

October 2020

This newsletter is produced by the SPS horizon scanning service and highlights recent new product launches and significant medicines regulatory changes. Most of these changes are recorded in the [New Medicines](#) section of the SPS website. New medicines monographs added to the SPS website are also listed in this newsletter.

More detailed information on medicines expected to launch in the next 12 months and on marketed medicines that are expected to have major new indications approved can be found in [Prescribing Outlook – New Medicines](#).

[SPS home](#) | [Contact](#)

New product information

Launched in the UK (or licence change for existing products)

<p>Bevacizumab biosimilar (<i>Aybintio</i>)</p>	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
<p>Bilastine (<i>Ilaxten</i>)</p>	Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticarial in children aged 6 to 11 years with a body weight ≥ 20 kg [new 10mg orodispersible formulation and new indication]
<p>Burosumab (<i>Crysvita</i>)</p>	Treatment of X-linked hypophosphataemia, in children and adolescents aged 1 to 17 years with radiographic evidence of bone disease, and in adults [licence change from use only in children and adolescents]
<p>Dasatinib (<i>Sprycel</i>)</p>	Treatment of paediatric patients with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukaemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib, and newly diagnosed Ph+ acute lymphoblastic leukaemia in combination with chemotherapy [new oral suspension formulation]
<p>Glasdegib (<i>Daurismo</i>)</p>	Use in combination with low-dose cytarabine for treatment of newly diagnosed de novo or secondary acute myeloid leukaemia in adults who are not candidates for standard induction chemotherapy
<p>Letermovir (<i>Prevymis</i>)</p>	Prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients of an allogeneic haematopoietic stem cell transplant [new intravenous formulation]

New product information

Recent (or pending) product launches considered for a safety assessment

Each month, SPS utilise a scoring tool to identify which recently launched products are high enough risk to benefit from a full safety assessment. Details of this process can be viewed [here](#). Some products do not warrant a full assessment but safety issues have nonetheless been identified which are considered helpful to take account of when managing entry into the NHS. These are listed below together with details of the products where a full assessment is planned. A list of all published safety assessments can be viewed [here](#).

Generic name (Trade name)	Indication(s)	Safety issues identified (NB. not comprehensive)	SPS safety assessment
Somatropin (<i>Norditropin FlexPro</i>)	In children, growth failure due to growth hormone deficiency, Turner syndrome, chronic renal disease and Noonan syndrome. Also growth disturbance in short children born small for gestational age.	<i>Norditropin FlexPro</i> is a solution in cartridge for use with a <i>NordiPen</i> injection device. There are some differences in licensed indications between available somatropin products. There is potential risk of confusion between <i>FlexPro</i> strengths, with other similarly named Norditropin somatropin products and with other available somatropin products.	Not planned
	In adults, childhood and adult onset growth hormone deficiency.	Ensure somatropin products are prescribed by brand name, followed by the concentration and recommended daily dose in units.	

To access monographs, click on the drug name or visit www.sps.nhs.uk

Direct links to short monographs are included
Complete monographs are password protected – please [register](#) for access

Regulatory changes in the EU

Approved in the UK/EU

Bevacizumab biosimilar (<i>Equidacent</i>)	Treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and carcinoma of the cervix
Bupivacaine + meloxicam (<i>Zynrelef</i>)	Treatment of somatic postoperative pain from small to medium-sized surgical wounds in adults [new formulation]
Indacaterol + mometasone (<i>Ateectura</i>)	Maintenance treatment of asthma in adults and adolescents aged ≥ 12 years not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists [new formulation]
Insulin aspart (<i>Insulin aspart Sanofi</i>)	Treatment of diabetes mellitus in adults, adolescents and children aged ≥ 1 year
Misoprostol (<i>Angusta</i>)	Induction of labour [new oral formulation]

