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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)*** | |
| Amivantamab (*Rybrevant*)  350mg in 7mL vial | Use in combination with carboplatin and pemetrexed for the treatment of adults with advanced non‑small cell lung cancer with epidermal growth factor (EGFR) Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor [new indication] |
| Atezolizumab (*Tecentriq*)  840mg in 14mL, 1,200mg in 20mL and 1,875mg in 10mL vials | Use as monotherapy for the first-line treatment of adults with advanced non-small cell lung cancer who are ineligible for platinum-based therapy [new indication] |
| Danicopan (*Voydeya*)  50mg and 100mg tablets | Use as an add-on to ravulizumab or eculizumab for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have residual haemolytic anaemia |
| Daratumumab (*Darzalex*)  100mg in 5mL, 400mg in 20mL and 1,800mg in 15mL vials | 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 [new indication] |
| Dolutegravir + abacavir + lamivudine (*Triumeq*)  5mg/60mg/30mg dispersible tablet | Treatment of Human Immunodeficiency Virus type 1 infected children aged ≥3 months weighing ≥6kg to <25kg  [licence change for dispersible tablets from use only in children weighing ≥14kg to <25kg] |
| Donanemab (*Kisunla*)  350mg in 20mL vial | Treatment of mild cognitive impairment and mild dementia due to Alzheimer’s disease in adults that are apolipoprotein E ε4 heterozygotes or non-carriers |
| Encorafenib (*Braftovi*)  50mg and 75mg capsules | Use in combination with binimetinib for the treatment of adults with advanced non-small cell lung cancer with a BRAF V600E mutation [new indication] |
| Fosdenopterin (*Nulibry*)  9.5mg vial | Treatment of patients with molybdenum cofactor deficiency Type A |
| Liraglutide biosimilar  (*Diavic/Liraglutide SUN*)  18mg in 3mL prefilled pen | Treatment of adults, adolescents and children aged ≥10 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications and in addition to other medicinal products for the treatment of diabetes |
| Melatonin (*Slenyto*)  1mg and 5mg tablets | Treatment of insomnia in children and adolescents aged 2-18 years with autism spectrum disorder (ASD) and/or neurogenetic disorders with aberrant diurnal melatonin secretion and/or nocturnal awakenings, where sleep hygiene measures have been insufficient [licence change from use in ASD and/or Smith Magenis syndrome] |
| Remimazolam (*Byfavo*)  50mg vial | Use in adults for intravenous induction and maintenance of general anaesthesia [new higher strength formulation with new indication] |
| Thiamine hydrochloride (*Thiamine Hydrochloride*)  250mg in 5mL ampoules | Thiamine deficiency conditions where oral therapy is not possible; treatment of Wernicke´s encephalopathy associated with alcohol addiction and/or alcohol withdrawal syndrome and prevention of Wernicke-Korsakoff syndrome; treatment of peripheral neuropathy (dry beriberi) and heart failure (wet beriberi) due to thiamine malabsorption; treatment of anorexia – refeeding syndrome  [new intramuscular injection/intravenous infusion formulation] |
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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)* (continued)** | |
| Ublituximab (*Briumvi*)  150mg in 6mL vial | Treatment of adults with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features |
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| **Regulatory changes in the UK or EU** | | |
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| ***Approved in the UK*** | | |
| Bimatoprost + timolol (*Bimiduo*)  0.3mg/5mg in 1mL eye drops in 3mL and 9mL multi-dose bottles | | Reduction of intraocular pressure in adults with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues [new formulation] |
| COVID-19 vaccine (recombinant, adjuvanted) (*Nuvaxovid JN.1*)  Single-dose vial | | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥12 years |
| Denosumab biosimilar (*Jubbonti*)  60mg in 1mL prefilled syringe | | 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. |
| Denosumab biosimilar (*Wyost*)  120mg in 1.7mL vial | | 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. |
| Inebilizumab (*Uplizna*)  100mg in 10mL vial | | Use as monotherapy for the treatment of adults with neuromyelitis optica spectrum disorders who are anti-aquaporin-4 immunoglobulin G seropositive |
