PPM Services S.A.
Viale Serfontana 10
6834 Morbio Inferiore
Switzerland
T: +41 91 69 61 710

EudraCT Team
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

August 6th, 2021

Re:	**Notice of Definitive Study Termination**
EudraCT number	2016-001684-36
Sponsor Code:	GED0507-UC-001
Study Title:	A PHASE 2, RANDOMIZED, PLACEBO-CONTROLLED, MULTICENTER STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF GED-0507-34-LEVO (GED0507) FOR TREATMENT OF SUBJECTS WITH ACTIVE ULCERATIVE COLITIS

Dear EudraCT Team,

At this time, PPM Services SA (PPM Services) is notifying EMA that a decision has been made to definitively terminate the Phase II study GED0507-UC-001, concerning GED-0507-34-Levo Tablets in the treatment of subjects with active, mild to moderate, Ulcerative Colitis .

The study title is "A Phase 2, randomized, placebo-controlled, multicenter study to investigate the efficacy and safety of GED-0507-34-Levo (GED0507) for treatment of subjects with active Ulcerative Colitis", the study number is GED0507-UC-001 and the EudraCT number is 2016-001684-36.

The date for the global end of the trial was July 31st, 2017. The end of the trial date was the last patient, last visit.
A delay in study recruitment led PPM Services to terminate the clinical trial earlier than expected (October 2017). Completion of the study could not be progressed in a realistic timeframe to render the study outcomes (expected patients n=200) within the estimated timelines.

The study was initiated on November 28th, 2016. Globally, 66 Investigative Sites were opened with 50 patients enrolled, of which 19 patients were treated. The last patient was randomized on July 4th, 2017.
In conjunction with the investigators, all patients enrolled in the study were switched to suitable alternative treatment, as appropriate.

No other clinical trial using this study drug has been initiated.

PPM Services S.A.
Viale Serfontana 10
6834 Morbio Inferiore
Switzerland
T: +41 91 69 61 710

During the study, one patient experienced one adverse event: the subject presented a worsening of ulcerative colitis and was hospitalized. Severity of the event was reported as moderate. The investigator confirmed that the subject was treated with standard therapy according to local practice during hospitalization. The subject, after recovery, was discharged in good general conditions.

No statistical analysis have been performed.

Please do not hesitate to contact me directly should you need any additional clarification.

Yours sincerely,

Dr. Salvatore Bellinvia, M.D.

Managing Director

PPM Services SA