|  |
| --- |
| [**SPS home**](http://www.sps.nhs.uk) **|** **Contact** |

|  |
| --- |
| **New product information**  |
|  |
| ***Launched in the UK (or licence change for existing products)*** |
| Binimetinib (*Mektovi*)15mg and 45mg capsules | Use in combination with encorafenib for the treatment of adults with advanced non-small cell lung cancer with a BRAF V600E mutation [new indication] |
| Crovalimab (*PiaSky*)340mg in 2mL vial | Use as monotherapy for the treatment of adult and paediatric patients aged ≥12 years with a weight ≥40kg with paroxysmal nocturnal haemoglobinuria, in patients with haemolysis with clinical symptom(s) indicative of high disease activity, and in patients who are clinically stable after having been treated with a complement component 5 inhibitor for at least the past 6 months |
| Durvalumab (*Imfinzi*)120mg in 2.4mL and 500mg in 10mL vials | Use in combination with carboplatin and paclitaxel for the first-line treatment of adults with primary advanced or recurrent endometrial cancer​ who are candidates for systemic therapy, followed by maintenance treatment with *Imfinzi* as monotherapy in endometrial cancer that is mismatch repair deficient, or in combination with olaparib in endometrial cancer that is mismatch repair proficient [new indication] |
| Eplontersen (*Wainzua*)45mg in 0.8mL prefilled pen | Treatment of hereditary transthyretin-mediated amyloidosis in adults with Stage 1 and 2 polyneuropathy |
| Erdafitinib (*Balversa*)3mg, 4mg and 5mg tablets | Use as monotherapy for the treatment of adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting  |
| Lecanemab (*Leqembi*)500mg in 5mL and 200mg in 2mL vials | Treatment of mild cognitive impairment and mild dementia due to Alzheimer’s disease in adults that are apolipoprotein E ε4 heterozygotes or non-carriers |
| Macitentan (*Opsumit*)10mg tablet | Use as monotherapy or in combination for the long-term treatment of pulmonary arterial hypertension in paediatric patients aged <18 years and bodyweight ≥40kg with WHO Functional Class II to III [new indication] |
| Olaparib (*Lynparza*)100mg and 150mg tablets | Use in combination with durvalumab for the maintenance treatment of adults with primary advanced or recurrent endometrial cancer that is mismatch repair proficient whose disease has not progressed on first-line treatment with durvalumab in combination with carboplatin and paclitaxel [new indication] |
| Pembrolizumab (*Keytruda*)100mg in 4mL vial | Use in combination with enfortumab vedotin for the first-line treatment of unresectable or metastatic urothelial carcinoma in adults [new indication] |
| Pneumococcal conjugate vaccine (*Prevenar 20*)Single-dose prefilled syringe | Active immunisation for the prevention of pneumococcal disease caused by *Streptococcus pneumoniae* in individuals aged ≥6 weeks [licence change from use only in adults] |
| Setmelanotide (*Imcivree*) 10mg in 1mL vial | Treatment of obesity and the control of hunger associated with genetically confirmed Bardet‑Biedl syndrome, loss-of-function biallelic pro-opiomelanocortin, including PCSK1, deficiency or biallelic leptin receptor deficiency in adults and children aged ≥2 years [licence change from use only in children aged ≥6 years] |
|  |
|  |

|  |
| --- |
| **New product information**  |
|  |
| ***Launched in the UK (or licence change for existing products)* (continued)** |
| 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] |
| Zanubrutinib (*Brukinsa*)80mg capsule | Monotherapy for the treatment of adults with mantle cell lymphoma who have received at least one prior therapy [new indication] |
|  |
|  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |
| ***Approved in the UK*** |
| Bimekizumab (*Bimzelx*)320mg in 2mL prefilled pen and syringe | Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy, use alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs, for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein and/or magnetic resonance imaging who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs, for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy, and for the treatment of active moderate to severe hidradenitis suppurativa (HS, acne inversa) in adults with an inadequate response to conventional systemic HS therapy [new higher dose formulation] |
| Delgocitinib (*Anzupgo*)20mg in 1g cream | Treatment of moderate to severe chronic hand eczema in adults for whom topical corticosteroids are inadequate or inappropriate |
| Factor VIII inhibitor bypassing fraction (*Feiba*)500U in 5mL, 1,000U in 10mL and 2,500U in 25mL vials | Treatment of bleeding in haemophilia A with inhibitors, treatment of bleeding in haemophilia B with inhibitors if no other specific treatment is available, treatment of bleeding in non-haemophilia with acquired inhibitors to factor VIII, and prophylaxis of bleeding in haemophilia A with inhibitors in people who are at high risk of or have experienced a significant bleed in all age groups [new reduced volume formulations] |
