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Title: EPITOME-4, a phase 3b study evaluating a new formulation of epoprostenol sodium in pulmonary arterial hypertension following switch from Flolan®

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Body: Rationale: Classical intravenous epoprostenol sodium (Flolan®) is used for treating pulmonary arterial hypertension (PAH). A new epoprostenol sodium formulation with arginine and sucrose excipients (epoprostenol AS), improving stability at room temperature, has been developed to improve quality of life. The primary objective was to evaluate safety and tolerability of switching from Flolan® to epoprostenol AS. Methods: This was a two-site, open label, single-arm phase 3b study. Eight adult Japanese PAH patients treated with Flolan® on a stable dose were switched to epoprostenol AS, and followed for 12 weeks. Changes from baseline to 12 weeks were evaluated for hemodynamic parameters. Treatment satisfaction was assessed by the Treatment Satisfaction Questionnaire for Medication (TSQM-9). Results: The mean age was 48 years and 7 patients were female. There were no unexpected safety or tolerability concerns after switching up to Week 12. The dosage of the study treatment was maintained after switching. In terms of pulmonary hemodynamics, the Wilcoxon signed rank sum test did not reveal any significant differences in change from baseline to Week 12 at the 5% level.

Hemodynamics at baseline and Week 12

	Baseline: n=8	Week 12: n=8
mPAP, mmHg Mean	31.1	31,4
CO, L/min Mean	4.289	4.499
PVR, dyn sec/cm5 Mean	448.3	453.6

Treatment satisfaction as assessed by TSQM-9 showed a significant improvement in terms of convenience. Conclusions: Switching from Flolan® to epoprostenol AS at the same dosage was well tolerated up to Week 12. In addition, patient treatment satisfaction appeared to be improved with use of epoprostenol AS.