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| **New product information** | |
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| ***Launched in the UK (or licence change for existing products)*** | |
| Anastrozole  1mg tablet | Primary prevention of breast cancer in postmenopausal women at moderate or high risk [new indication initially for Accord brand only] *For more details, see NHS England* [*news article*](https://www.england.nhs.uk/2023/11/tens-of-thousands-of-women-set-to-benefit-from-repurposed-nhs-drug-to-prevent-breast-cancer/) |
| Azelastine (*Azelair*)  0.15% nasal spray | Symptomatic treatment of allergic rhinitis in adults, adolescents and children aged ≥6 years [new formulation] |
| Glofitamab (*Columvi*)  10mg in 10mL vial | Monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma, after two or more lines of systemic therapy |
| Pegunigalsidase alfa (*Elfabrio*) 20mg in 10mL vial | Long-term enzyme replacement therapy in adults with a confirmed diagnosis of Fabry disease (deficiency of alpha-galactosidase) |
| Pembrolizumab (*Keytruda*)  100mg in 4mL vial | Use in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥1 [new indication] |
| Sapropterin  (*Sapropterin Dihydrochloride*)  100mg and 500mg powder for oral solution in sachets | Treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria who have been shown to be responsive to such treatment. Also licensed for the treatment of HPA in adults and paediatric patients of all ages with tetrahydrobiopterin deficiency who have been shown to be responsive to such treatment [new powder for oral solution formulation] |
| Talquetamab (*Talvey*)  3mg in 1.5mL and 40mg in 1mL vials | Monotherapy for the treatment of adults with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy |
| Trifluridine + tipiracil  (*Lonsurf*)  15mg/6.14mg and 20mg/8.19mg tablets | Use in combination with bevacizumab for the treatment of adults with metastatic colorectal cancer who have received two prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents [new indication] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Approved in the UK*** | | |
| Adagrasib (*Krazati*)  200mg tablet | | Use as monotherapy for the treatment of adults with advanced non-small cell lung cancer with KRAS G12C mutation and have progressive disease after prior therapy with, or intolerance to, platinum-based chemotherapy and/or anti-PD-1/PD-L1 immunotherapy |
| Aflibercept biosimilar (*Yesafili*) 4mg in 0.1mL vial | | Use in 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 |
| Exagamglogene autotemcel (*Casgevy*)  4 to 13×10x6 cells/mL in one or more 1.5mL to 20mL vials | | Treatment of sickle cell disease in patients aged ≥12 years with recurrent vaso-occlusive crises who have the βS/βS, βS/β+ or βS/β0 genotype, for whom a haematopoeitic stem cell transplantation is appropriate and a human leukocyte antigen matched related haematopoietic stem cell donor is not available |
| Exagamglogene autotemcel (*Casgevy*)  4 to 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 |
| Ivacaftor (*Kalydeco*)  13.4mg granules in sachet | | Use as monotherapy for the treatment of infants aged ≥1 month, toddlers and children weighing 3kg to <25kg with cystic fibrosis (CF) who have an R117H CFTR mutation or one of the following gating (class III) mutations in the CF transmembrane conductance regulator gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R [new lower strength formulation] |
| Ivacaftor (*Kalydeco*)  25mg, 50mg and 75mg granules in sachet | | Use as monotherapy for the treatment of infants aged ≥1 month, toddlers and children weighing 3kg to <25kg with cystic fibrosis (CF) who have an R117H CFTR mutation or one of the following gating (class III) mutations in the CF transmembrane conductance regulator gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R  [licence change from use only in infants aged ≥4 months, toddlers and children weighing 5kg to <25kg] |
| Ivacaftor (*Kalydeco*)  13.4mg, 25mg, 50mg and 75mg granules in sachet | | Use in a combination regimen with ivacaftor/tezacaftor/elexacaftor for the treatment of cystic fibrosis (CF) in paediatric patients aged 2 to <6 years who have at least one F508del mutation in the CF transmembrane conductance regulator gene [new indication] |
| Ivacaftor (*Kalydeco*)  59.5mg granules in sachet | | Use as monotherapy for the treatment of infants aged ≥1 month, toddlers and children weighing 3kg to <25kg with cystic fibrosis (CF) who have an R117H CFTR mutation or one of the following gating (class III) mutations in the CF transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R. Also use in a combination regimen with ivacaftor/tezacaftor/ elexacaftor for the treatment of CF in paediatric patients aged 2 to <6 years who have at least one F508del mutation in the CFTR gene [new strength formulation] |
| Ivacaftor + tezacaftor + elexacaftor (*Kaftrio*)  60mg/40mg/80mg and 75mg/50mg/100mg granules in sachet | | Use in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in paediatric patients aged 2 to <6 years who have at least one F508del mutation in the CF transmembrane conductance regulator gene [new granule formulations with new indication] |
