Clinical Study Report Synopsis	
Drug Substance	Cotadutide (MEDI0382)
Study Code	D5670C00021
Edition Number	1.0
Date	31 October 2022
EudraCT Number	2018-001220-19
NCT Number	NCT04019561

An Exploratory Phase IIa, Randomised, Double blind, Placebo controlled Study to Evaluate the Effect of MEDI0382 on Energy Balance in Overweight and Obese Subjects with Type 2 Diabetes Mellitus

Study dates: First subject enrolled: 22 October 2018
Last subject last visit: 22 December 2019
The analyses presented in this report are based on a clinical data lock date of 31 January 2020

Phase of development: Therapeutic exploratory (II)

International Co-ordinating Investigator: CCI
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Sponsor's Responsible Medical Officer: CCI
MedImmune Limited, a wholly owned subsidiary of AstraZeneca, Milstein Building, Granta Park, Cambridge, CB21 6GH UK

This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

This CSR addendum reports the results of the secondary objective; to assess the effect of cotadutide titrated up to a dose level of CCI versus placebo on total energy expenditure (TEE) in percentage and absolute change in TEE as measured by doubly labelled water in kJ per kg of fat body mass from baseline (Day 17) to the end of treatment (Day 58 or 59).

Due to COVID-19 pandemic a full analysis could not be performed due to logistical challenges and equipment failure and no further conclusions can be drawn. The results from the secondary analyses presented in this CSR Addendum do not impact any of the conclusions presented in the CSR, (Data cut off [DCO] 31 January 2020).

For further details of this study, see Section 2 of the CSR (DCO 31 January 2020).