SECONDARY SAFETY ENDPOINT – IMMUNOGENICITY

Anti-HLA Abs were measured at baseline, Day 28, Month 3, and Month 6 with the Luminex technique. This technique assessed both anti-HLA Class I Abs (locus A, locus B, locus C) and Class II Abs (locus DR, locus DQ, locus DP).

A total of 7 patients (30.4%) presented anti-HLA Abs at levels ≥ 2000 MFI during the course of the study.

In 5 patients (21.7%), anti-HLA Class I and/or Class II Abs were detected at baseline, including preformed DSA that persisted throughout the study (up to Month 6) in 2 patients (one of them had preformed DSA at Screening with MFI ≥ 5000). Newly developed transitory anti-HLA Class I or Class II DSA were also detected (with MFI ≥ 5000) in 2 of these 5 patients.

Two other patients (8.7%) without anti-HLA Abs at baseline developed transitory anti-HLA Class II Abs after HepaStem treatment including newly developed Class II DSA (with MFI ≥ 5000) for 1 patient.

Of note, 2 events of fever were reported for 1 patient who had preformed anti-HLA Abs at baseline: a first event about 24 hours after the second HepaStem infusion (unlikely related to the study drug) and a second event after the third HepaStem infusion (possible related to the study drug). Two other events of fever after infusion were reported for 2 other patients without any anti-HLA Abs.