This summary is for informational purposes only.

PROTOCOL ID: APD334-006

PROTOCOL TITLE: A Phase 2a, Proof of Concept, Open-label Study Evaluating the Efficacy and Safety of Etrasimod (APD334) in Inflammatory Bowel Disease Patients With Active Skin Extra-intestinal Manifestations

EUDRACT NUMBER: 2016-003797-40

STUDY CENTERS: Multi-center

STUDY START DATE: 17 July 2017

FINAL COMPLETION DATE: 06 December 2017 (Prematurely Ended)

Trial was terminated by the Sponsor due to limited enrollment.

PHASE OF DEVELOPMENT: Phase 2a

STUDY OBJECTIVES:

Efficacy: To determine the treatment effect of etrasimod in inflammatory bowel disease (IBD) patients on the clinical improvement of active skin extra-intestinal manifestations (EIM).

Safety: To determine the safety profile and tolerability of etrasimod.

NUMBER OF SUBJECTS (PLANNED AND ANALYZED:

Enrollment was planned for up to 20 subjects (with up to 10 subjects with anti-tumor necrosis factor [TNF] alpha induced psoriasis). One subject was enrolled in the study and completed treatment.

RESULTS:

Subject Disposition and Demography: Not available

Efficacy results: No efficacy analyses were conducted. Measurements that were originally planned to assess efficacy for this subject are provided in the case report forms.

Safety results: There were no reported adverse events in this study. All lab abnormalities with an indication of clinically significant were part of the medical profile of the disease being studied and not classified as adverse events. Safety results for this subject are provided in the case report forms.

CONCLUSION:

No efficacy or safety conclusions were made for this study.