| Givinostat (*Duvyzat*)8.86mg in 1mL oral suspension | Treatment of Duchenne muscular dystrophy in patients aged ≥6 years |
| Leuprorelin (*Camcevi*)42mg prefilled syringe | Metastatic prostate cancer, locally advanced prostate cancer, as an alternative to surgical castration, as an adjuvant treatment to radiotherapy in patients with high-risk localisedor locally advanced prostate cancer, as an adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression, and as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer [new 6-month prolonged-release suspension for injection formulation] |
| Liraglutide biosimilar (*Plaobes*)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. Also 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 |
| Sotatercept (*Winrevair*)45mg and 60mg vials | Use in combination with other pulmonary arterial hypertension (PAH) therapies, for the treatment of PAH in adults with WHO Functional Class II to III, to improve exercise capacity |
|  |
|  |  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |
| ***Recommended for approval in the UK or EU*** |
| Acoramidis (*Beyonttra*) | Treatment of wild-type or variant transthyretin amyloidosis in adults with cardiomyopathy [EU] |
| Aflibercept biosimilar (*Eydenzelt*) | Treatment of adults with 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 neovascularization [EU] |
| Belzutifan (*Welireg*) | Monotherapy for the treatment of adults with advanced clear cell renal cell carcinoma that progressed following two or more lines of therapy that included a PD-(L)1 inhibitor and at least two VEGF-targeted therapies [EU] |
| Belzutifan (*Welireg*) | Monotherapy for the treatment of adults with von Hippel-Lindau disease who require therapy for associated, localised renal cell carcinoma, central nervous system haemangioblastomas, or pancreatic neuroendocrine tumours, and for whom localised procedures are unsuitable [EU] *Note: Already launched in UK*  |
| Blinatumomab (*Blincyto*) | Use as monotherapy as part of consolidation therapy for the treatment of adults with newly diagnosed Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia [EU] [new indication] |
| Blinatumomab (*Blincyto*) | Use as monotherapy for the treatment of paediatric patients aged ≥1 month with Philadelphia chromosome-negative CD19 positive B-cell precursor acute lymphoblastic leukaemia which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic haematopoietic stem cell transplantation [EU] [licence change from use only in paediatric patients aged ≥1 year] |
| Blinatumomab (*Blincyto*) | Use as monotherapy for the treatment of paediatric patients aged ≥1 month with high-risk first relapsed Philadelphia chromosome-negative CD19 positive B-cell precursor acute lymphoblastic leukaemia as part of the consolidation therapy [EU] [licence change from use only in paediatric patients aged ≥1 year] |
| Cabotegravir (*Vocabria*) | Use in combination with rilpivirine tablets, for the short-term treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (aged ≥12 years and weighing ≥35kg), who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor and integrase inhibitor class for oral lead-in to assess tolerability of *Vocabria* and rilpivirine prior to administration of long acting cabotegravir injection plus long acting rilpivirine injection, and oral therapy for adults and adolescents who will miss planned dosing with cabotegravir injection plus rilpivirine injection [EU] [licence change from use only in adults] |
| Cabotegravir (*Vocabria*) | Use in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (aged ≥12 years and weighing ≥35kg), who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor and integrase inhibitor class [EU] [licence change from use only in adults] |
| Denosumab biosimilar (*Osenvelt*) | 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] |
| Denosumab biosimilar (*Stoboclo*) | 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] |
|  |  |
|  |  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |  |
| ***Recommended for approval in the UK or EU* (continued)** |
| Dostarlimab (*Jemperli*) | Use in combination with carboplatin and paclitaxel for the first-line treatment of adults with primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy [EU] [licence change from use only in adults with mismatch repair deficient/microsatellite instability‑high cancer] |
| Filgrastim biosimilar (*Zefylti*) | Reduction in duration of neutropenia and incidence of febrile neutropenia in adults and children treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for reduction in duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. Also mobilisation of peripheral blood progenitor cells and for treatment of persistent neutropenia (ANC ≤1.0 x 109/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate [EU] |
