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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)*** | |
| Aflibercept (*Eylea 114.3 mg/ml*) 30.1mg in 0.263mL vial | Use in adults for the treatment of neovascular (wet) age-related macular degeneration and visual impairment due to diabetic macular oedema  [new high-dose extended-interval formulation] |
| Bevacizumab biosimilar (*Versavo*)  100mg in 4mL and 400mg in 16mL vials | Treatment of adults with metastatic carcinoma of the colon or rectum, metastatic breast cancer, unresectable advanced, metastatic or recurrent non-small cell lung cancer, advanced and/or metastatic renal cell cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer, and persistent, recurrent, or metastatic carcinoma of the cervix |
| Diphtheria + tetanus + pertussis vaccine (*Adacel*)  Single-dose prefilled syringe | Active immunisation against tetanus, diphtheria and pertussis in persons aged ≥4 years as a booster following primary immunisation. Also for passive protection against pertussis in early infancy following maternal immunisation during pregnancy. |
| Efgartigimod alfa (*Vyvgart*)  1,000mg in 5.6mL vial | Use as an add-on to standard therapy for the treatment of generalised myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive [new subcutaneous formulation] |
| Foslevodopa + foscarbidopa (*Produodopa*)  2,400mg/120mg in 10mL vial | Treatment of advanced levodopa-responsive Parkinson’s disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results |
| Human normal immunoglobulin  (*HyQvia*) 200units in 1.25mL, 400units in 2.5mL, 800units in 5mL, 1,600units in 10mL, and 2,400units in 15mL vials | Immunomodulatory therapy in adults, children and adolescents aged 0 to 18 years in chronic inflammatory demyelinating polyneuropathy as maintenance therapy after stabilisation with intravenous immunoglobulin [new indication] |
| Levomepromazine (*Levorol*)  5mg in 1mL oral solution | Second- or third-line treatment of adults with refractory nausea unassociated with chemotherapy, where other agents have failed to give adequate control  [new indication] |
| Midazolam (*Epistatus*)  2.5mg in 0.25mL, 5mg in 0.5mL, 7.5mg in 0.75mL and 10mg in 1mL prefilled oral syringes | Treatment of prolonged, acute, convulsive seizures in adults, adolescents, children and infants aged ≥3 months [licence change to include use in adults] |
| Morphine hydrochloride trihydrate  (*Sendolor*) 100mg in 100mL bag | Treatment of severe acute pain, cancer pain and breakthrough cancer pain  [new infusion bag formulation] |
| Natalizumab biosimilar (*Tyruko*)  300mg in 15mL vial | Use as single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) for the following patient groups: patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy, or patients with rapidly evolving severe RRMS defined by ≥2 disabling relapses in one year, and with ≥1 Gadolinium enhancing lesions on brain Magnetic Resonance Imaging (MRI) or a significant increase in T2 lesion load as compared to a previous recent MRI |
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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)* (continued)** | |
| Rezafungin (*Rezzayo*)  200mg vial | Treatment of adults with invasive candidiasis |
| Sacubitril valsartan (*Entresto*)  6mg/6mg and 15mg/16mg granules in capsule for opening | Use in children and adolescents aged ≥1 year for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction  [new granules in capsule formulation] |
| Zilucoplan (*Zilbrysq*)  16.6mg in 0.416mL, 23mg in 0.574mL and 32.4mg in 0.81mL prefilled syringes | Use as an add-on to standard therapy for the treatment of generalised myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive |
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| **Regulatory changes in the UK or EU** | | |
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| ***Approved in the UK*** | | |
| Bismuth subcitrate potassium + metronidazole + tetracycline (*Pylera*)  140mg/125mg/125mg capsule | | Use in combination with omeprazole for the eradication of *Helicobacter pylori* and prevention of relapse of peptic ulcers in patients with active, or a history of, *H. pylori* associated ulcers [new formulation] |
| Denosumab (*Xgeva*)  120mg in 1.7mL prefilled syringe | | Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone, and treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity |
| Etrasimod (*Velsipity*)  2mg tablet | | Treatment of patients aged ≥16 years with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent |
| Ganaxolone (*Ztalmy*)  50mg in 1mL oral suspension | | Adjunctive treatment of epileptic seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients aged 2 to 17 years. *Ztalmy* may be continued in patients aged ≥18 years. |
| Quizartinib (*Vanflyta*)  17.7mg and 26.5mg tablets | | Use in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, followed by *Vanflyta* single-agent maintenance therapy for adults with newly diagnosed acute myeloid leukaemia that is FLT3-ITD positive |