Recommended for approval in the UK/EU

Adalimumab (<i>Humira</i>)	Treatment of moderately to severely active ulcerative colitis in children aged ≥ 6 years who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies [licence change from use only in adults]
Arachis hypogaea (<i>Palforzia</i>)	Treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy (<i>Palforzia</i> may be continued in patients 18 years of age and older)
Autologous lentiviral ARSA gene therapy (<i>Libmeldy</i>)	Treatment of metachromatic leukodystrophy characterised by biallelic mutations in the arylsulphatase A (ARSA) gene leading to a reduction of the ARSA enzymatic activity in children with late infantile or early juvenile forms, without clinical manifestations of the disease, and in children with the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline
Blinatumomab (<i>Blinicyto</i>)	Monotherapy for the treatment of adults with CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). Patients with Philadelphia chromosome positive B-precursor ALL should have failed treatment with ≥ 2 tyrosine kinase inhibitors and have no alternative treatment options [new indication]
Brexucabtagene autoleucel (<i>Tecartus</i>)	Treatment of adults with relapsed or refractory mantle cell lymphoma after ≥ 2 lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor
Budesonide + formoterol + glycopyrrolate (<i>Trixeo Aerosphere</i>)	Maintenance treatment in adults with moderate to severe chronic obstructive pulmonary disease who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist [new formulation]
Cabotegravir (<i>Vocabria</i>)	Use in combination with rilpivirine injection, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults 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 NNRTI and INI class
Dapagliflozin (<i>Forxiga</i>)	Treatment of symptomatic chronic heart failure with reduced ejection fraction in adults with and without type-2 diabetes [new indication]
Dupilumab (<i>Dupixent</i>)	Treatment of severe atopic dermatitis in children 6 to 11 years old who are candidates for systemic therapy [licence change from use only in patients aged ≥ 12 years]
Fenfluramine (<i>Fintepla</i>)	Treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients aged ≥ 2 years [new formulation]

This is a NHS document not to be used for commercial purposes

New Medicines Newsletter is one of several horizon scanning resources produced by the Specialist Pharmacy Service to support managed introduction of new medicines into the NHS, to help organisations develop medicines management policies and to inform prescribing decisions when a product has been launched. For more information, contact your regional medicines information centre.

Contact nwmedinfo@nhs.net if you have a question about this newsletter.

Recommended for approval in the UK/EU (continued)

Guselkumab (<i>Tremfya</i>)	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 a prior disease-modifying antirheumatic drug therapy [new indication]
Inclisiran (<i>Leqvio</i>)	Use in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated
Lacosamide (<i>Vimpat</i>)	Use as adjunctive therapy in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children aged ≥ 4 years with idiopathic generalised epilepsy [new indication]
Lumasiran (<i>Oxlumo</i>)	Treatment of primary hyperoxaluria type 1 in all age groups
Nivolumab (<i>Opdivo</i>)	Treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy [new indication]
Peginterferon beta-1a (<i>Plegridy</i>)	Relapsing remitting multiple sclerosis in adults [new intramuscular route of administration]
Relebactam + cilastatin + imipenem (<i>Recarbrio</i>)	Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults, and treatment of bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults [new indication]
Rilpivirine (<i>Rekambys</i>)	Use in combination with cabotegravir injection, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults 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 NNRTI and INI class [new formulation]

Filed for approval in the UK/EU

Aducanumab	Alzheimer's disease
Avalglucosidase alfa	Treatment of patients with Pompe disease (acid α -glucosidase deficiency)
Belimumab (<i>Benlysta</i>)	Lupus nephritis in adults uncontrolled on standard care [new indication]
Betamethasone + calcipotriol (<i>Wynzora</i>)	Topical treatment of plaque psoriasis in adults [new formulation]
COVID-19 vaccine	Coronavirus disease 2019 prevention [BioNTech and Pfizer formulation]
COVID-19 vaccine	Coronavirus disease 2019 prevention [Moderna formulation]
COVID-19 vaccine	Coronavirus disease 2019 prevention [Oxford Vaccine Group, Jenner Institute and AstraZeneca formulation]
Elivaldogene tavalentvec (<i>Lenti-D</i>)	Treatment of cerebral adrenoleukodystrophy
Evinacumab	Homozygous familial hypercholesterolaemia
Lisocabtagene maraleucecl	Treatment of relapsed or refractory aggressive large B cell non-Hodgkin lymphoma, including diffuse large B-cell lymphoma
Pegcetacoplan	Paroxysmal nocturnal haemoglobinuria
Pembrolizumab (<i>Keytruda</i>)	Locally advanced or metastatic colorectal cancer, with a microsatellite instability high or mismatch repair deficient biomarker – first-line [new indication]

