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| [**SPS home**](http://www.sps.nhs.uk) **|** [**Contact**](mailto:nwmedinfo@nhs.net?subject=New%20Medicines%20Newsletter) |

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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)*** | |
| Adalimumab biosimilar (*Imraldi*)  40mg in 0.4mL prefilled pen and syringe | Treatment of rheumatoid arthritis in adults, juvenile idiopathic arthritis, axial spondyloarthritis in adults (including ankylosing spondylitis), psoriatic arthritis in adults, psoriasis in adults, paediatric plaque psoriasis, hidradenitis suppurativa in adults, Crohn´s disease in adults and children, ulcerative colitis in adults and children, and uveitis in adults and children [new higher strength citrate- and sorbitol-free formulation] *See* [*SmPC*](https://www.medicines.org.uk/emc/search?q=imraldi) *for full details of indication* |
| Avapritinib (*Ayvakyt*)  100mg, 200mg and 300mg tablets | Monotherapy for the treatment of adults with aggressive systemic mastocytosis, systemic mastocytosis with an associated haematological neoplasm or mast cell leukaemia [new indication] |
| Aztreonam + avibactam (*Emblaveo*)  1.5g/0.5g vial | Treatment of the following infections in adults: Complicated intra-abdominal infection; hospital-acquired pneumonia, including ventilator-associated pneumonia; complicated urinary tract infection, including pyelonephritis. Also treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options. |
| Baloxavir marboxil (*Xofluza*)  80mg tablet | Treatment of uncomplicated influenza in patients aged ≥1 year and post-exposure prophylaxis of influenza in individuals aged ≥1 year  [new higher strength formulation for people weighing ≥80kg] |
| Brentuximab vedotin (*Adcetris*)  50mg vial | Use for adults with previously untreated CD30+ Stage III or IV Hodgkin lymphoma in combination with doxorubicin, vinblastine and dacarbazine  [licence change from use only in Stage IV disease] |
| Bretovameran  (*Comirnaty JN.1 3micrograms/dose)*  3-dose multi-dose vial | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in infants and children aged 6 months to 4 years |
| Bretovameran  (*Comirnaty JN.1 10micrograms/dose)*  10microgram in 0.3mL single-dose vial | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in children aged 5 to 11 years |
| Bretovameran  (*Comirnaty JN.1 30micrograms/dose)*  6-dose multi-dose vial and 30micrograms in 0.3mL single-dose prefilled syringe | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥12 years |
| Budesonide (*Budenofalk*)  4mg suppository | Short-term treatment of mild to moderate acute ulcerative colitis limited to the rectum (ulcerative proctitis) in adults [new suppository formulation] |
| Capivasertib (*Truqap*)  160mg and 200mg tablets | Use in combination with fulvestrant for the treatment of adults with hormone receptor-positive, human epidermal growth factor receptor 2-negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine based regimen |
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\*amended

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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)* (continued)** | |
| Ciclosporin (*Cequa*)  0.9mg in 1mL eye drops in single dose container | Treatment of moderate-to-severe dry eye disease (keratoconjunctivitis sicca) in adults who have not responded adequately to artificial tears |
| Dupilumab (*Dupixent*)  300mg in 2mL prefilled pen and syringe | 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 [new indication] |
| Elacestrant (*Korserdu*)  86mg\* 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 |
| 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] |
| Evinacumab (*Evkeeza*)  345mg in 2.3ml and 1,200mg in 8mL vials | Use as an adjunct to diet and other low-density lipoprotein-cholesterol lowering therapies for treatment of adult and paediatric patients aged ≥5 years with homozygous familial hypercholesterolaemia  [licence change from use only in adults and children aged ≥12 years] |
| Exagamglogene autotemcel (*Casgevy*)  4-13×10x6 cells/mL in one or more 1.5mL to 20mL vials | Treatment of transfusion-dependent β-thalassemia in patients aged ≥12 years for whom a human leukocyte antigen-matched related haematopoietic stem cell donor is appropriate and a human leukocyte antigen matched related haematopoietic stem cell donor is not available |
| Gefapixant (*Lyfnua*) 45mg tablet | Use in adults for the treatment of refractory or unexplained chronic cough  *Note: Available on private prescriptions only* |
| Human normal immunoglobulin (*Panzyga*) 50mL, 60mL, 100mL, 200mL and 300mL bottles, and 10mL and 25ml vials | Measles pre-/post exposure prophylaxis for susceptible adults, children and adolescents (aged 0-18 years) in whom active immunisation is contraindicated or not advised [new indication] |
| Human normal immunoglobulin (*Octagam 5%*) 100mL, 200mL and 500mL bottles, and 20mL and 50mL vials | Measles pre-/post exposure prophylaxis for susceptible adults, children and adolescents (aged 0-18 years) in whom active immunisation is contraindicated or not advised [new indication] |