| Garadacimab (*Andembry*) | Routine prevention of recurrent attacks of hereditary angioedema in adult and adolescent patients aged ≥12 years [EU] |
| Guanfacine (*Paxneury*) | Treatment of attention deficit hyperactivity disorder in children and adolescents aged 6‑17 years for whom stimulants are not suitable, not tolerated or have been shown to be ineffective [EU] |
| Imetelstat (*Rytelo*) | Monotherapy for the treatment of adults with transfusion-dependent anaemia due to very low, low or intermediate risk myelodysplastic syndromes without an isolated deletion 5q cytogenetic (non-del 5q) abnormality and who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy [EU] |
| Influenza vaccine (*Fluad*) | Prophylaxis of influenza in adults aged ≥50 years [EU]  |
| Influenza vaccine (*Flucelvax Tetra*) | Prophylaxis of influenza in adults and children aged ≥6 months [EU] [licence change from use only in adults and children aged ≥2 years] *Note: Already licensed in UK* |
| Methylphenidate (*Tuzulby*) | Use as part of a comprehensive treatment programme for attention-deficit / hyperactivity disorder in children aged ≥6 years of age when remedial measures alone prove insufficient [EU] |
| Mirikizumab (*Omvoh*) | 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 biologic treatment [EU] [new indication and new 200mg prefilled pen and syringe formulations] |
| Nemolizumab (*Nemluvio*) | Treatment of adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy [EU] |
| Nemolizumab (*Nemluvio*) | Treatment of moderate-to-severe atopic dermatitis in patients aged ≥12 years who are candidates for systemic therapy [EU] |
| Nintedanib (*Ofev*) | Use in children and adolescents aged 6 to 17 years old for the treatment of clinically significant, progressive fibrosing interstitial lung diseases [EU] [new indication and new 25mg capsule formulation] |
| Nintedanib (*Ofev*) | Use in adults, adolescents and children aged ≥6 years for the treatment of systemic sclerosis associated interstitial lung disease [EU] [licence change from use only in adults] |
| Rilpivirine (*Rekambys*) | Use in combination with cabotegravir injection, for the treatment of human immunodeficiency virus type 1 (HIV‑1) infection in adults and adolescents (aged ≥12 years and weighing ≥35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with, agents of the non-nucleoside reverse transcriptase inhibitor and integrase inhibitor class [EU] [licence change from use only in adults] |
|  |  |
|  |  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |  |
| ***Recommended for approval in the UK or EU* (continued)** |
| Seladelpar (*Seladelpar Gilead*) | Treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA [EU] |
| Sipavibart (*Kavigale*) | Pre‑exposure prophylaxis of COVID‑19 in adults and adolescents aged ≥12 years weighing ≥40kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments [EU] |
| Sugammadex (*Bridion*) | Routine reversal of rocuronium induced blockade in paediatric patients from birth to 17 years [EU] [licence change from use in paediatric patients aged ≥2 years] |
| Tocilizumab biosimilar (*Avtozma*)  | Use as monotherapy or in combination with methotrexate (MTX) for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX, and treatment of moderate to severe active RA in adults who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs or tumour necrosis factor antagonists. Also for treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation, use as monotherapy or in combination with MTX for treatment of active systemic juvenile idiopathic arthritis in patients aged **≥2 years** who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs and systemic corticosteroids, use as monotherapy or in combination with MTX for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients aged **≥2 years**, and treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and paediatric patients aged ≥2 years [EU] [concentrate for solution for infusion formulation] |
| Tocilizumab biosimilar (*Avtozma*)  | Use as monotherapy or in combination with methotrexate (MTX) for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX, and treatment of moderate to severe active RA in adults who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs or tumour necrosis factor antagonists. Also use as monotherapy or in combination with MTX for treatment of active systemic juvenile idiopathic arthritis in patients aged **≥1 year** who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs and systemic corticosteroids, use as monotherapy or in combination with MTX for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients aged **≥2 years** who have responded inadequately to previous therapy with MTX, and treatment of giant cell arteritis in adults [EU] [prefilled syringe formulation] |