This is a NHS document not to be used for commercial purposes

New Medicines Newsletter is one of several horizon scanning resources produced by the Specialist Pharmacy Service to support managed introduction of new medicines into the NHS, to help organisations develop medicines management policies and to inform prescribing decisions when a product has been launched. For more information, contact your regional medicines information centre.

Contact nwmedinfo@nhs.net if you have a question about this newsletter.

Filed for approval in the UK/EU (continued)

Pembrolizumab (<i>Keytruda</i>)	Relapsed or refractory classical Hodgkin lymphoma in patients who have not had brentuximab, following autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option [new indication]
Ranibizumab biosimilar – SB11	Neovascular age-related macular degeneration
Ripretinib (<i>Qinlock</i>)	Advanced gastrointestinal stromal tumours
Sitoiganap (<i>Gliovac</i>)	Recurrent glioblastoma
Upadacitinib (<i>Rinvoq</i>)	Treatment of adults and adolescents with moderate to severe atopic dermatitis [new indication]

Other UK/EU developments

Edasalonexent	Duchenne muscular dystrophy – development discontinued
Ibrutinib (<i>Imbruvica</i>)	First-line treatment of graft versus host disease – development discontinued
Idebenone (<i>Puldysa</i>)	Duchenne muscular dystrophy – EU filing withdrawn and development discontinued
Ivosidenib (<i>Tibsovo</i>)	Relapsed or refractory isocitrate dehydrogenase-1 mutation-positive acute myeloid leukaemia – EU filing withdrawn
Ixazomib (<i>Ninlaro</i>)	Previously untreated multiple myeloma, in combination with lenalidomide and dexamethasone – development discontinued
Levosimendan	Amyotrophic lateral sclerosis (motor neurone disease) – development discontinued
Sarilumab (<i>Kevzara</i>)	Giant cell arteritis – development discontinued
Sarilumab (<i>Kevzara</i>)	Polymyalgia rheumatica – development discontinued

New monographs (7)

UK (EU/US)*

BAN2401	Pre-clinical Alzheimer's disease	None (PIII)
Cabozantinib (<i>Cabometyx</i>)	Metastatic castration-resistant prostate cancer in men previously treated with one, and only one, novel hormonal therapy – in combination with atezolizumab	None (None/PIII)
Cabozantinib (<i>Cabometyx</i>)	Renal cell carcinoma, intermediate- or poor-risk advanced or metastatic – first-line in combination with nivolumab and ipilimumab	PIII (PIII)
Daxibotulinum toxin A	Spasmodic torticollis	PIII (PIII)
Deferiprone (<i>Ferriprox</i>)	Transfusional iron overload due to sickle cell disease or other anaemias – gastro-resistant tablet formulation	PIII (None)
Lenacapavir	HIV infection	None (PIII)
Trifluridine + tipiracil (<i>Lonsurf</i>)	Unresectable or metastatic colorectal cancer – first-line in combination with bevacizumab in patients not suitable for standard full dose combination chemotherapy with irinotecan or oxaliplatin	PIII (PIII/None)

* If trials ongoing in the EU and US are the same phase, only one phase is stated

This is a NHS document not to be used for commercial purposes

New Medicines Newsletter is one of several horizon scanning resources produced by the Specialist Pharmacy Service to support managed introduction of new medicines into the NHS, to help organisations develop medicines management policies and to inform prescribing decisions when a product has been launched. For more information, contact your regional medicines information centre.

Contact nwmedinfo@nhs.net if you have a question about this newsletter.