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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)*** |
| Adalimumab biosimilar (*Hyrimoz*) 40mg in 0.4ml and 80mg in 0.8mL pre-filled pens and 20mg in 0.2mL, 40mg in 0.4mL and 80mg in 0.8mL prefilled syringes | Treatment of rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, Crohn´s disease, ulcerative colitis and uveitis in adults, hidradenitis suppurativa in adults and adolescents, juvenile idiopathic arthritis, paediatric plaque psoriasis, paediatric Crohn´s disease, paediatric ulcerative colitis and paediatric uveitis [new citrate-free 100mg/mL formulations] |
| Apalutamide (Erleada)240mg tablet | Use in adult men for the treatment of non-metastatic castration-resistant prostatecancer who are at high risk of developing metastatic disease, and for the treatment of metastatic hormone-sensitive prostate cancer in combination with androgen deprivation therapy [new high-strength formulation] |
| COVID-19 vaccine (*Nuvaxovid XBB.1.5*) 5-dose multidose vial | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥12 years |
| 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 [new prefilled syringe formulation] |
| Pegcetacoplan (*Aspaveli*)1,080mg in 20mL vial | Use as monotherapy in the treatment of adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia[licence change from use only after 3 months of treatment with a C5 inhibitor] |
| Pembrolizumab (*Keytruda*) 100mg in 4mL vial | Use in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, for the treatment of resectable non‑small cell lung carcinoma at high risk of recurrence in adults [new indication] |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK*** |
| Aripiprazole (*Abilify Maintena*) 960mg in 3.2mL and 720mg in 2.4mL prefilled syringes | Maintenance treatment of schizophrenia in adult patients stabilised with aripiprazole [new 2-monthly intramuscular formulation] |
| Cabotegravir (*Apretude*)30mg tablet and 600mg in 3mL vial | Use in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing ≥35kg [new injection and tablet formulations with new indication] |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK*** |
| Ciltacabtagene autoleucel (*Carvykti*) 3.2x106 to 1x108 CAR-positive viable T cells in 30mL or 70mL bag | Treatment of adults with relapsed and refractory multiple myeloma, who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide [licence change from use only after three prior therapies] |
| Enalapril 1mg in 1mL oral solution | Treatment of hypertension, treatment of symptomatic heart failure, and prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction (ejection fraction ≤ 35%) [new oral solution formulation for use in all ages except neonates and in paediatric patients with glomerular filtration rate <30mL/minute/1.73 m2] |
| Escitalopram (*Enalto*)5mg, 10mg, 15mg and 20mg orodispersible tablets | Treatment of major depressive episodes, panic disorder with or without agoraphobia, social anxiety disorder (social phobia), generalised anxiety disorder and obsessive-compulsive disorder [new orodispersible tablet formulation for use in adults] |
| Oxybutynin (*Velariq*) 10mg in 10mL prefilled syringe | Suppression of neurogenic detrusor overactivity in children aged ≥6 years and adults, who are managing bladder emptying by clean intermittent catheterisation, not adequately managed with oral anticholinergics [new intravesical formulation] |
| Povidone iodine (*Betadine*)5% cream | Treatment and prevention of infections in minor wounds (cuts and abrasions) and burns [new cream formulation] |
| Tenecteplase (*Metalyse*)5,000units (25mg) vial | Use in adults for the thrombolytic treatment of acute ischaemic stroke within 4.5 hours from last known well and after exclusion of intracranial haemorrhage[new 5,000unit vial formulation with new indication] |
| Ustekinumab biosimilar (*Pyzchiva*) 130mg in 26mL vial | Treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies |
| Ustekinumab biosimilar (*Pyzchiva*) 45mg in 0.5mL and 90mg in 1mL prefilled syringes | Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A); treatment of moderate to severe plaque psoriasis in children and adolescent patients aged ≥6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; use alone or in combination with MTX for the treatment of active psoriatic arthritis in adults when the response to previous non- biological disease-modifying anti-rheumatic drug therapy has been inadequate; treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies |
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| ***Recommended for approval in the UK or EU*** |
