Universitätsklinikum Hamburg-Eppendorf

Zentrum für Innere Medizin
III. Medizinische Klinik und Poliklinik
Schwerpunkte: Nephrologie,
Rheumatologie - Nierentransplantation
Arbeitsbereich
Endokrinologie/Diabetologie
Direktor: Prof. Dr. T. B. Huber

Universitätsklinikum Hamburg-Eppendorf Martinistraße 52 20246 Hamburg
III. Medizinische Klinik und Poliklinik

06.01.2021

ESR-16-12160/UKE-DapEx-001

Dear Sir or Madam,

Although the inclusion and exclusion criteria were determined in close cooperation with the involved study centers who are experienced in conducting clinical studies, the planned number of patients recruitment was not achieved and the study had to be terminated prematurely.
The possible reasons might be:

- The daily insulin dose defined as the inclusion criterion might have been too high
- The patients who met the inclusion criterion of the daily insulin dose were currently or in the past mostly treated in combination with one of the new substances (especially GLP-1 analogues, please refer to exclusion criterion number 29 of Section 9.3.2), which was defined as an exclusion criterion ("Had been treated, was currently being treated, or was expected to re-quire or undergo treatment with any of the following treatment excluded medications: any DPP-4 inhibitor within 3 months prior to Visit 0 (Screening), any GLP-1 analogue within 1 year prior to Visit 0 (Screening). The exclusion criterion number 29 of Section 9.3.2 should have been limited to a shorter period of time.

As the efficacy analysis based on enrollment of 60 patients, due to poor recruitment and premature termination of this trial an analysis of the efficacy according to protocol was not possible. Hence, the primary and secondary objectives of the trial were not achieved.

Prof. Dr. med. Jens Aberle
Principal Investigator