| Rozanolixizumab (*Rystiggo*) 280mg in 2mL vial | | Use as an add-on to standard therapy for treatment of generalised myasthenia gravis in adults who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive |
| Sodium fluoride (*Duraphat Protify 5000ppm toothpaste*)  51g tube | | Prevention of dental caries in adolescents and adults, particularly amongst patients at risk from multiple caries (coronal and/or root caries) [new formulation containing cocamidopropyl betaine as a foaming agent rather than sodium laurilsulphate] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Recommended for approval in the UK or EU*** | | |
| Aztreonam + avibactam  (*Emblaveo*) | | Treatment of the following infections in adults: Complicated intra-abdominal infection; hospital-acquired pneumonia, including ventilator-associated pneumonia; complicated urinary tract infection, including pyelonephritis. Also treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options. [EU] |
| Bempedoic acid (*Nilemdo*) | | Use in adults with established or at high risk for atherosclerotic cardiovascular (CV) disease to reduce CV risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in patients on a maximum tolerated dose of a statin with or without ezetimibe or, alone or in combination with ezetimibe in patients who are statin-intolerant, or for whom a statin is contraindicated [EU] [new indication] |
| Bempedoic acid + ezetimibe (*Nustendi*) | | Use in adults with established or at high risk for atherosclerotic cardiovascular (CV) disease to reduce CV risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in patients on a maximum tolerated dose of a statin and not adequately controlled with additional ezetimibe treatment or, in patients who are either statin-intolerant, or for whom a statin is contraindicated, and not adequately controlled with ezetimibe treatment or, in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets [EU] [new indication] |
| Bevacizumab (*Lytenava*) | | Use in adults for treatment of neovascular (wet) age-related macular degeneration [EU]  [new ophthalmic formulation] |
| Bimekizumab (*Bimzelx*) | | Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy [EU] [new indication] |
| Dantrolene (*Agilus*) | | Use in combination with adequate support measures for the treatment of malignant hyperthermia in adults and children of all ages [EU] [new formulation] |
| Denosumab biosimilar (*Jubbonti*) | | Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women denosumab significantly reduces the risk of vertebral, non-vertebral and hip fractures. Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, denosumab significantly reduces the risk of vertebral fractures. Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture. [EU] |
| Denosumab biosimilar (*Wyost*) | | Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone. Also treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity. [EU] |
| Dopamine (*Neoatricon*) | | Treatment of hypotension in haemodynamically unstable neonates, infants and children aged <18 years [EU] [new lower strength formulations] |
| Eculizumab biosimilar (*Epysqli*) | | Use in adults and children for the treatment of atypical haemolytic uraemic syndrome [EU] [new indication – wording still to be confirmed, not yet on EMA website] |
| Enzalutamide (*Xtandi*) | | Use as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer who are unsuitable for salvage radiotherapy [EU] [new indication] |
| Insulin icodec (*Awiqli*) | | Treatment of diabetes mellitus in adults [EU] |
| Iptacopan (*Fabhalta*) | | Use as monotherapy in the treatment of adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia [EU] |
| Irinotecan sucrosofate  (*Onivyde pegylated liposomal*) | | Use in combination with oxaliplatin, 5‑fluorouracil and leucovorin for the first-line treatment of adults with metastatic adenocarcinoma of the pancreas [EU] [new indication] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Recommended for approval in the UK or EU* (continued)** | | |
| Omalizumab biosimilar (*Omlyclo*) | | In adults and adolescents (aged ≥12 years), use as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and who have reduced lung function (FEV1 <80%) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. In children (aged 6 to <12 years), use as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Use as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults with severe chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control. Use as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescents (aged ≥12 years) with inadequate response to H1 antihistamine treatment. [EU] |
| Oritavancin (*Tenkasi*) | | Treatment of acute bacterial skin and skin structure infections in adults [EU]  [new 1,200mg vial formulation] |
| Risankizumab (*Skyrizi*) | | Treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy [EU] [new 90mg prefilled syringe formulation] |
| Selpercatinib (*Retsevmo*) | | Use as monotherapy for the treatment of adults with advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted [EU] [new indication] |