| Apadamtase alfa (*Adzynma*) | Enzyme replacement therapy for the treatment of ADAMTS13 deficiency in children and adults of all ages with congenital thrombotic thrombocytopenic purpura [EU] |
| Apixaban (*Eliquis*) | Treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to <18 years of age [EU] [new indication and new 0.15mg granules in capsules for opening, and 0.5, 1.5 and 2mg coated granules in sachet formulations] |
| Bevacizumab biosimilar (*Avzivi*) | Treatment of adults with metastatic carcinoma of the colon or rectum, metastatic breast cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, unresectable advanced, metastatic or recurrent non-small cell lung cancer, advanced and/or metastatic renal cell cancer, and persistent, recurrent, or metastatic carcinoma of the cervix [EU] *Note: We have shortened the wording of this indication to save space* |
| Budesonide (*Kinpeygo*) | Treatment of adults with primary immunoglobulin A nephropathy with a urine protein excretion ≥1.0g/day (or urine protein-to-creatinine [UPCR] ratio ≥0.8g/g) [EU] [licence change from use only in adults at risk for rapid disease progression with UPCR ≥1.5g/g] |
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| **Regulatory changes in the UK or EU**  |
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| ***Recommended for approval in the UK or EU* (continued)** |
| Chikungunya vaccine (*Ixchiq*) | Active immunisation for the prevention of disease caused by chikungunya virus in individuals aged ≥18 years [EU] |
| Dasiglucagon (*Zegalogue*) | Treatment of severe hypoglycaemia in adults, adolescents, and children aged ≥6 years with diabetes mellitus [EU] |
| Dupilumab (*Dupixent*) | Use in adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate [EU] [new indication] |
| Fidanacogene elaparvovec (*Durveqtix*) | Treatment of severe and moderately severe haemophilia B (congenital factor IX deficiency) in adults without a history of factor IX inhibitors and without detectable antibodies to variant AAV serotype Rh7 [EU] |
| Maralixibat (*Livmarli*) | Treatment of progressive familial intrahepatic cholestasis in patients aged ≥3 months [EU] [new indication] |
| Ocrelizumab (*Ocrevus*) | Treatment of adults with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features, and treatment of adults with early primary progressive multiple sclerosis in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity [EU] [new subcutaneous formulation] |
| Osimertinib (*Tagrisso*) | Use in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adults with advanced non-small cell lung cancer whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations [EU] [new indication] |
| Polyhexanide (*Akantior*) | Treatment of Acanthamoeba keratitis in adults and children aged ≥12 years [EU] |
| Risankizumab (*Skyrizi*) | Treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy [EU] [new indication] |
| Sugemalimab (*Cejemly*) | Use in combination with platinum-based chemotherapy for the first‑line treatment of adults with metastatic non‑small cell lung cancer with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations [EU] |
| Tislelizumab (*Tevimbra*) | Use as monotherapy for the treatment of adults with locally advanced or metastatic non-small cell lung cancer after prior platinum-based therapy [EU] [new indication] |
| Tislelizumab (*Tevimbra*) | Use in combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of adults with squamous non-small cell lung cancer (NSCLC) who have locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic NSCLC [EU] [new indication] |
| Tislelizumab (*Tevimbra*) | Use in combination with pemetrexed and platinum‑containing chemotherapy for the first-line treatment of adults with non-squamous non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on ≥50% of tumour cells with no EGFR or ALK positive mutations and who have locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic NSCLC [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*** |
| Atropine  | Myopia in children aged ≥3 years and adolescents [EU] [new eye drop formulation with new indication] |
| Bevacizumab (*Lytenava*) | Use in adults for treatment of neovascular (wet) age-related macular degeneration [UK] [new ophthalmic formulation] |
| Brentuximab vedotin (*Adcetris*) | Treatment of adults with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV Hodgkin lymphoma in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone [EU] [new indication] |
| Denosumab biosimilar – HLX14  | Postmenopausal osteoporosis and other *Prolia* indications [EU] |
| Denosumab biosimilar – HLX14  | Prevention of skeletal related events in adults with advanced malignancies involving bone and other *Xgeva* indications [EU] |
| Deutivacaftor + tezacaftor + vanzacaftor  | Cystic fibrosis in patients aged ≥6 years with ≥1 F508del mutation in the CFTR gene [EU] |
