14 April 2011
EMA/CHMP/273603/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Nulojix

belatacept

On 14 April 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nulojix 250 mg powder for concentrate for solution for infusion, intended for the prophylaxis of graft rejection in adults receiving a renal transplant. The applicant for this medicinal product is Bristol-Myers Squibb. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Nulojix is belatacept, a selective immunosuppressants (ATC code: L04AA28). Belatacept binds to CD80 and CD86 on antigen presenting cells. As a result, belatacept blocks CD28 mediated co-stimulation of T cells inhibiting their activation, thus leading to immunosuppression.

The benefits of Nulojix are its ability to be non-inferior to ciclosporin for patient and graft survival at 12 months in both low and high risk populations, with positive effects on renal function. Results were sustained through 36 months. A superior effect on renal function was only demonstrated in the low risk population, while more episodes of acute rejection occurred with belatacept treatment compared to ciclosporin in this population.

The most common serious adverse reactions reported with belatacept in either regimen are urinary tract infection, CMV infection, pyrexia, increased blood creatinine, pyelonephritis, diarrhoea, gastroenteritis, graft dysfunction, leukopenia, pneumonia, basal cell carcinoma, anaemia, dehydration. The most commonly reported adverse reactions among patients treated with a belatacept-based regimen are diarrhoea, anaemia, urinary tract infection, peripheral oedema, constipation, hypertension, pyrexia, nausea, graft dysfunction, cough, vomiting, leukopenia, hypophosphataemia, and headache.

A pharmacovigilance plan for Nulojix will be implemented as part of the marketing authorisation.

The approved indication is: “Nulojix, in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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recommended to add an interleukin (IL)-2 receptor antagonist for induction therapy to this belatacept-based regimen". It is proposed that Nulojix is prescribed and supervised by specialist physicians experienced in the management of immunosuppressive therapy and of renal transplant patients.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Nulojix and therefore recommends the granting of the marketing authorisation.