<Date>

NULOJIX (belatacept): Further extension of the temporary restriction in supply up until 3Q 2022

Dear Healthcare Professional,

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

Summary

- The temporary restriction in supply of Nulojix (belatacept) will be further extended until 3Q 2022.

- Due to the restriction in supply, Nulojix can only 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, BMS Medical Information should be contacted to confirm that adequate supplies are available (see contact details below {by country}).

Background on the supply shortage

Since March 2017, distribution of Nulojix has been restricted to existing patients worldwide. 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. The temporary restriction in supply is further extended to allow for the final transition to a new, higher capacity manufacturing process. Nulojix manufactured with the new process is expected to be available in 3Q 2022, a communication will be sent to Healthcare Professionals ahead of its distribution.

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>*

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of Nulojix (belatacept) in accordance with the national spontaneous reporting system <include the details (e.g., name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

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>

Communication Plan for Direct Healthcare Professional Communication

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 4Q 2021 until Q3 2022.
DHPC recipients	Healthcare Professionals involved in the prescribing and/or preparation of NULOJIX for administration: • Transplant Centres • Transplant Surgeons and Nephrologists • Transplant Coordinators • Transplant Nurses • Professional Transplant Societies • Pharmacists/Pharmacies • General Nephrologists • Nurses for Home Infusion (France specific) The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	Austria, Denmark, France, Germany, Hungary, Italy, the Netherlands, Northern Ireland, Norway, Spain, Sweden

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	20 December 2021
Submission of translated DHPCs to the national competent authorities for review	by 27 December 2021
Agreement of translations by national competent authorities	by 10 January 2022
Dissemination of DHPC	by 17 January 2022