| Lisocabtagene maraleucel  (*Breyanzi*)  5.1 to 322 × 106 CAR+ viable T cells in 4.6mL vials (CD4+ and CD8+ cell components in separate vials) | | Treatment of adults with relapsed or refractory diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma and follicular lymphoma grade 3B after two or more lines of systemic therapy |
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| **Regulatory changes in the UK or EU** | | |
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| ***Approved in the UK* (continued)** | | |
| Respiratory syncytial virus vaccine (*Abrysvo*)  Single-dose vial | | Active immunisation of individuals aged ≥60 years for the prevention of lower respiratory tract disease caused by respiratory syncytial virus |
| Respiratory syncytial virus vaccine (*Abrysvo*)  Single-dose vial | | Passive protection against lower respiratory tract disease caused by respiratory syncytial virus in infants from birth through 6 months of age following maternal immunisation during pregnancy |
| Ritlectinib (*Litfulo*)  50mg capsule | | Treatment of severe alopecia areata in adults and adolescents aged ≥12 years |
| Satralizumab (*Enspryng*)  120mg in 1mL prefilled syringe | | Use as a monotherapy or in combination with immunosuppressive therapy for the treatment of neuromyelitis optica spectrum disorders in adults and adolescents aged ≥12 years who are anti-aquaporin-4 IgG seropositive |
| Tirzepatide (*Mounjaro*)  2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg single-dose prefilled pens | | For weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity 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 comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes or type 2 diabetes mellitus) [new indication] |
| Tocilizumab biosimilar (*Tyenne*)  162mg in 0.9mL prefilled pen and syringe, and 80mg in 4mL, 200mg in 10mL and 400mg in 20mL vials | | Use in combination with methotrexate (MTX), for treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX; 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; treatment of active systemic juvenile idiopathic arthritis in patients aged ≥1 year who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, for use in combination with MTX for 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 for treatment of giant cell arteritis in adults |
| Tezepelumab (*Tezspire*)  210mg in 1.91mL prefilled pen | | Use as an add-on maintenance treatment in adults and adolescents aged ≥12 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment [new prefilled pen formulation] |
| Ublituximab (*Briumvi*)  150mg in 6mL vial | | Treatment of adults with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features |
| Ustekinumab (*Stelara*)  45mg and 90mg prefilled pens | | 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); use alone or in combination with MTX, for treatment of active psoriatic arthritis in adults when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate; 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; treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies [new prefilled pen formulations] |
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| **Regulatory changes in the UK or EU** | | |
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| ***Recommended for approval in the UK or EU*** | | |
| Adagrasib (*Krazati*) | | Use as monotherapy for the treatment of adults with advanced non-small cell lung cancer with KRAS G12C mutation and disease progression after at least one prior systemic therapy [EU] *Note: Already approved in the UK* |
| Aflibercept (*Eylea 8mg*) | | Treatment of adults with neovascular (wet) age-related macular degeneration and visual impairment due to diabetic macular oedema [EU] [new high-dose extended-interval formulation] |
| Atezolizumab (*Tecentriq*) | | Breast cancer, hepatocellular carcinoma, non-small cell lung cancer, small cell lung cancer and urothelial carcinoma [EU] [new subcutaneous formulation]  *Note: Already approved in the UK* |
| Avapritinib (*Ayvakyt*) | | Treatment of adults with indolent systemic mastocytosis with moderate to severe symptoms inadequately controlled on symptomatic treatment [EU] [new indication] |
| Concentrate of proteolytic enzymes enriched in bromelain (*NexoBrid*) | | Use in all age groups for removal of eschar in patients with deep partial- and full-thickness thermal burns [EU] [licence change from use only in adults] |
| Dabigatran (*Pradaxa*) | | Treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from the time the child is able to swallow soft food to <18 years of age [EU] [licence change from use from birth and removal of the powder and solvent for oral solution formulation] |
| Empagliflozin (*Jardiance*) | | Use in adults and children aged ≥10 years for treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or in addition to other medicinal products for the treatment of diabetes [EU] [licence change from use only in adults] |
| Evinacumab (*Evkeeza*) | | 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 [EU] [licence change from use only in adults and children aged ≥12 years] |