| Eflornithine (*Iwilfin*) | High-risk neuroblastoma in adults and children [UK] [new oral formulation with new indication] |
| Evinacumab (*Evkeeza*) | Treatment of paediatric patients with homozygous familial hypercholesterolaemia aged 6 months to 4 years [EU] [licence change from use only in adults and children aged ≥5 years] *Note: In the UK, currently only licensed for use in adults and adolescents aged ≥12 years* |
| Guselkumab (*Tremfya*) | Active, moderate to severe Crohn's disease in adults [EU] [new indication and new intravenous formulation, for intravenous induction and subcutaneous maintenance] |
| Guselkumab (*Tremfya*) | Moderately to severely active ulcerative colitis in adults, after conventional or biological therapy, or Janus kinase inhibitor [EU] [new indication, new intravenous formulation and new 200mg subcutaneous prefilled pen/syringe formulations, for intravenous induction and subcutaneous maintenance] |
| Inavolisib  | Treatment of adults with PIK3CA-mutated, hormone receptor-positive, human epidermal growth factor receptor 2-negative, locally advanced or metastatic breast cancer [EU] |
| Ipilimumab (*Yervoy*) | Use in combination with nivolumab for the first-line treatment of adults with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer [EU] [new indication] |
| Isatuximab (*Sarclisa*) | Use in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of adults with newly diagnosed active multiple myeloma who are not eligible for autologous stem cell transplant (ASCT) or with no intent for ASCT [EU] [new indication] |
| Mirikizumab (*Omvoh*) | Active, moderately to severely Crohn's disease in adults [EU] [new indication] |
| Nivolumab (*Opdivo*) | Use in combination with ipilimumab for the first-line treatment of adults with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer [EU] [new indication] |
| Osimertinib (*Tagrisso*) | Treatment of adults with locally advanced, unresectable (stage III) non-small cell lung cancer whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy for *Tagrisso* as monotherapy [EU] [new indication] |
| Pembrolizumab (*Keytruda*) | Use in combination with pemetrexed and platinum chemotherapy for the first-line treatment of adults and adolescents aged ≥12 years with unresectable advanced or metastatic malignant pleural mesothelioma [EU] [new indication] |
| Seladelpar  | Treatment of primary biliary cholangitis including pruritus in adults without cirrhosis or with compensated cirrhosis, in combination with ursodeoxycholic acid (UDCA), in those who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA [UK] |
| Sepiapterin  | Treatment of hyperphenylalaninemia in adult and paediatric patients with phenylketonuria [EU] |
| Teprotumumab (*Tepezza*) | Treatment of moderate to severe thyroid eye disease [EU] |
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| **Regulatory changes in the UK or EU**  |
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| ***Other UK/EU developments*** |
| Abemaciclib (*Verzenios*) | High-risk metastatic, hormone-sensitive prostate cancer in adults, first-line with abiraterone and prednisolone – development discontinued (lack of efficacy) |
| Afamelanotide (*Scenesse*) | Prevention of phototoxicity in adolescents aged 12 to 17 years with erythropoietic protoporphyria – EU filing withdrawn |
| Ataluren (*Translarna*) | Duchenne muscular dystrophy in patients aged 6 months to 2 years with nonsense mutation – UK development discontinued (company decision)  |
| Fluticasone furoate + umeclidinium + vilanterol (*Trelegy Ellipta*) | Maintenance treatment in adults with asthma whose symptoms could not be controlled well enough with a combination of inhaled corticosteroid and a long-acting beta-2 agonist – UK filing withdrawn |
| Lisocabtagene maraleucel (*Breyanzi*) | Relapsed or refractory chronic lymphocytic leukaemia or small lymphocytic lymphoma in adults – UK development discontinued (company decision) |
| Omecamtiv mecarbil (*Kinharto*) | Chronic heart failure in adults with left ventricular systolic dysfunction and reduced ejection fraction – EU filing withdrawn |
| Opnurasib  | Advanced non-small cell lung cancer, KRAS G12C mutant in previously treated adults – development discontinued (company decision) |
| Pembrolizumab + vibostolimab  | High-risk, completely resected melanoma in adults, adjuvant therapy – development discontinued (lack of efficacy) |
| TAK-007 | B-cell haematological malignancies in adults – development discontinued (company decision) |
| VTX-801 | Wilson’s disease in adults – development discontinued (company decision) |
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