Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

19 December 2023

Dear [redacted]

Re: FOI 23/839

Many thanks for your request for information, dated 02 November 2023, where you requested the following:

For the product name ‘Keytruda’
Clinical Study Report for NCT02362594 (Keynote-054)
Clinical Study Report for NCT03553836 (Keynote-716)

Please find enclosed the latest version of the above clinical study reports that we hold for KEYTRUDA 25 mg/mL concentrate for solution for infusion (PLGB 53095/0040).

Please note that confidential information has been redacted in the Clinical Study Reports, according to Section 40 (personal information) of the Freedom of Information Act. Section 40 is an absolute exemption and no consideration of the public interest is required.

We now consider this FOI request closed. If you require any further information, please respond to the FOI Licensing Team at FOILicensing@mhra.gov.uk.

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option, please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at:
The Information Commissioner’s Office
Wycliffe House
Water Lane

Wilmslow
Cheshire
SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,
FOI Team