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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)*** |
| Atezolizumab (*Tecentriq*) 1,875mg in 15mL vial | Breast cancer, hepatocellular carcinoma, non-small cell lung cancer, small cell lung cancer and urothelial carcinoma [new subcutaneous formulation] |
| Epcoritamab (*Tepkinly*)4mg in 0.8mL and 48mg in 0.8mL vials | Monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy |
| Hydrocortisone (*Hydrocortisone Oral Solution*) 5mg in 5mL and 10mg in 5mL oral solutions | Replacement therapy in adrenal insufficiency in infants, children and adolescents (from 1 month to <18 years old) [new oral solution formulation] |
| Methylphenidate (*Meflynate XL*)10mg, 20mg, 30mg, 40mg and 60mg capsules | Use as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder in children aged ≥6 years and adults when remedial measures alone prove insufficient [new once-daily capsule formulation] |
| Nivolumab (*Opdivo*) 40mg in 4mL, 100mg in 10mL, 120mg in 12mL and 240mg in 24mL vials | Use as monotherapy for the adjuvant treatment of adults with Stage IIB or IIC melanoma, or melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection [new indication] |
| Paracetamol + ibuprofen (*Combogesic IV*) 1,000mg + 300mg in 100mL vial | Use in adults for the short-term symptomatic treatment of acute moderate pain and the reduction of fever, where an intravenous route of administration is considered clinically necessary and/or when other routes of administration are not possible [new intravenous formulation] |
| Risankizumab (*Skyrizi*)360mg in 2.4mL cartridge and 600mg in 10mL vial | Treatment of patients aged ≥16 years 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 [new 360mg in 2.4mL subcutaneous and 600mg in 10mL intravenous formulations with new indication] |
| Risdiplam (*Evrysdi*) 0.75mg/mL powder for oral solution | Treatment of 5q spinal muscular atrophy (SMA) in patients with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies [licence change from use only in patients aged ≥2 months] |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK*** |
| 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 |
| Eculizumab biosimilar (*Bekemv*)300mg in 30mL vial | Use in adults and children for the treatment of paroxysmal nocturnal haemoglobinuria |
| Elacestrant (*Korserdu*) 84mg and 345mg tablets | Use as monotherapy for the treatment of postmenopausal women and men with estrogen receptor-positive, HER2-negative, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have disease progression following at least one line of endocrine therapy including a CDK 4/6 inhibitor |
| Fezolinetant (*Veoza*) 45mg tablet | Treatment of moderate to severe vasomotor symptoms associated with menopause |
| Nivolumab + relatlimab (*Opdualag*) 240mg/80mg in 20mL vial | First-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents aged ≥12 years |
| Pegzilarginase (*Loargys*) 2mg in 0.4mL and 5mg in 1mL vials | Treatment of arginase 1 deficiency, also known as hyperargininemia, in adults, adolescents and children aged ≥2 years |
| Tislelizumab (*Tevimbra*)100mg in 10mL vial | Use as monotherapy for the treatment of adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy |
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| ***Recommended for approval in the UK or EU*** |
| Bezlotoxumab (*Zinplava*) | Prevention of recurrence of Clostridioides difficile infection (CDI) in adult and paediatric patients aged ≥1 year at high risk for recurrence of CDI [EU] [licence change from use only in adults] |
| Etrasimod (*Velsipity*) | 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 [EU] |
| Exagamglogene autotemcel (*Casgevy*) | Treatment of severe sickle cell disease in patients aged ≥12 years with recurrent vaso‑occlusive crises for whom haematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen‑matched related HSC donor is not available [EU] *Note: Already approved in the UK* |
| Exagamglogene autotemcel (*Casgevy*) | Treatment of transfusion‑dependent β‑thalassemia in patients aged ≥12 years for whom haematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen‑matched related HSC donor is not available [EU] *Note: Already approved in the UK* |
