

Bristol-Myers Squibb cordially invite you to attend a symposium session on:

Seven Year Graft and Patient Survival From the NULOJIX Pivotal Trials

BENEFIT Study 7 Year Results

Dr Flavio Vincenti

(San Francisco, USA)

BENEFIT-EXT Study 7 Year Results

Dr Antoine Durrbach

(Villejuif, France)

Co-Chairs:

Dr Klemens Budde

(Berlin, Germany)

Dr Christophe Legendre

(Paris, France)

Tuesday, September 15th

13:00-14:00

Gold Hall

 **Nulojix[®]**
(belatacept)
250 mg lyophilized powder for
injection, for intravenous use

▼ This medicinal product is subject to additional monitoring.

NULOJIX 250 mg powder for concentrate for solution for infusion.

Active Substance: Belatacept (fusion protein produced in cells by recombinant DNA technology).

Composition: One vial contains 250 mg of belatacept

List of excipients: Sucrose, sodium dihydrogen phosphate monohydrate, sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment).

Therapeutic indications: 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 recommended to add an interleukin (IL) -2 receptor antagonist for induction therapy to this belatacept-based regimen.

Contraindications: Transplant recipients who are Epstein-Barr virus (EBV) seronegative or serostatus unknown. Hypersensitivity to the active substance or to any of the excipients.

Adverse Reactions: Very common: urinary tract infection, upper respiratory infection, cytomegalovirus infection, bronchitis, anaemia, leukopenia, hypophosphataemia, hypokalaemia, dyslipidaemia, hyperkalaemia, hyperglycaemia, hypocalcaemia, insomnia, anxiety, headache, hypertension, hypotension, dyspnoea, cough, diarrhoea, constipation, nausea, vomiting, abdominal pain, arthralgia, back pain, pain in extremity, proteinuria, blood creatinine increased, dysuria, haematuria, oedema peripheral, pyrexia, graft dysfunction.

Common: sepsis, pneumonia, influenza, gastroenteritis, herpes zoster, sinusitis, herpes simplex, oral candidiasis, pyelonephritis, onychomycosis, BK virus infection, respiratory tract infection, candidiasis, rhinitis, cellulitis, wound infection, localised infection, herpes virus infection, fungal infection, fungal skin infection, squamous cell carcinoma of skin, basal cell carcinoma, skin papilloma, thrombocytopenia, neutropenia, leukocytosis, polycythaemia, lymphopenia, blood immunoglobulin G decreased, blood immunoglobulin M decreased, cushingoid, weight increase, diabetes mellitus, dehydration, weight decrease, acidosis, fluid retention, hypercalcaemia, hypoproteinaemia, depression, tremor, paraesthesia, cerebrovascular accident, dizziness, syncope, lethargy, neuropathy peripheral, cataract, ocular hyperaemia, vision blurred, vertigo, ear pain, tinnitus, tachycardia, bradycardia, atrial fibrillation, cardiac failure, angina pectoris, left ventricular hypertrophy, shock, infarction, haematoma, lymphocele, angiopathy, arterial fibrosis, pulmonary oedema, wheezing, hypocapnea, orthopnoea, epistaxis, oropharyngeal pain, dyspepsia, aphthous stomatitis, abdominal hernia, cytolytic hepatitis, liver function test abnormal, acne, pruritis, alopecia, skin lesion, rash, night sweats, hyperhidrosis, myalgia, muscular weakness, bone pain, joint swelling, intervertebral disc disorder, joint lock, muscle spasms, osteoarthritis, renal tubular necrosis, renal vein thrombosis, renal artery stenosis, glycosuria, hydronephrosis, vesicoureteric reflux, urinary incontinence, urinary retention, nocturia, hydrocele, chest pain, fatigue, malaise, impaired healing, c-reactive protein increased, blood parathyroid hormone increased, chronic allograft nephropathy (CAN), incisional hernia.

Uncommon: progressive multifocal leukoencephalopathy, cerebral fungal infection, cytomegalovirus (CMV) colitis, polyomavirus-associated nephropathy, genital herpes, staphylococcal infection, endocarditis, tuberculosis, bronchiectasis, osteomyelitis, strongyloidiasis, blastocystis infection, giardiasis, lymphangitis, EBV associated lymphoproliferative disorder, lung cancer, rectal cancer, breast cancer, sarcoma, kaposi's sarcoma, prostate cancer, cervix carcinoma, laryngeal cancer, lymphoma, multiple myeloma, transitional cell carcinoma, monocytopenia, pure red cell aplasia, agranulocytosis, haemolysis, hypercoagulation, hypogammaglobulinaemia, seasonal allergy, adrenal insufficiency, diabetic ketoacidosis, diabetic foot, alkalosis, decreased appetite, vitamin D deficiency, abnormal dreams, mood swings, attention deficit/hyperactivity disorder, libido increased, encephalitis, Guillain-Barré syndrome*, brain oedema, intracranial pressure increased, encephalopathy, convulsion, hemiparesis, demyelination, facial palsy, dysgeusia, cognitive disorder, memory impairment, migraine, burning sensation, diabetic neuropathy, restless leg syndrome, retinitis, conjunctivitis, eye inflammation, keratitis, photophobia, eyelid oedema, hypoacusis, acute coronary syndrome, atrioventricular block second degree, aortic valve disease, arrhythmia supraventricular, venous thrombosis, arterial thrombosis, thrombophlebitis, arterial stenosis, intermittent claudication, flushing, acute respiratory distress syndrome, pulmonary hypertension, pneumonitis, haemoptysis, bronchopneumopathy, painful respiration, pleural effusion, sleep apnoea syndrome, dysphonia, oropharyngeal blistering, gastrointestinal disorder, pancreatitis, large intestinal ulcer, melaena, gastroduodenal ulcer, rectal haemorrhage, small intestinal obstruction, cheilitis, gingival hyperplasia, salivary gland pain, faeces discoloured, cholelithiasis, hepatic cyst, hepatic steatosis, psoriasis, hair growth abnormal, onychoclasia, penile ulceration, swelling face, trichorrhexis, bone metabolism disorder, osteitis, osteolysis, synovitis, renal artery thrombosis, nephritis, nephrosclerosis, renal tubular atrophy, cystitis haemorrhagic, kidney fibrosis, epididymitis, priapism, cervical dysplasia, breast mass, testicular pain, vulval ulceration, atrophic vulvovaginitis, infertility, scrotal oedema, hypophosphatasia, infusion related reaction, irritability, fibrosis, inflammation, disease recurrence, feeling hot, ulcer, pancreatic enzymes increased, troponin increased, electrolyte imbalance, prostate-specific antigen increased, blood uric acid increased, urine output decreased, blood glucose decreased, CD4 lymphocytes decreased, transplant failure, transfusion reaction, wound dehiscence, fracture, tendon rupture, procedural hypotension, procedural hypertension, post-procedural haematoma, procedural pain, procedural headache, contusion.

Further Information: See Summary of Product Characteristics; prescription drug.

This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions.

Marketing Authorisation Holder: Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB81DH, United Kingdom.

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