| Liothyronine  (*Enolio/Liothyronine Sodium Alturix*)  10micrograms/mL oral solution | | Use in adults and children for the treatment of coma of myxoedema, the management of severe chronic thyroid deficiency and hypothyroid states occurring in the treatment of thyrotoxicosis, and for the treatment of thyrotoxicosis as an adjunct to carbimazole to prevent sub-clinical hypothyroidism developing during treatment [new oral solution formulation] |
| Liraglutide biosimilar (*Biolide*)  18mg in 3mL prefilled pen | | Use as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with an initial body mass index (BMI) of ≥30kg/m² (obesity), or ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. And, use as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients aged ≥12 years with obesity (BMI corresponding to ≥30kg/m2 for adults by international cut-off points)\* and body weight >60kg |
| Liraglutide biosimilar  (*Liraglutide Biocon*)  18mg in 3mL prefilled pen | | Treatment of adults, adolescents and children aged ≥10 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, and in addition to other medicinal products for the treatment of diabetes |
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| **Regulatory changes in the UK or EU** | | | |
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| ***Approved in the UK* (continued)** | | | |
| Liraglutide biosimilar (*Pinsubet*)  18mg in 3mL prefilled pen | | | Treatment of adults, adolescents and children aged ≥10 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, and in addition to other medicinal products for the treatment of diabetes |
| KP.2  (*Comirnaty KP.2 3 micrograms/dose*)  3-dose multi-dose vial | | | Active immunisation to prevent COVID-19 caused by SARSCoV-2, in infants and children aged 6 months to 4 years |
| KP.2  (*Comirnaty KP.2 10 micrograms/dose*)  6-dose multi-dose vial and single-dose vial | | | Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years |
| KP.2  (*Comirnaty KP.2 30 micrograms/dose*)  Single-dose vial | | | Active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals aged ≥12 years |
| Rilpivirine (*Edurant*)  25mg tablet | | | Treatment of human immunodeficiency virus type 1 (HIV‑1) infection in adults and paediatric patients weighing ≥25kg without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor class, and with a viral load ≤100,000 HIV‑1 RNA copies/mL  [licence change from use only in patients aged ≥12 years] |
| Rilpivirine (*Edurant*)  2.5mg dispersible tablet | | | Use in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV‑1) infection in paediatric patients aged 2 to <18 years and weighing ≥14kg to <25kg without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor class, and with a viral load ≤100,000 HIV‑1 RNA copies/mL  [new dispersible tablet formulation with new indication] |
| Sparsentan (*Filspari*)  200mg and 400mg tablets | | | Treatment of adults with primary immunoglobulin A nephropathy with a urine protein excretion >1.0g/day (or urine protein-to-creatinine ratio ≥0.75g/g) |
| Spironolactone (*Urospir*)  5mg in 1mL and 10mg in 1mL oral solutions | | | Congestive cardiac failure, hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome and diagnosis and treatment of primary aldosteronism [new oral solution formulations] |
| Toripalimab (*Loqtorzi*)  240mg in 6mL vial | | | Use in combination with cisplatin and gemcitabine, for the first-line treatment of adults with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma |
| Toripalimab (*Loqtorzi*)  240mg in 6mL vial | | | Use in combination with cisplatin and paclitaxel for the first-line treatment of adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma |
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| ***Recommended for approval in the UK or EU*** | | | |
| Aflibercept biosimilar  (*Ahzantive, Baiama*) | | Use for adults for the treatment of neovascular (wet) age-related macular degeneration, visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), visual impairment due to diabetic macular oedema, and visual impairment due to myopic choroidal neovascularisation [EU] | |
| Amivantamab (*Rybrevant*) | | Use in combination with lazertinib for the first‑line treatment of adults with advanced non‑small cell lung cancer with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations [EU] [new indication] | |
| Arachis hypogaea (*Palforzia*) | | Treatment of patients aged 1 to 17 years with a confirmed diagnosis of peanut allergy. *Palforzia* may be continued in patients 18 years of age and older. [EU]  [licence change from use only in patients aged ≥4 years] | |
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| **Regulatory changes in the UK or EU** | | |
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| ***Recommended for approval in the UK or EU*** | | |
