GlaxoSmithKline
Research & Development
Limited
Stockley Park West
Uxbridge
Middlesex
UB11 1BU

Tel. +44 (0)20 8990 9000
www.gsk.com

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: IV Zanamivir

Procedure No. EMA/H/K/002287/CU

To Whom it may concern

The GlaxoSmithKline IV Zanamivir compassionate use programme, which provided zanamivir aqueous solution on a named-patient basis, was terminated as of 6 May 2019.

Following receipt of the Dectova (IV zanamivir) MAA on 26th April 2019, granted in exceptional circumstances as stated in Article 14 (8) of Regulation (EC) No 726/2004, the Article 83, Regulation (EC) No 726/2004, IV zanamivir compassionate use supply is no longer applicable as Dectova (IV zanamivir) is an authorised medicinal product in the EU.

Dectova - Zanamivir 10 mg/mL solution for infusion
Licence Number - EU/1/18/1349/001

Intended indication(s):
Dectova is indicated for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥6 months) when:

- The patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or
- Other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient.

Dectova should be used in accordance with official guidance.

[redacted]

Registered in England & Wales
No. 835139

Registered Office
980 Great West Road
Brentford
Middlesex. TW8 9GS