Specialist Pharmacy Service New Medicines Newsletter

May 2019

This newsletter is produced by the UKMi horizon scanning service and highlights recent significant medicines regulatory changes. 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, plus a Focus section of medicines in development for a specific disease.

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.

New product information

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

Dupilumab (*Dupixent*)	Add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, in patients aged ≥12 years who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment [licence change]
Empagliflozin + linagliptin (*Glyxambi*)	Use in adults with type 2 diabetes mellitus to improve glycaemic control when metformin and/or sulphonylurea and one of the monocomponents of *Glyxambi* do not provide adequate glycaemic control or when already being treated with the free combination of empagliflozin and linagliptin [new formulation]
Lenalidomide (*Revlimid*)	Use as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone for treatment of adults with previously untreated multiple myeloma who are not eligible for transplant [licence change from use only with dexamethasone, or in combination with melphalan and prednisone followed by maintenance with lenalidomide]
Leuprorelin (*Prostap DCS*)	Adjuvant treatment of endocrine responsive early stage breast cancer in pre- and perimenopausal women at higher risk of disease recurrence (young age, high grade tumour, lymph node involvement), in combination with tamoxifen or an aromatase inhibitor [licence change]
Leuprorelin (*Prostap DCS*)	Treatment of advanced breast cancer in pre- and perimenopausal women suitable for hormonal manipulation [licence change]
Plerixafor (*Mozobil*)	Use in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children aged 1 to <18 years with lymphoma or solid malignant tumours, either pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or who previously failed to collect sufficient haematopoietic stem cells [licence change from use only in adults]
Pomalidomide (*Imnovid*)	Treatment of adults with multiple myeloma who have received at least one prior treatment regimen (including lenalidomide), in combination with bortezomib and dexamethasone [licence change from use only in adults who have received at least two prior treatment regimens]
Risankizumab (*Skyrizi*)	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy
Tenofovir disoproxil (*Viread*)	Treatment of chronic hepatitis B in patients aged 6 to <12 years who weigh from 28kg to <35kg, with compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels or histological evidence of moderate to severe inflammation and/or fibrosis [licence change for 123mg, 163mg and 204mg film-coated tablets from use only for HIV-1 infection]
Tenofovir disoproxil (*Viread*)	Treatment of chronic hepatitis B in patients aged 2 to <12 years, for whom a solid dosage form is not appropriate, with compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels or histological evidence of moderate to severe inflammation and/or fibrosis [licence change for 33mg/g granules from use only in adults and adolescents aged 12 to <18 years]

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 EU and/or UK

Hydrogen peroxide (*Eskeriele*)	Treatment of seborrheic keratosis that are not pedunculated and have up to a maximum diameter of 15mm each [new formulation]
Lorlatinib (*Lorviqua*)	Monotherapy for the treatment of adults with anaplastic lymphoma kinase (ALK)‑positive advanced non‑small cell lung cancer whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy, or crizotinib and at least one other ALK TKI
Pegvaliase (*Palynziq*)	Treatment of patients with phenylketonuria aged ≥16 years who have inadequate blood phenylalanine control (blood phenylalanine levels >600micromol/L) despite prior management with available treatment options
Volanesorsen (*Waylivra*)	An adjunct to diet in adults with genetically confirmed familial chylomicronaemia syndrome and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate

EU positive opinions

Rifamycin SV MMX (*Aemcolo*)	Treatment of travellers' diarrhoea
Romosozumab (*Evenity*)	Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture

Filed for approval in the EU

Buprenorphine (*Sublocade*)	Opioid dependence [new once-monthly SC injection formulation]
Carbetocin (*Pabal*)	Prevention of post-partum haemorrhage due to uterine atony following vaginal delivery [new IM formulation]
Idebenone (*Raxone*)	Duchenne muscular dystrophy in patients who are not using glucocorticoids
Eculizumab (*Soliris*)	Relapsing neuromyelitis optica [licence change]
Indacaterol + mometasone	Asthma
Lefamulin	Community-acquired pneumonia in adults
Netarsudil mesylate (*Rhokiinsa*)	Lowering elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension

Other EU developments

Abatacept (*Orencia*)	Primary Sjogren syndrome – development discontinued
Dabigatran (*Pradaxa*)	Secondary prevention of stroke in patients with embolic stroke of unknown source – development discontinued
Depatuxizumab mafodotin (*Depatux-M*)	EGFR-amplified glioblastoma multiforme, first-line – development discontinued
Edaravone (*Radicava*)	Amyotrophic lateral sclerosis – filing withdrawn
Glutamine (*Xyndari*)	Sickle cell anaemia – first negative opinion
Grass pollen vaccine (*Grazax*)	Asthma prevention in children with grass pollen induced allergy – development discontinued

New Medicines *Newsletter* is one of several horizon scanning resources produced by UK Medicines Information 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.

New Medicines *Newsletter*

New monographs (13)		*Phase in EU (US)*
AUTO-3	Relapsed or refractory B-cell acute lymphoblastic leukaemia in young adults and children	PII (PII)
AUTO-3	Relapsed or refractory diffuse large B-cell lymphoma	PII (PII)
Bimekizumab	Psoriatic arthritis	PII (PIII)
Cannabidiol (*Zygel*)	Fragile X syndrome in paediatric and adolescent patients	PII (PIII)
Centanafadine	Attention-deficit hyperactivity disorder in adults	None (PIII)
Diazepam (*Valtoco*)	Epilepsy – intermittent use for acute repetitive or cluster seizures	None (Filed)
Dupilumab (*Dupixent*)	Moderate-to-severe chronic obstructive pulmonary disease (COPD) with type 2 inflammation	PIII (PIII)
Ivosidenib (*Tibsovo*)	Cholangiocarcinoma in patients with an isocitrate dehydrogenase 1 mutation, whose disease has progressed after one or two systemic therapies	PIII (PIII)
Macitentan + tadalafil	Pulmonary arterial hypertension	PIII (None)
Secukinumab (*Cosentyx*)	Moderate-to-severe hidradenitis suppurativa (HS) in adults with an inadequate response to conventional systemic HS therapy	PIII (PIII)
Spesolimab	Ulcerative colitis in patients who have failed previously biologic therapy	PIII (PIII)
Ublituximab	Non-Hodgkin lymphoma – in combination with umbralisib	PIII (PIII)
VX-445 + ivacaftor + tezacaftor	Cystic fibrosis in patients aged 6 to 11 years who are heterozygous for F508del mutation and a minimal function mutation, or homozygous for F508del mutation	None (PIII)

Focus: Drugs in development for pneumonia		*Phase in EU (US)*
Amikacin	Inhaled, aerosolised liquid formulation of an aminoglycoside antibiotic	Discontinued
Ceftolozane + tazobactam (*Zerbaxa*)	IV combination of a novel cephalosporin with a beta-lactamase inhibitor	Filed (Approved)
Dalbavancin (*Xydalba*)	IV glycopeptide antibiotic	Discontinued
Delafloxacin (*Quofenix*)	Oral DNA gyrase inhibitor, DNA topoisomerase IV inhibitor and a protein 50S ribosomal subunit inhibitor	Filed (Launched)
Lefamulin	Oral pleuromutilin antibiotic, which interferes with bacterial protein synthesis via a specific interaction with the 23S rRNA of the 50S bacterial ribosome subunit	Filed (Filed)
Omadacycline (*Nuzyra*)	Oral first-in-class broad-spectrum aminomethylcycline antibiotic	Filed (Approved)
Solithromycin	Oral fourth-generation macrolide antibiotic	Discontinued
Tedizolid (*Sivextro*)	Oral second-generation oxazolidinone antibiotic that is a ribosomal protein inhibitor	PIII (PIII)

Focus: Drugs in development for tuberculosis		*Phase in EU (US)*
Bedaquiline (*Sirturo*)	Oral mycobacterial ATP synthase inhibitor – add-on therapy for multi-drug resistant tuberculosis in children and adolescents	Filed (None)
Pretomanid	Oral inhibitor of cell-wall synthesis and protein synthesis	Filed (Filed)

New Medicines *Newsletter* is one of several horizon scanning resources produced by UK Medicines Information 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.