| Influenza vaccine (*Quadrivalent Influenza Vaccine [Split Virion, Inactivated] High‐Dose*)  Single-dose prefilled syringe | Active immunisation in adults aged ≥60 years for the prevention of influenza disease |
| Iptacopan (*Fabhalta*)  200mg capsule | Use as monotherapy in the treatment of adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia |
| Ivermectin  3mg tablets | Treatment of gastrointestinal strongyloidiasis (anguillulosis), suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti, and human sarcoptic scabies in adults and children weighing ≥15kg  [new Vygoris formulation] |
| Linzagolix (*Yselty*)  100mg and 200mg tablets | Treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age |
| mRNA-1273.167 (*Spikevax JN.1*)  5-dose and 10-dose multi-dose vials | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥6 months |
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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)* (continued)** | |
| Omalizumab (*Xolair*) 75mg in 0.5mL prefilled pen | Treatment of allergic asthma in adults, adolescents and children aged 6 to 11 years and chronic rhinosinusitis with nasal polyps in adults [new prefilled pen formulation]  *Note: For full details, see* [*SmPC*](https://products.mhra.gov.uk/search/?search=xolair&page=1&doc=Spc&rerouteType=0) |
| Osimertinib (*Tagrisso*) 40mg and 80mg tablets | 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 [new indication] |
| Posaconazole (*Noxafil*)  300mg sachet (in a kit containing 8 sachets with 473mL solvent bottle, bottle adapter, mixing cup and syringes) | Use in the treatment of the following fungal infections in paediatric patients aged ≥2 years: Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. Also for prophylaxis of invasive fungal infections in the following paediatric patients aged ≥2 years: Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia or myelodysplastic syndromes expected to result in prolonged neutropenia and who are at high-risk of developing invasive fungal infections; Haematopoietic stem cell transplant recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high-risk of developing invasive fungal infections [new gastro-resistant powder and solvent for oral suspension formulation] |
| Relugolix + estradiol + norethisterone (*Ryeqo*) 40mg/1mg/0.5mg tablet | Use in adult women of reproductive age for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis [new indication] |
| Risankizumab (*Skyrizi*)  180mg in 1.2mL cartridge with on-body injector | 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, or if such therapies are not advisable, and treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy [new subcutaneous formulation including with new UC indication] |
| Rozanolixizumab (*Rystiggo*)  280mg in 2mL vial | Use as an add-on to standard therapy for treatment of generalised myasthenia gravis in adults who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive |
| Sofosbuvir + velpatasvir + voxilaprevir (*Vosevi*) 200mg/50mg/50mg tablet | Treatment of chronic hepatitis C virus infection in patients aged ≥12 years and weighing ≥30kg [new low-strength formulation] |
| Talazoparib (*Talzenna*) 100microgram capsule | For use as monotherapy for the treatment of adults with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy. Also for use in combination with enzalutamide for the treatment of adults with metastatic castration-resistant prostate cancer in whom chemotherapy is not clinically indicated. [new lower strength formulation] |
| Zolbetuximab (*Vyloy*)  100mg vial | Use in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2‑negative gastric or gastro-oesophageal junction adenocarcinoma whose tumours are Claudin 18.2 positive |
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| **Regulatory changes in the UK or EU** | | | |
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| ***Approved in the UK*** | | | |
| Fruquintinib (*Fruzaqla*)  1mg and 5mg capsules | | | Monotherapy for the treatment of adults with metastatic colorectal cancer who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan‑based chemotherapies, anti‑VEGF agents, and anti‑EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine‑tipiracil or regorafenib  *Note: Indication and formulation based on EU SmPC –* [*please check UK SmPC once available*](https://www.gov.uk/government/news/fruquintinib-approved-to-treat-adult-patients-with-metastatic-colorectal-cancer) |
| Idecabtagene vicleucel  (*Abecma*)  260 to 500 x 106 CAR-positive viable T cells infusion bag | | | Treatment of adults with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti CD38 antibody and have demonstrated disease progression on the last therapy [licence change from use only after three prior therapies] |
| Leniolisib (*Joenja*)  70mg tablet | | | Treatment of activated phosphoinositide 3-kinase delta syndrome in adult and paediatric patients aged ≥12 years |
| mRNA-1273.167 (*Spikevax JN.1*)  Single-dose prefilled syringe | | | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥6 months |
| Ustekinumab biosimilar (*Steqeyma*)  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, 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 |
