NULOJIX (belatacept): Extension of the temporary restriction in supply up until 4Q 2021 (initiated in March 2017).

Dear Healthcare Professional,

Bristol Myers-Squibb in agreement with the European Medicines Agency and {the National Competent Authority} would like to inform you of the following:

Summary

- As of 11 March 2019, Nulojix can be prescribed to new patients if the following two criteria are met:
    1. Nulojix is the best treatment option for the patient
    2. BMS has confirmed that supplies are adequate for new and existing patients.
- Before initiating Nulojix treatment in new patients, a member of the transplant team should contact BMS Medical Information to confirm that adequate supplies are available (see contact details below {by country}).
- This requirement to confirm available supplies before initiating treatment for new patients is now expected to remain in place until 4Q 2021.

Background on the supply shortage

Since March 2017, distribution of Nulojix has been restricted to existing patients worldwide. Only patients with an urgent medical need for Nulojix, who had exhausted all other options, were permitted to start Nulojix. The supply shortage is related to a temporary production capacity issue. It is not related to a quality defect of the product or a safety issue. As production of Nulojix returned to normal capacity, these restrictions were eased in March 2019 to allow new patients to be treated with Nulojix when the above-mentioned criteria are met. In September 2020, the restriction is being extended to allow for the final transition to a new, higher capacity manufacturing process.

Management of the supply shortage

<This section needs to be tailored to National communication:

- *In France, a system of controlled distribution to registered patients has been set up in agreement with ANSM*
- *In other countries, prescribers were invited to cooperate in avoiding initiation of a Nulojix-based regimen in new patients. Mention may be made that a finite number of vials has been allocated to each specific market based on existing demand, and HCP are expected to allocate accordingly, otherwise there is a risk of potential stock out. Specific mechanism if needed subject to agreement with National HA.*
- *The current update will be tailored to the initial National communication plan>*

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

<Any schedule for follow-up action(s) by the marketing authorisation holder/competent authority, if applicable>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	NULOJIX (belatacept)
Marketing authorisation holder(s)	Bristol-Myers Squibb EEIG
Safety concern and purpose of the communication	Extension of the temporary restriction in supply of Nulojix from 3Q 2020 up until 4Q 2021.
DHPC recipients	- Renal transplant surgeons, - Nephrology physicians, - Transplant nurses/ transplant clinics - Hospital chief pharmacists - Transplantation societies - Any other parties as requested by National HA
Member States where the DHPC will be distributed	Austria, Denmark, France, Germany, Hungary, Italy, the Netherlands, Norway, Spain, Sweden, UK.

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	10 Sep 2020
Submission of translated DHPCs to the national competent authorities for review	Within 3 working days of confirmed CHMP agreement 15 Sep 2020
Agreement of translations by national competent authorities	within 3 working days of translations received 18 Sep 2020
Dissemination of DHPC	within 3 working days of agreement of translations 23 Sep 2020