| Influenza vaccine  (*Fluad Tetra*) | | Prophylaxis of influenza in adults aged ≥50 years [EU]  [licence change from use only in adults aged ≥65 years] |
| Momelotinib (*Omjjara*) | | Treatment of disease-related splenomegaly or symptoms in adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase inhibitor naïve or have been treated with ruxolitinib [EU] |
| Patiromer (*Veltassa*) | | Treatment of hyperkalaemia in adults and adolescents aged 12 to 17 years [EU]  [licence change from use only in adults and new powder for oral suspension formulation] |
| Pembrolizumab (*Keytruda*) | | Use in combination with gemcitabine and cisplatin for first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults [EU] [new indication] |
| Ranibizumab biosimilar (*Rimmyrah*) | | Use in adults for treatment of neovascular (wet) age-related macular degeneration, treatment of visual impairment due to diabetic macular oedema, treatment of proliferative diabetic retinopathy, treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and treatment of visual impairment due to choroidal neovascularisation [EU] |
| Rozanolixizumab (*Rystiggo*) | | 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 [EU] |
| Talazoparib (*Talzenna*) | | Use in combination with enzalutamide for treatment of adults with metastatic castration-resistant prostate cancer in whom chemotherapy is not clinically indicated [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)** | | |
| Tirzepatide (*Mounjaro*) | | For weight management, including weight loss and weight maintenance, as an adjunct to a reduced-calorie diet and increased physical activity 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 comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes mellitus) [EU] [new indication] *Note: Already approved in the UK* |
| Trametinib (*Spexotras*) | | Use in combination with dabrafenib for treatment of paediatric patients aged ≥1 year with low-grade glioma with a BRAF V600E mutation who require systemic therapy, and use in combination with dabrafenib for treatment of paediatric patients aged ≥1 year with high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment [EU] |
| Ustekinumab biosimilar (*Uzpruvo*) | | 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 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 [EU] |
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| ***Filed for approval in the UK or EU*** | | |
| Amino acids | | Treatment of decompensation episodes in maple syrup urine disease patients [EU] |
| Aztreonam + avibactam | | Serious bacterial infections due to gram-negative bacteria in adults [EU] [new formulation] |
| Beremagene geperpavec  (*Vyjuvek*) | | Treatment of skin wounds associated with dystrophic epidermolysis bullosa [EU] |
| Bimekizumab (*Bimzelx)* | | Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy [EU] [new 320mg prefilled pen and syringe formulations] |
| Binimetinib (*Mektovi*) | | Use in combination with encorafenib for treatment of adults with advanced non-small cell lung cancer with a BRAF V600 mutation [EU] [new indication] |
| Binimetinib (*Mektovi*) | | Use in combination with encorafenib for treatment of adults with unresectable or metastatic melanoma with a BRAF V600 mutation [EU] [new 45mg tablet formulation] |
| Blarcamesine | | Treatment of early Alzheimer's disease [EU] |
| Budesonide (*Kinpeygo*) | | Treatment of primary immunoglobulin A nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio ≥1.5g/gram [EU]  *Note: Filed for full approval; already has conditional approval* |
| Capivasertib (*Truqap*) | | Use in combination with fulvestrant for treatment of locally advanced or metastatic HR-positive, HER2-negative breast cancer [UK] |
| Clascoterone (*Winlevi*) | | Treatment of acne vulgaris [EU] |
| Dolutegravir + abacavir + lamivudine (*Triumeq*) | | Treatment of human immunodeficiency virus-infected children weighing 6kg to <25kg [EU] [licence change from use only in children weighing ≥25kg] |
| Dupilumab (*Dupixent*) | | Treatment of adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease with type 2 inflammation on triple therapy or double therapy if inhaled corticosteroids are contraindicated [EU] [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* (continued)** | | |
| Durvaluamb (*Imfinzi*) | | Use in combination with olaparib for maintenance treatment of adults with newly diagnosed advanced or recurrent endometrial cancer following treatment with durvalumab and platinum-based chemotherapy [EU] [new indication] |
| Elafibranor | | Treatment of primary biliary cholangitis [EU] |
| Encorafenib (*Braftovi*) | | Use in combination with binimetinib for treatment of adults with advanced non-small cell lung cancer with a BRAF V600 mutation [EU] [new indication] |
| Epcoritamab (*Tepkinly*) | | Treatment of relapsed or refractory follicular lymphoma [EU] [new indication] |
| Eplontersen | | Treatment of adults with polyneuropathy associated with hereditary transthyretin-mediated amyloidosis [EU] |