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| ***Filed for approval in the UK or EU*** | | |
| Amivantamab (*Rybrevant*) | | Advanced non-small cell lung cancer with EGFR Exon 20 insertions – first-line with carboplatin and pemetrexed chemotherapy [UK] [new indication] |
| Blinatumomab (*Blincyto*) | | Treatment as part of consolidation therapy of patients with Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia [EU] [new indication] |
| Casirivimab + imdevimab  (*Ronapreve*) | | Treatment of paediatric patients aged 2 to 11 years, weighing ≥10kg, who do not require supplemental oxygen and who are at increased risk of progression to severe COVID-19 [EU] [new indication] |
| Cedazuridine + decitabine (*Inaqovi*) | | Treatment of adults with myelodysplastic syndromes and treatment of adults with chronic myelomonocytic leukaemia [EU] [new indication] |
| Ceftazidime + avibactam (*Zavicefta*) | | Treatment of adults and paediatric patients from birth in the following infections: complicated intraabdominal infection, complicated urinary tract infection, including pyelonephritis, hospital-acquired pneumonia, including ventilator associated pneumonia, and in the treatment of infections due to aerobic Gram-negative organisms in patients with limited treatment options [EU] [licence change from use only in adults and paediatric patients aged ≥3 months] |
| Daratumumab (*Darzalex*) | | Use in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant [EU] [new indication for subcutaneous formulation] |
| Datopotamab deruxtecan | | Treatment of adults with locally advanced or metastatic non-squamous non-small cell lung cancer who require systemic therapy following prior treatment [EU] |
| Datopotamab deruxtecan | | Treatment of adults with unresectable or metastatic hormone receptor-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have progressed on and are not suitable for endocrine therapy and received at least one additional systemic therapy [EU] [new indication] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Filed for approval in the UK or EU* (continued)** | | |
| Dupilumab (*Dupixent*) | | Treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents aged ≥12 years, who are symptomatic despite treatment with H1 antihistamines and who are intolerant to or inadequately controlled by anti-IgE therapy [EU] [new indication] |
| Eculizumab biosimilar (*Epysqli*) | | Use in adults and children for the treatment of atypical haemolytic uraemic syndrome [UK] [new indication] |
| Enalapril (*Aqumeldi*) | | Treatment of heart failure in children from birth to <18 years [EU]  [new 1mg orodispersible tablet formulation] |
| HIPRA SARS-CoV-2 vaccine XBB.1.16 | | Coronavirus disease 2019 (COVID-19) prevention in adults [EU]  [new Accord Healthcare booster formulation] |
| Nirogacestat (*Ogsiveo*) | | Treatment of adults with desmoid tumours [EU] |
| Resmetirom (*Rezdiffra*) | | Treatment for adults with metabolic dysfunction-associated steatohepatitis with liver fibrosis [EU] |
| Seladelpar | | Treatment of primary biliary cholangitis including pruritus in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA [EU] |
| Standardised allergen extract from house dust mites *D. pteronyssinus* and *D. farinae* (*Acarizax*) | | Use in children aged 5 to 11 years diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication [EU] [licence change from use only in adolescents aged 12 to 17 years] |
| Tislelizumab (*Tevimbra*) | | Use in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of adults with human epidermal growth factor receptor-2 negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma [EU] [new indication] |
| Tislelizumab (*Tevimbra*) | | Use in combination with platinum-based chemotherapy for the first-line treatment of adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma [EU] [new indication] |
| Ustekinumab biosimilar (*Uzpruvo*) | | Moderate to severe chronic plaque psoriasis in adults and other *Stelara* indications (except ulcerative colitis) [EU] [new intravenous formulation] |
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| ***Other UK/EU developments*** | | |
| Abatacept (*Orencia*) | | Prevention of acute graft-versus-host disease in adults and children aged ≥2 years – EU filing withdrawn |
| Atezolizumab (*Tecentriq*) | | Adjuvant treatment of squamous cell carcinoma of head and neck in adults – development discontinued (lack of efficacy) |
| Brentuximab vedotin (*Adcetris*) | | Use in adults with previously untreated CD30-positive peripheral T-cell lymphoma not otherwise specified – EU filing withdrawn |
| Invimestrocel (*Multistem*) | | Ischaemic stroke in adults – development discontinued outside Japan (company failed) |
| Opicapone (*Ongentys*) | | Treatment of signs and symptoms of Parkinson’s disease – EU filing withdrawn |
| Pimavanserin (*Nuplazid*) | | Schizophrenia, predominant negative symptoms, in adults – development discontinued  (lack of efficacy) |
| Vemircopan | | Paroxysmal nocturnal haemoglobinuria in adults – development discontinued  (company decision) |
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