| Ustekinumab biosimilar (*Steqeyma*)  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 |
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| ***Recommended for approval in the UK or EU*** | | | |
| Aflibercept biosimilar (*Afqlir*) | | 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, or visual impairment due to myopic choroidal neovascularisation [EU] | |
| Aflibercept biosimilar (*Opuviz*) | | 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, or visual impairment due to myopic choroidal neovascularization [EU] | |
| Apremilast (*Otezla*) | | Treatment of moderate to severe plaque psoriasis in children and adolescents aged ≥6 years and weighing ≥20kg who are candidates for systemic therapy [EU] [new indication] | |
| Benralizumab (*Fasenra*) | | Use as an add-on treatment for adults with relapsing or refractory eosinophilic granulomatosis with polyangiitis [EU] [new indication] | |
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| **Regulatory changes in the UK or EU** | | |
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| ***Recommended for approval in the UK or EU* (continued)** | | |
| Ceftazidime + avibactam (*Zavicefta*) | | Use in adults and paediatric patients from birth for the treatment of complicated intra-abdominal infection, complicated urinary tract infection, including pyelonephritis, hospital-acquired pneumonia, including ventilator associated pneumonia. Also for the treatment of infections due to aerobic Gram-negative organisms in adults and paediatric patients from birth with limited treatment options [EU]  [licence change from use only in adults and paediatric patients aged ≥3 months] |
| Daratumumab (*Darzalex*) | | 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 [EU] [new indication] |
| Dupilumab (*Dupixent*) | | Treatment of eosinophilic esophagitis in adults, and adolescents and children aged ≥1 year weighing ≥15kg who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy [EU]  [licence change from use only in adults, adolescents and children aged ≥12 years weighing ≥40kg] |
| Empagliflozin + metformin (*Synjardy*) | | Use in adults and children aged ≥10 years for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise in patients insufficiently controlled on their maximally tolerated dose of metformin alone, in combination with other medicinal products for the treatment of diabetes in patients insufficiently controlled with metformin and these medicinal products, and in patients already being treated with the combination of empagliflozin and metformin as separate tablets [EU] [licence change from use only in adults] |
| Fenofibrate + pravastatin  (*Pravafenix*) | | Use as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the treatment of mixed hyperlipidaemia in adults at high cardiovascular risk to reduce triglycerides and increase HDL-C when LDL-C levels are adequately controlled while on a treatment with pravastatin 40mg monotherapy or on another moderate-intensity statin regimen [EU] [licence change from use only in patients who are inadequately controlled on treatment with pravastatin 40mg monotherapy] |
| Marstacimab (*Hympazvi*) | | Routine prophylaxis of bleeding episodes in patients aged ≥12 years, weighing ≥35kg, with severe haemophilia A (congenital factor VIII deficiency, FVIII <1%) without factor VIII inhibitors, or severe haemophilia B (congenital factor IX deficiency, FIX <1%) without factor IX inhibitors [EU] |
| Meningococcal ABCWY vaccine (*Penbraya*) | | Active immunisation of individuals aged ≥10 years to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W and Y [EU] |
| Midazolam (*Buccolam*) | | Treatment of prolonged, acute, convulsive seizures in infants aged ≥3 months to adults [EU] [licence change from use only in in toddlers, children and adolescents aged ≥3 months to 17 years] |
| Mirvetuximab soravtansine (*Elahere*) | | Monotherapy for the treatment of adults with folate receptor-alpha-positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens [EU] |
| Pembrolizumab (*Keytruda*) | | Use in combination with carboplatin and paclitaxel, for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults who are candidates for systemic therapy [EU] [new indication] |
| Pembrolizumab (*Keytruda*) | | Use in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy [EU] [new indication] |
| Serplulimab (*Hetronifly*) | | Use in combination with carboplatin and etoposide for the first‑line treatment of adults with extensive‑stage small cell lung cancer [EU] |
| Smallpox vaccine (*Imvanex*) | | Active immunisation against smallpox, monkeypox and disease caused by *vaccinia* virus in individuals aged ≥12 years [EU] [licence change from use only in adults] |
| Turoctocog alfa pegol  (*Esperoct*) | | Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency) [EU] [licence change from use only in patients aged ≥12 years] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Filed for approval in the UK or EU*** | | |
| Amivantamab (*Rybrevant*) | | Non-small cell lung cancer with EGFR Exon 19, 20 or 21 mutations in adults [EU]  [new subcutaneous formulation] |