| Isavuconazole (*Cresemba*) | | Use in adults and paediatric patients aged ≥6 years for treatment of invasive aspergillosis, and mucormycosis in patients for whom amphotericin B is inappropriate [EU] [licence change from use only in adults for the 100mg capsule formulation and new 40mg capsule formulation] |
| Isavuconazole (*Cresemba*) | | Use in adults and paediatric patients aged ≥1 year for treatment of invasive aspergillosis, and mucormycosis in patients for whom amphotericin B is inappropriate [EU] [licence change from use only in adults for the IV formulation] |
| Mirvetuximab soravtansine  (*Elahere*) | | Treatment of patients with folate receptor alpha-positive, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer [EU] |
| Nintedanib (*Ofev*) | | Treatment of fibrosing interstitial lung diseases in children and adolescents from 6 to 17 years of age [EU] [new indication and new 25mg capsule formulation] |
| Olaparib (*Lynparza*) | | Use in combination with durvalumab for maintenance treatment of adults with newly diagnosed advanced or recurrent endometrial cancer following treatment with durvalumab and platinum-based chemotherapy [EU] [new indication] |
| Pembrolizumab (*Keytruda*) | | Use in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy) for treatment of high-risk locally advanced cervical cancer in adults who have not received prior definitive therapy [Stage IB2-IIB (with node-positive disease) or Stage III-IVA based on FIGO 2014] [EU] [new indication] |
| Semaglutide (*Rybelsus*) | | Type 2 diabetes mellitus in adults [EU] [new 1.5mg, 4mg and 9mg oral formulations] |
| Semaglutide (*Rybelsus*) | | Type 2 diabetes mellitus in adults [EU] [new 25mg and 50mg oral formulations] |
| Semaglutide (*Wegovy*) | | Reduction in risk of major adverse cardiovascular events (cardiovascular death, non-fatal heart attack or non-fatal stroke) in people with an initial BMI ≥27 kg/m2 and established cardiovascular disease [EU] [new indication] |
| Sodium phenylbutyrate  (*Pheburane)* | | Urea cycle disorders involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase [EU] [new 500mg tablet formulation] |
| Sotatercept | | Treatment of pulmonary arterial hypertension in adults [EU] |
| Tirzepatide (*Mounjaro*) | | Treatment of adults 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, or in addition to other medicinal products for the treatment of diabetes [EU] [new multidose pre-filled pen formulation] *Note: Presume licence will also include use for weight management which is currently recommended for approval in EU/approved in UK* |
| Tiratricol | | Treatment of monocarboxylate transporter 8 deficiency [EU] |
| Troriluzole | | Treatment of adults with spinocerebellar ataxia genotype 3 [EU] |
| Ustekinumab biosimilar – FYB202 | | Moderate to severe chronic plaque psoriasis in adults and other *Stelara* indications [EU] |
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| **Regulatory changes in the UK or EU** | | | |
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| ***Other UK/EU developments*** | | | |
| ACHM CNGB3 | | | Achromatopsia due to mutations in the CNGB 3 gene – development discontinued (company decision) |
| Alpelisib (*Vijoice*) | | | Treatment of PIK3CA-related growth spectrum in adults and children aged ≥2 years – EU filing withdrawn |
| Asundexian | | | Stroke prevention in adults with atrial fibrillation at risk of stroke – development discontinued (lack of efficacy) |
| Budesonide + salbutamol  (*Airsupra*) | | | As needed treatment or prevention of bronchoconstriction and prevention of exacerbations of asthma in adults – UK development discontinued (company decision) |
| FLT190 | | | Fabry's disease – development discontinued (company decision) |
| Fluticasone + vilanterol  (*Relvar Ellipta*) | | | Regular treatment in children aged 6 to 11 years not adequately controlled with inhaled corticosteroids and as needed inhaled short acting beta-2-agonists – UK and EU development discontinued (company decision) |
| Gefapixant (*Lyfnua*) | | | Use in adults for the treatment of refractory or unexplained chronic cough – UK development discontinued (company decision) |
| Gemogenovatucel-T (*Vigil*) | | | Ewing sarcoma – development discontinued (company decision) |
| Glibenclamide | | | Stroke, treatment of large hemispherical infarction – development discontinued (company decision) |
| Human retinal pigment epithelial cell therapy | | | Stargardt's disease – development discontinued (company decision) |
| Ilixadencel (*Intuvax-RCC*) | | | Renal cell carcinoma – development discontinued (company decision) |
| Letetresgene autoleucel | | | Non-small cell lung cancer – development discontinued (company decision) |
| Lixmabegagene relduparvovec | | | GM1 gangliosidoses – development discontinued (company failed) |
| Odevixibat | | | Treatment of cholestatic pruritus in Alagille syndrome in patients aged ≥6 months – EU filing withdrawn |
| Olenasufligene relduparvovec | | | Mucopolysaccharidosis IIIA – development discontinued (company failed) |
| Trastuzumab duocarmazine  (*Jivadco*) | | | HER2-positive unresectable locally advanced or metastatic breast cancer – development discontinued (company decision) |
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