| COVID-19 vaccine (recombinant, adjuvanted) (*Nuvaxovid JN.1*) | | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥12 years [EU] |
| Denosumab biosimilar (*Obodence*) | | Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture [EU] |
| Denosumab biosimilar (*Xbryk*) | | 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 [EU] |
| Evinacumab (*Evkeeza*) | | Use as an adjunct to diet and other low-density lipoprotein-cholesterol lowering therapies for the treatment of adult and paediatric patients aged ≥6 months with homozygous familial hypercholesterolaemia [EU]  [licence change from use only in patients aged ≥5 years] |
| Ipilimumab (*Yervoy*) | | Use in combination with nivolumab for the first-line treatment of adults with mismatch repair deficient or microsatellite instability-high unresectable or metastatic colorectal cancer [EU] [new indication] |
| Isatuximab (*Sarclisa*) | | Use in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant |
| Lazertinib (*Lazcluze*) | | Use in combination with amivantamab for the first‑line treatment of adults with advanced non‑small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R substitution mutations [EU] |
| Lecanemab (*Leqembi*) | | Treatment of adults with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer’s disease (early Alzheimer’s disease) who are apolipoprotein E ε4 non-carriers or heterozygotes with confirmed amyloid pathology [EU] |
| Mycophenolate (*Cellcept*) | | Use in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in adult and paediatric patients (aged 1 to 18 years) receiving allogeneic renal, cardiac or hepatic transplants [EU]  [licence change from use only in patients aged ≥2 years] |
| Nivolumab (*Opdivo*) | | Use in combination with ipilimumab for the first-line treatment of adults with mismatch repair deficient or microsatellite instability-high unresectable or metastatic colorectal cancer [EU] [new indication] |
| Osimertinib (*Tagrisso*) | | Treatment of adults with locally advanced, unresectable 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 [EU] [new indication] |
| Pembrolizumab (*Keytruda*) | | Use in combination with pemetrexed and platinum chemotherapy for the first-line treatment of adults with unresectable non-epithelioid malignant pleural mesothelioma [EU] [new indication] |
| Repotrectinib (*Augtyro*) | | Monotherapy for the treatment of adult and paediatric patients aged ≥12 years with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have received a prior NTRK inhibitor, or have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted, and as monotherapy for the treatment of adults with ROS1-positive advanced non-small cell lung cancer [EU] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Recommended for approval in the UK or EU* (continued)** | | |
| Ruxolitinib (*Jakavi*) | | Treatment of adults and paediatric patients aged ≥28 days with acute graft versus host disease who have inadequate response to corticosteroids or other systemic therapies [EU] [licence change for *Jakavi* tablets from use only in patients aged ≥12 years] |
| Ruxolitinib (*Jakavi*) | | Treatment of adults and paediatric patients aged ≥28 days with acute graft versus host disease who have inadequate response to corticosteroids or other systemic therapies, and treatment of adults and paediatric patients aged ≥6 months with chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies [EU] [new oral solution formulation for patients who cannot swallow tablets] |
| Ruxolitinib (*Jakavi*) | | Treatment of adults and paediatric patients aged ≥6 months with chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies [EU] [licence change for *Jakavi* tablets from use only in patients aged ≥12 years] |
| Sarilumab (*Kevzara*) | | Treatment of active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive or negative polyarthritis and extended oligoarthritis) in patients aged ≥2 years, who have responded inadequately to previous therapy with conventional synthetic disease modifying anti-rheumatic drugs as monotherapy or in combination with methotrexate [EU] [new 175 mg in 1mL strength vial with new indication] |
| Vilobelimab (*Gohibic*) | | Treatment of adults with SARS‑CoV2‑induced acute respiratory distress syndrome who are receiving systemic corticosteroids as part of standard of care and receiving invasive mechanical ventilation (with or without extracorporeal membrane oxygenation) [EU] |
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| ***Filed for approval in the UK or EU*** | | |