| Tocilizumab biosimilar (*Avtozma*)  | Use as monotherapy or in combination with methotrexate (MTX) for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX, and treatment of moderate to severe active RA in adults who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs or tumour necrosis factor antagonists. Also use as monotherapy or in combination with MTX for treatment of active systemic juvenile idiopathic arthritis in patients aged **≥12 years** who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs and systemic corticosteroids, use as monotherapy or in combination with MTX for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients aged **≥12 years** who have responded inadequately to previous therapy with MTX, and treatment of giant cell arteritis in adults [EU] [prefilled pen formulation] |
| Tiratricol (*Emcitate*) | Treatment of peripheral thyrotoxicosis in patients with monocarboxylate transporter 8 deficiency (Allan-Herndon-Dudley Syndrome) from birth [EU] |
|  |  |
|  |  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |  |
| ***Recommended for approval in the UK or EU* (continued)** |
| Ustekinumab biosimilar (*Yesintek*) | 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, treatment of active psoriatic arthritis in adults (alone or in combination with MTX), when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate, and 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 [EU] |
| Zapomeran (*Kostaive*) | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥18 years [EU] |
|  |  |
|  |  |
| ***Filed for approval in the UK or EU*** |
| Bifikafusp alfa + onfekafusp alfa (*Nidlegy*) | Neoadjuvant treatment of locally advanced fully resectable melanoma in adults [EU] |
| Blarcamesine  | Treatment of Alzheimer’s disease [EU] |
| Darolutamide (*Nubeqa*) | Use in combination with androgen deprivation therapy for the treatment of adults with metastatic hormone-sensitive prostate cancer [EU] [new indication] |
| Darunavir + cobicistat (*Rezolsta*) | Use in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 infection in paediatric patients aged ≥6 years with body weight ≥25kg [EU] [licence extension from use only in adults and adolescents aged ≥12 years, weighing ≥40kg and new 675mg/150mg tablet formulation] |
| Denosumab biosimilar – TVB-009P | Postmenopausal osteoporosis and other *Prolia* indications [EU] |
| Dorocubicel  | Treatment of adults with haematological malignancies requiring an allogeneic haematopoietic stem cell transplantation who lack a readily available suitable donor [EU] |
| Durvalumab (*Imfinzi*) | Treatment of adults with limited-stage small cell lung cancer whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy [EU] [new indication] |
| Elinzanetant  | Treatment of adult women with moderate to severe vasomotor symptoms associated with menopause [EU] |
| Glofitamab (*Columvi*) | Use in combination with gemcitabine and oxaliplatin to treat relapsed or refractory diffuse large B-cell lymphoma in patients who have received at least one prior line of therapy and who are not candidates for autologous stem cell transplant [EU] [new indication] |
| Histamine  | Maintenance therapy of adults with acute myeloid leukaemia in first remission concomitantly treated with interleukin-2 [UK] |
| Insulin icodec + semaglutide  | Type 2 diabetes mellitus in adults [EU] |
| Mitapivat  | Treatment of adults with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia [EU] [new indication] |
| Olezarsen (*Tryngolza*) | Use as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome |
| Pegunigalsidase alfa (*Elfabrio*) | Long-term enzyme replacement therapy in adults with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase) [EU] [new 4-weekly dose regimen] |
|  |  |
|  |  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |  |
| ***Filed for approval in the UK or EU* (continued)** |
| Rilzabrutinib  | Treatment of persistent or chronic immune thrombocytopenia in adults and children aged ≥12 years [EU] |
| Trastuzumab deruxtecan(*Enhertu*) | Unresectable or metastatic, HER2-low, HR-positive breast cancer in adults who have progressed on ≥2 endocrine therapies [EU] [new indication] |
|  |  |
|  |  |
| ***Other UK/EU developments*** |
| Atropine  | Myopia in adolescents and children aged ≥3 years (Thea formulation) – UK development discontinued (company decision)  |
| Baclofen + naltrexone + sorbitol (*Syngility*) | Mild-to-moderate type 1a Charcot-Marie-Tooth disease in people aged ≥16 years – development discontinued (lack of efficacy) |
| Benralizumab (*Fasenra*) | Severe bilateral chronic sinusitis with nasal polyps in adults who are symptomatic despite standard therapy – development discontinued (lack of efficacy) |
| Bucindolol (*Gencaro*) | Prevention of recurrence of atrial fibrillation in adults with heart failure and/or left ventricular dysfunction and the ADRB1 Arg389Arg genotype – development discontinued (company decision) |