| Baloxavir marboxil (*Xofluza*) | | Treatment of uncomplicated influenza in infants aged <1 year [EU]  [licence change form use only in patients aged ≥1 year] |
| Guselkumab (*Tremfya*) | | Active, moderate to severe Crohn's disease in adults [EU]  [new subcutaneous induction dosing regimen] |
| Isatuximab (*Sarclisa*) | | Relapsed or refractory multiple myeloma in adults [EU] [new subcutaneous formulation] |
| Lutetium (177Lu) oxodotreotide (*Lutathera*) | | Unresectable or metastatic, Grade 2 or 3 somatostatin receptor-positive gastroentero-pancreatic neuroendocrine tumours, newly diagnosed in adults, with octreotide [EU] |
| Mirdametinib | | Treatment of type 1 neurofibromatosis in children aged ≥2 years, adolescents and adults, who have symptomatic, inoperable plexiform neurofibromas [EU] |
| Nemolizumab (*Nemluvio*) | | Treatment of adults and adolescents with moderate to severe atopic dermatitis [UK] |
| Nipocalimab | | Treatment of adults with generalised myasthenia gravis [EU] |
| Respiratory syncytial virus vaccine (*Abrysvo*) | | Active immunisation of individuals aged 18 to 59 years at high risk of severe respiratory syncytial virus (RSV) disease due to certain chronic medical conditions for the prevention of lower respiratory tract disease caused by respiratory syncytial virus [EU] [new indication] |
| Rilpivirine (*Rekambys*) | | HIV infection in adolescents, with cabotegravir (injectable formulation) [EU] |
| Sebetralstat | | On-demand treatment of hereditary angioedema in adults and adolescents aged ≥12 years [EU] |
| Somatrogon (*Ngenla*) | | Long-term replacement of endogenous growth hormone of adults with growth hormone deficiency [EU] [new indication] |
| Teprotuzumab (*Tepezza*) | | Treatment of moderate to severe thyroid eye disease [UK] |
| Ustekinumab (*Stelara*) | | Moderately to severely active Crohn's disease in children aged 2 to 17 years [EU]  [licence change from use only in adults] |
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| **Regulatory changes in the UK or EU** | | | |
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| ***Other UK/EU developments*** | | | |
| Atezolizumab (*Tecentriq*) | | Early relapsing, advanced inoperable, triple negative breast cancer in adults, with capecitabine or carboplatin/gemcitabine – development discontinued (lack of efficacy) | |
| Atezolizumab (*Tecentriq*) | | Hepatocellular carcinoma in adults at high risk of recurrence, adjuvant therapy with bevacizumab – EU filing withdrawn and development discontinued (lack of efficacy) | |
| Atezolizumab (*Tecentriq*) | | Metastatic castration-resistant prostate cancer in adults, with cabozantinib after 1 hormonal treatment – UK and EU development discontinued (company decision) | |
| Bimatoprost (*Durysta*) | | Reduction of intraocular pressure in adults with open angle glaucoma or ocular hypertension – EU filing withdrawn | |
| Brigimadlin | | De-differentiated liposarcoma in adults, first-line with doxorubicin – development discontinued (lack of efficacy) | |
| Cabozantinib (*Cabometyx*) | | Metastatic castration-resistant prostate cancer in adults, with atezolizumab after 1 hormonal treatment – UK and EU development discontinued (company decision) | |
| Empagliflozin (*Jardiance*) | | Reduction in risk of cardiovascular death or hospitalisation with heart failure following acute myocardial infarction in adults – development discontinued (lack of efficacy) | |
| Idecabtagene vicleucel  (*Abecma*) | | Newly diagnosed multiple myeloma in adults who have suboptimal response to transplant – development discontinued (company decision) | |
| Ozanimod (*Zeposia*) | | Moderate-to-severe active Crohn's disease in adults – development discontinued  (lack of efficacy) | |
| Pegcetacoplan (*Syfovre*) | | Geographic atrophy caused by age-related macular degeneration in adults – not recommended for approval in EU (second negative opinion) | |
| Secukinumab (*Cosentyx*) | | Moderate to severe rotator cuff tendinopathy in adults with partial/no tear and active disease, who have failed conventional therapy – development discontinued (company decision) | |
| Selexipag (*Uptravi*) | | Pulmonary arterial hypertension (WHO functional class II-III) in children aged 2 to 17 years – UK development discontinued (company decision) | |
| Soticlestat | | Lennox-Gastaut syndrome in adults and children aged ≥2 years – development discontinued (lack of efficacy) | |
| Voxelotor (*Oxbryta*) | | Treatment of haemolytic anaemia due to sickle cell disease in adult and paediatric patients aged ≥12 years as monotherapy or in combination with hydroxycarbamide – withdrawn from all markets (safety concern) | |
| Voxelotor (*Oxbryta*) | | Treatment of haemolytic anaemia due to sickle cell disease in children aged 4 to 11 years – development discontinued (safety concern) | |
| Voxelotor (*Oxbryta*) | | Treatment of sickle cell disease- associated leg ulcers, in adults and children aged ≥12 years – development discontinued (safety concern) | |
| Voxelotor (*Oxbryta*) | | Treatment of sickle cell disease in children aged 2 to 16 years – development discontinued (safety concern) | |
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