FOI 23/109

14th March 2023

Dear

Thank you for your request under the Freedom of Information Act (FOIA).

The medicinal product Veklury Remdesivir 100 mg powder for concentrate for solution for infusion (PLGB 11972/0036) is authorised for the treatment of coronavirus disease 2019 (COVID 19) in:

- adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment)
- adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

To address the point made, this medicine is not "experimental with no benefit on treating any known disease." The assessment of this product, including assessment of its safety and efficacy, is available in the Public Assessment Reports published by the EMA – a link to these is provided below:

https://www.ema.europa.eu/en/medicines/human/EPAR/veklury

For questions concerning the use of remdesivir in the clinical setting, including informed consent and compassionate use, please consult with DHSC dhsc.publicenquiries@dhsc.gov.uk or NHS England https://www.england.nhs.uk/contact-us/.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF

Yours sincerely

Communications and engagement team Medicines and Healthcare products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU Telephone 020 3080 6000