2. SYNOPSIS

This supplemental clinical study report (CSR) presents the data from the long term follow-up of the phase 2 study MT103-202. Results of the primary analysis are presented in CSR MT103-202 PA dated 07 November 2013.

The aim of the post study follow-up period analysis for MT103-202 was to describe the long term relapse-free survival (RFS) and MRD results for the Full Analysis Set (FAS) (N=20) and within prespecified subgroups of interest— baseline genetic alteration and dose cohort. Analyses included hematological RFS, MRD progression, duration of MRD response, and MRD relapse.

Subjects received blinatumomab as continuous intravenous infusion at a dose of 15 µg/m^2/day over 4 weeks followed by a treatment-free period of 2 weeks. Blinatumomab dose was escalated to 30 µg/m^2/day in 3 subjects who did not achieve reduction in MRD level ≥ 1 log, per data review committee decision.

Median RFS was not reached after a median follow-up time of 1550 days (> 4 years). Of the 20 subjects in the FAS, 11 completed the study in remission. Ten subjects were relapse free after 5 years of follow-up (duration of follow up ranged from 1816 to 2138 days). Nine subjects had an RFS event: 8 subjects had hematological relapse, and 1 subject died without relapse.

MRD progression occurred in 7/20 subjects in the FAS. By dose cohort, MRD progression occurred in 1/3 subjects with dose increase. The median time to MRD progression overall was 7.2 months. For the 13 subjects who did not experience MRD progression, the duration of follow-up ranged from 15 to 1955 days. By baseline genetic alteration, MRD progression occurred in 3/13 subjects with only rearrangements at baseline and in 4/7 subjects with translocations at baseline. (Subjects with both translocations and rearrangements at baseline were analyzed in the stratum of subjects with translocations.)

The median duration of MRD response for responders in the FAS (N=16) was 13.0 months

(95% confidence interval: 2.8, not estimable). MRD relapse occurred in 5/16 subjects in the FAS. All 5 subjects received blinatumomab 15 µg/m^2/day. By baseline genetic alteration, MRD relapse occurred in 2/12 subjects with only rearrangements at baseline and in 3/4 subjects who had translocations at baseline. For the 11 subjects who did not experience MRD relapse, the duration of follow-up ranged from 15 to 1955 days.

The results of the follow-up evaluation were consistent with those of the primary analysis reported in CSR MT103-202 PA.