| Belantamab mafodotin  (*Blenrep*) | | Treatment of multiple myeloma in combination with bortezomib and dexamethasone in adults, who have received at least one prior therapy [UK] |
| Belantamab mafodotin  (*Blenrep*) | | Treatment of multiple myeloma in combination with pomalidomide and dexamethasone in adults, who have received at least one prior therapy including lenalidomide [UK] |
| Belimumab (*Benlysta*) | | Use as add-on therapy in patients aged ≥5 years with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity despite standard therapy [EU] [licence change for the subcutaneous injection formulation from use only in adults] |
| Canagliflozin (*Invokana*) | | Treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise in children aged ≥10 years [EU] [licence change from use only in adults] |
| Chikungunya vaccine | | Prevention of chikungunya virus infection in adults and adolescents [EU]  [new Nordic Pharma formulation] |
| Chikungunya vaccine (*Ixchiq*) | | Prevention of chikungunya virus infection in adolescents aged 12 to 17 years who are at increased risk of exposure to chikungunya virus [EU] [licence change from use only in adults] |
| Daratumumab (*Darzalex*) | | Monotherapy for the treatment of high-risk smouldering multiple myeloma in adults [EU] [new indication] |
| Golimumab biosimilar – AVT05 | | Treatment of rheumatoid arthritis and axial spondyloarthritis in adults [EU] |
| Lifileucel (*Amtagvi*) | | Treatment of adults with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor [UK] |
| Lisocabtagene maraleucel  (*Breyanzi*) | | Treatment of adults with relapsed or refractory follicular lymphoma who have received two or more prior lines of systemic therapy [EU] [new indication] |
| Nogapendekin alfa inbakicept  (*Anktiva*) | | Treatment of adults with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors [UK] |
| Obecabtagene autoleucel  (*Aucatzyl*) | | Treatment of adults with relapsed or refractory B cell precursor acute lymphoblastic leukaemia [UK] |
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| **Regulatory changes in the UK or EU** | | | |
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| ***Filed for approval in the UK or EU* (continued)** | | | |
| Pridopidine | | | Treatment of adults with Huntington’s disease [EU] |
| Riociguat (*Adempas*) | | | Treatment of pulmonary arterial hypertension in paediatric patients aged <18 years and body weight ≥50 kg with WHO Functional Class II to III in combination with endothelin receptor antagonists [EU] [new granules for oral suspension formulation] |
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| ***Other UK/EU developments*** | | | |
| ATL001 | | | Advanced, smoking-related non-small cell lung cancer in adults – development discontinued (company decision) |
| ATL001 | | | Metastatic or recurrent melanoma in adults, second-line or later after PD-1/PD-L1 inhibitor – development discontinued (company decision) |
| Coacillium (*Cinainu*) | | | Alopecia areata in children and adolescents – EU negative opinion |
| Cobitolimod (*Kappaproct*) | | | Refractory ulcerative colitis – development discontinued (lack of efficacy) |
| Domofenogene zalfaparvovec | | | Phenylketonuria in adults with phenylalanine hydroxylase deficiency – development discontinued (company decision) |
| Ganaxolone (*Ztalmy*) | | | Tuberous sclerosis complex in adults and children aged ≥1 year, add-on therapy for inadequately controlled seizures – development discontinued (lack of efficacy) |
| Cedazuridine + decitabine  (*Inaqovi*) | | | Higher risk myelodysplastic syndromes in adults – EU filing withdrawn |
| Dianhydrogalactitol | | | Newly diagnosed or recurrent, MGMT-methylated or unmethylated glioblastoma in adults – development discontinued (lack of efficacy) |
| Human allogeneic liver-derived progenitor cells (*HepaStem*) | | | Acute-on-chronic liver failure in adults – development discontinued (lack of efficacy) |
| Losmapimod | | | Facioscapulohumeral muscular dystrophy – development discontinued (lack of efficacy) |
| SGT-001 | | | Duchenne muscular dystrophy in children aged 4 to 17 years – development discontinued (company decision) |
| TG6002 | | | Colorectal cancer in adults with unresectable metastases – development discontinued (company decision) |
| Vesleteplirsen | | | Duchenne muscular dystrophy in patients amenable to exon 51 skipping aged 7 to 21 years – development discontinued (company decision) |
| Zuranolone (*Zurzuvae*) | | | Major depressive disorder in adults – development discontinued (company decision) |
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