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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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