GlaxoSmithKline UK Ltd
980 Great West Road
Brentford, Middlesex
TW8 9GS

Tel. +44 (0)20 8047 5000
www.gsk.com

Date: 2 May 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Zejula ▼ (niraparib) 100mg capsules:
Interim Supply of UK (Northern Ireland) Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: GSK is currently experiencing supply disruption with Zejula (niraparib) 100mg capsules in the UK (Northern Ireland).

To ensure continuity of supply, GSK has obtained approval from the Medcines and Healthcare products Regulatory Agency (MHRA) to supply product intended for UK (GB) to UK (NI): Zejula (niraparib) 100mg Capsules (batch number 2585303, pack size x84, Qty 234 packs). This product is expected to be on the Northern Ireland market from May 2022 to October 2022.

Please note the following:

- This product is considered licensed in the UK (NI)
- The product from the rest of the UK (GB) has the same formulation as the UK(NI) product
- The product from UK (GB) is manufactured according to the same manufacturing process and quality controls as the UK(NI) product.
- There are minor differences between the UK (GB) and UK (NI) product information. The differences are the batch release site and the MA holder details. For additional copies of the leaflet, please refer to https://www.emcmedicines.com/en-GB/northernireland or contact the GSK UK Medical information team at ukmedinfo@gsk.com.
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Zejula (niraparib)

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Zejula (niraparib) 100mg capsules are indicated:

- as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.
- as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Registered in England & Wales
No. 4310159

Registered office
980 Great West Road
Brentford, Middlesex. TW8 9GS

Reporting of side effects:
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point:
If you have any questions about this letter or require more information about Zejula (niraparib) please contact a member of the GSK Medical Team.

Dr John Fleming	Dr Farah Dunlop, Ph.D
Oncology Medical Head, UK & Ireland	Zejula (niraparib) Medical Lead, GSK UK
john.d.fleming@gsk.com	Farah.n.dunlop@gsk.com

For medical information enquiries, please call 0800 221 441 (option 2), 8:30am to 5:00pm GMT, Monday – Friday, or email ukmedinfo@gsk.com

Dr Karen Mullen MBBS MRCP MFPM
Country Medical Director, GSK UK & Ireland

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.