| Human fibrinogen + human thrombin (*VeraSeal*) | Supportive treatment in patients where standard surgical techniques are insufficient: for improvement of haemostasis, as suture support – in vascular surgery. *VeraSeal* is indicated in all age groups. [EU] [licence change from use only in adults] |
| Human normal immunoglobulin (*HyQvia*) | Immunomodulatory therapy in adults, children and adolescents aged 0 to 18 years in chronic inflammatory demyelinating polyneuropathy as maintenance therapy after stabilization with intravenous immunoglobulin [EU] [new indication] |
| Omaveloxolone (*Skyclarys*) | Treatment of Friedreich’s ataxia in adults and adolescents aged ≥16 years [EU] |
| Tenecteplase (*Metalyse*) | 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 [EU] [new 5,000unit vial formulation with 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*** |
| Aflibercept biosimilar – CT-P42  | Wet age-related macular degeneration, and visual impairment due to macular oedema following retinal vein occlusion, diabetic macular oedema or myopic choroidal neovascularisation [EU] |
| Aflibercept biosimilar – FYB203 | Wet age-related macular degeneration, and visual impairment due to macular oedema following retinal vein occlusion, diabetic macular oedema or myopic choroidal neovascularisation [EU] |
| Atezolizumab (*Tecentriq*) | Use in combination with bevacizumab for the adjuvant treatment of adults with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation [EU] [new indication] |
| Bedaquiline (*Sirturo*) | Multi-drug resistant tuberculosis in adults and adolescents aged ≥15 years for whom other treatment regimens are suitable [EU] [licence change from use only when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability] |
| Bempedoic acid (*Nilemdo*) | Prevention of cardiovascular events in patients who are at high risk for cardiovascular disease, with documented statin intolerance [EU] [new indication] |
| Bulevirtide (*Hepcludex*) | Treatment of chronic hepatitis delta virus infection in paediatric patients aged ≥3 years weighing ≥10kg with compensated liver disease [EU] [licence change from use only in adults] |
| Durvalumab (*Imfinzi*) | Use in combination with chemotherapy for the neoadjuvant treatment of resectable non-small cell lung cancer in adults followed by adjuvant monotherapy [EU] [new indication] |
| Elafibranor  | Treatment of primary biliary cholangitis [UK] |
| Garadacimab  | Prevention of hereditary angioedema in adults and children aged ≥12 years [EU] |
| Ivacaftor (*Kalydeco*) | Use in a combination regimen with ivacaftor/tezacaftor/elexacaftor tablets for the treatment of patients with cystic fibrosis (CF) aged ≥2 years who do not carry any F508del mutations and have at least one ivacaftor/tezacaftor/elexacaftor-responsive mutation in the CF transmembrane conductance regulator gene [EU] [new indication] |
| Ivacaftor + tezacaftor + elexacaftor (*Kaftrio*) | Use in a combination regimen with ivacaftor for the treatment of patients with cystic fibrosis (CF) aged ≥2 years who do not carry any F508del mutations and have at least one ivacaftor/tezacaftor/elexacaftor-responsive mutation in the CF transmembrane conductance regulator gene [EU] [new indication] |
| Murcidencel (*DCVax-L*) | Treatment of newly diagnosed and recurrent glioblastoma in adults [UK] |
| Peginterferon alpha 2a (*Pegasys*) | Treatment of polycythaemia vera and essential thrombocytopenia in adults [EU] [new indication] |
| Ribociclib (*Kisqali*) | Use in combination with an aromatase inhibitor for the adjuvant treatment of early-stage HR-positive, HER2-negative breast cancer at risk of relapse [EU] [new indication] |
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| ***Other UK/EU developments*** |
| Alpelisib (*Piqray*) | Ovarian cancer – development discontinued (lack of efficacy and safety concerns) |
| Anetumab ravtansine  | Mesothelioma – development discontinued (company decision) |
| Atezolizumab (*Tecentriq*) | Cervical cancer – development discontinued (company decision) |
