emicizumab, if any bleeding episode occurred during prophylaxis. Bleeding episodes that occurred after dose modifications were summarized according to the modified dose when calculating annualized bleeding rate (ABR).

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