GMIHO
INNOVATION IN HEMATOLOGY AND MEDICAL ONCOLOGY

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Subject: Justification on the reasons of results which become not yet available in the EudraCT database for the clinical trial *"THE COMBINATION OF LENALIDOMIDE AND DEXAMETHASONE WITH OR WITHOUT INTENSIFICATION BY HIGH-DOSE MELPHALAN IN THE TREATMENT OF MULTIPLE MYELOMA" (DSMM XIII)*
EudraCT No: 2008-004083-39
Dresden, 23 May 2022

To Whom It May Concern.

This letter provides a justification for the delay in posting of final results for the clinical trial with the study title *"The combination of Lenalidomide and Dexamethasone with or without intensification by high-dose Melphalan in the treatment of multiple myeloma"* caused by the COVID-19 pandemic in 2020 and 2021.

Due to the COVID-19 pandemic and it's declared lockdown regulations and restrictions by the Federal Government in Germany in March 2020 the previously planned monitoring activities could not be entirely performed. Therefore, no or limited source data verification (SDV) for primary and secondary endpoints at the trial sites were possible.

Obligatory established hygienical concepts at the clinical trial sites as well as at the CRO (responsible for monitoring) also resulted to significant delays in collecting remaining data from Case Report Forms which were paper based. This led to the fact that the data for the final analysis were not available at the scheduled time.

Due to the fact that the last patient with the last visit (LPLV) left the study on 30th January 2020, we decided not to interrupt the clinical trial during the COVID-19 pandemic.

According to our last efforts in the last months, we are now able to perform the final analysis in the upcoming weeks, which will result in a final study report latest in autumn 2022.

Yours faithfully,
GMIHO mbH

M. Puttrich

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