| Capivasertib (*Truqap*) | Advanced, triple negative breast cancer in adults, first-line with paclitaxel – development discontinued (lack of efficacy) |
| Darvadstrocel (*Alofisel*) | Treatment of complex perianal fistulas in adults with nonactive/mildly active luminal Crohn’s disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy – withdrawn from EU market |
| Dexamethasone (*DexaSite*) | Ocular inflammation and pain post cataract surgery – development discontinued (company decision) |
| Dexmedetomidine (*Igalmi*) | Bipolar disorder-associated agitation in adults – UK development discontinued  |
| Dexmedetomidine (*Igalmi*) | Schizophrenia-associated agitation in adults – UK development discontinued  |
| Dirloctocogene samoparvovec | Severe or moderately-severe haemophilia A in adults – development discontinued (company decision) |
| Eculizumab (*Soliris*) | Relapsing neuromyelitis optica spectrum disorder, anti-aquaporin-4 antibody-positive, in children aged 2 to 17 years – development discontinued (company decision) |
| Enfortumab vedotin (*Padcev*) | Use in combination with pembrolizumab for the first-line treatment of adults with unresectable or metastatic urothelial cancer who are not eligible for platinum-containing chemotherapy – not approved in UK and EU |
| EYS606 | Chronic non-infectious uveitis in adults – development discontinued (company decision) |
| Favezelimab + pembrolizumab | Metastatic, PD-L1-positive colorectal cancer in previously treated adults – development discontinued (lack of efficacy) |
| Favezelimab + pembrolizumab | Relapsed or refractory, PD-(L)1-refractory classical Hodgkin lymphoma in adults, third-line monotherapy – development discontinued (company decision) |
| Ganaxolone  | Acute treatment of refractory status epilepticus in adults and children aged ≥12 years [intravenous formulation] – development discontinued (lack of efficacy) |
| Human apolipoprotein A-I | Acute coronary syndrome in adults with ST-segment elevation myocardial infarction (MI) or non-ST-segment elevation MI – development discontinued (lack of efficacy) |
| Ibrutinib (*Imbruvica*) | Relapsed or refractory mantle cell lymphoma in adults, second-line or greater with venetoclax – development discontinued (company decision) |
|  |  |
|  |  |

|  |
| --- |
| **Regulatory changes in the UK or EU**  |
|  |  |
| ***Other UK/EU developments* (continued)** |
| Inolimomab (*Leukotac*) | Severe acute steroid-resistant graft versus host disease in all ages – development discontinued (company decision) |
| Irsenontrine  | Lewy body dementia and Parkinson disease dementia in adults – development discontinued (company decision) |
| Licogliflozin + tropifexor | Metabolic dysfunction-associated steatohepatitis in adults with fibrosis stage 2 or 3 – development discontinued (company decision) |
| NGM313  | Metabolic dysfunction-associated steatohepatitis in adults with fibrosis stage 2 or 3 – development discontinued (company decision)  |
| Pembrolizumab + vibostolimab  | Locally advanced, unresectable non-small cell lung cancer in adults, first-line with chemoradiotherapy followed by pembrolizumab + vibostolimab maintenance – development discontinued (company decision) |
| Pembrolizumab + vibostolimab  | Metastatic, PD-L1-positive non-small cell lung cancer, first-line in adults in whom EGFR-, ALK- or ROS1-directed therapy is not indicated as primary therapy – development discontinued (lack of efficacy) |
| Pembrolizumab + vibostolimab  | Metastatic, squamous or non-squamous non-small cell lung cancer without EGFR mutations or ALK/ROS1 gene rearrangements, in adults, first-line – development discontinued (lack of efficacy) |
| Pneumococcal conjugate vaccine  | Pneumococcal infection prevention adults (24-valent formulation, GSK) – development discontinued (company decision) |
| Semorinemab  | Mild-to-moderate Alzheimer's disease in adults – development discontinued (company decision) |
| SER-287 | Active mild-to-moderate ulcerative colitis in adults – development discontinued (company decision) |
| SerpinPC | Severe haemophilia B with or without inhibitors, in adults and children aged ≥12 years – development discontinued (company decision) |
| Tarcocimab tedromer   | Diabetic macular oedema associated visual impairment in adults – development discontinued (lack of efficacy and safety concern) |
| TERN-101 | Metabolic dysfunction-associated steatohepatitis in adults with fibrosis stage 1, 2 or 3, as monotherapy or in combination with TERN-501 – development discontinued (company decision)  |
| Tirzepatide (*Mounjaro*) | Treatment of moderate to severe obstructive sleep apnoea in adults with obesity – not approved in EU as use in this population is already covered by the approved indication for weight management in people with a body mass index ≥27kg/m2 |
|  |  |
|  |  |