| Belantamab mafodotin (*Blenrep*) | Treatment of adults with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent – conditional licence confirmed as not recommended for renewal in EU following a re-examination of the opinion |
| Bupivacaine + meloxicam (*Zynrelef*) | Somatic postoperative pain from small- to medium-sized surgical wounds in adults – EU licence withdrawn (UK licence also to be withdrawn) |
| Camidanlumab tesirine  | Classical Hodgkin lymphoma – development discontinued (company decision) |
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| **Regulatory changes in the UK or EU**  |
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| ***Other UK/EU developments* (continued)** |
| Cannabidiol (*Epidyolex*) | Epilepsy with myoclonic atonic seizures – development discontinued (company decision) |
| Cerebroside sulfatase, recombinant  | Late infantile metachromatic leukodystrophy – development discontinued (lack of efficacy) |
| Clazosentan (*Pivlaz*) | Subarachnoid haemorrhage – development discontinued (lack of efficacy) |
| Derazantinib  | Bile duct cancer (cholangiocarcinoma) – development discontinued (company decision) |
| Durvalumab (*Imfinzi*) | Renal cell carcinoma, adjuvant monotherapy or with tremelimumab in adults at intermediate and high risk of relapse – development discontinued (company decision) |
| Efgartigimod alfa (*Vyvgart Hytrulo*) | Pemphigus vulgaris and pemphigus foliaceus – development discontinued (lack of efficacy) |
| Fazpilodemab  | Metabolic dysfunction-associated steatohepatitis – development discontinued (company decision) |
| Filgotinib (*Jyseleca*) | Crohn’s disease – development discontinued (lack of efficacy) |
| Futuximab + modotuximab  | Colorectal cancer – development discontinued (company decision) |
| Mirabegron (*Betmiga*) | Overactive bladder in children aged 5 to 17 years – development discontinued (company decision) |
| Nivolumab + relatlimab (*Opdualag*) | Colorectal cancer – development discontinued (lack of efficacy) |
| NYX-783  | Post-traumatic stress disorder in adults – development discontinued (company failed) |
| Olaparib (*Lynparza*) | Metastatic, squamous non-small cell lung cancer, first-line maintenance therapy with pembrolizumab – development discontinued (lack of efficacy) |
| Olaparib (*Lynparza*) | Recurrent platinum-resistant ovarian cancer, second- and third-line treatment with cediranib – development discontinued (lack of efficacy) |
| Pembrolizumab (*Keytruda*) | Metastatic, squamous non-small cell lung cancer, first-line maintenance therapy with olaparib – development discontinued (lack of efficacy) |
| Posoleucel (*Viralym-M*) | Prevention of clinically significant multi-virus infection in high-risk allogenic hematopoietic cell transplant adults and children – development discontinued (lack of efficacy) |
| Posoleucel (*Viralym-M*) | Treatment of adenovirus infections in adults and children following allogeneic hematopoietic stem cell transplant – development discontinued (lack of efficacy) |
| Posoleucel (*Viralym-M*) | Virus-associated haemorrhagic cystitis in adults and children after allogeneic hematopoietic stem cell transplant – development discontinued (lack of efficacy) |
| ReN003  | Retinitis pigmentosa – development discontinued (company decision) |
| RIVAL-01 | Solid tumours – development discontinued (company decision) |
| Rovaleucel  | Nasopharyngeal cancer – development discontinued (company failed) |
| RP3 | Solid tumours – development discontinued (company decision) |
| RT001  | Infantile neuroaxonal dystrophy homozygous for PLA2G6 deficiency in children aged 18 months to 10 years – development discontinued (company failed) |
| Sodium zirconium cyclosilicate (*Lokelma*) | Arrhythmia-related cardiovascular disorders in patients on chronic dialysis with recurrent hyperkalaemia – development discontinued (company decision) |
| Tavokinogene telseplasmid | Melanoma – development discontinued (company failed) |
| Tusamitamab ravtansine  | Non-small cell lung cancer – development discontinued (lack of efficacy) |
| Vupanorsen  | Hypertriglyceridaemia – development discontinued (company decision) |
| Zunsemetinib  | Rheumatoid arthritis – development discontinued (lack of efficacy) |
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