




Highlights of updates to NDO in January 2012

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Regulatory changes in the EU		<i>in Prescribing Outlook 2011</i>
Launched in the UK		
Asenapine (<i>Sycrest</i>)	Bipolar disorder – treatment of acute manic or mixed episodes	
Trastuzumab (<i>Herceptin</i>)	Breast cancer, early HER2 positive – neoadjuvant therapy [licence extension]	
Approved in the EU		
Aminolevulinic acid (<i>Ameluz</i>)	Actinic keratosis	
Trepstinil sodium (<i>Tyvaso</i>)	Pulmonary hypertension – intravenous formulation	
EU positive opinions		
Alendronic acid (<i>Steovess</i>)	Osteoporosis – once weekly effervescent formulation	
Infliximab (<i>Remicade</i>)	Ulcerative colitis, paediatric [licence extension]	
Pasireotide (<i>Signifor</i>)	Cushing's disease – second-line	
Filed for approval in the EU		
Lisdexamfetamine dimesylate (<i>Venvanse</i>)	Attention-deficit hyperactivity disorder	
Other EU developments		
Chlormethine	Cutaneous T-cell lymphoma – granted orphan drug status	
Elinogrel	Acute coronary syndrome – development discontinued	
Latrepidine (<i>Dimebon</i>)	Alzheimer's disease – development discontinued	
Pralatrexate (<i>Folotylin</i>)	Peripheral T-cell lymphoma, relapsed or refractory – negative opinion	
New monographs added (18)		<i>Phase in EU</i>
ACH 1625	Hepatitis C, treatment naive	PII (None UK)
Brentuximab (<i>Adcetris</i>)	Cutaneous T-cell lymphoma	PII
Cabozantinib	Hepatocellular carcinoma	PII
Cangrelor	Coronary disorders, prevention of thrombosis in patients undergoing CABG	None (PII US)
Cholic acid	Inborn error of metabolism – primary bile acid synthesis	Unknown
Cysteamine bitartrate	Nephropathic cystinosis	PIII
Factor IX with recombinant albumin (rIX-FP)	Haemophilia B – prophylaxis and treatment of bleeding	PIII
Fingertegrast	Multiple sclerosis, relapsing-remitting	PII
IDX184	Hepatitis C	PII (None UK)
Iferanserlin	Haemorrhoids	None (PIII US)
Ipilimumab (<i>Yervoy</i>)	Malignant melanoma – first- or second-line, new dose regimen	PIII
Itolizumab	Psoriasis, moderate-to-severe chronic plaque	None
Natalizumab	Multiple sclerosis, secondary progressive	PIII
Ozenoxacin	Impetigo	PIII
Rituximab	Follicular lymphoma - biosimilar	PII (None UK)

To access New Drugs Online monographs click on the drug name/indication or visit www.ukmi.nhs.uk/ndo

Direct links to abbreviated NDO monographs via NHS Evidence are included if available at the time of publication
Complete monographs are password protected and can be viewed at www.ukmi.nhs.uk/ndo

In January 2012 | 214 monographs updated | 35 evidence-based evaluations added | 2,482 registered NDO users

New monographs added (continued)		Phase in EU
Tanzisertib	Pulmonary fibrosis, idiopathic	None (PII US)
Tivantinib	Hepatocellular carcinoma, previously-treated	PII (None UK)
Tofacitinib	Juvenile idiopathic arthritis	PIII (None UK)
Focus: Drugs in development for breast cancer		Phase in EU
Afatinib (Tomtovok)	Oral EGFR and HER2 kinase inhibitor	PIII
Axitinib (Inlyta)	Oral angiogenesis inhibitor	PII
Bavituximab	IV phosphatidylserine (PS)-targeting monoclonal antibody	PII
Bevacizumab (<i>Avastin</i>)	IV VEGF antagonist – second-line / adjuvant (HER2 positive and negative) / adjuvant (triple negative) [licence extension]	All PIII
Cancer vaccine E75 (NeuVax)	Intradermal immunotherapy consisting of the E75 peptide derived from HER2 combined with the adjuvant GM-CSF	None (PIII US)
Capecitabine (Xeloda)	Oral thymidylate synthase inhibitor [licence extension]	PIII
Doxorubicin heat sensitive liposomes (ThermoDox)	IV heat sensitive liposomal encapsulation of doxorubicin	PI (None UK)
Emepepimut-s (Stimuvax)	SC vaccine against cancer cells expressing MUC-1	Discontinued
Entinostat	Oral small molecule inhibitor of class I histone deacetylases	PII (None UK)
Eribulin (Halaven)	IV analogue of halichondrin B [licence extension]	PIII
Everolimus (<i>Afinitor</i>)	Oral angiogenesis inhibitor – HER2 negative / HER2 positive / neoadjuvant [licence extension]	All PIII
Fulvestrant (Faslodex)	IM oestrogen antagonist [licence extension]	PIII
Iniparib	IV poly (ADPribose) polymerase (PARP1) inhibitor	PIII (None UK)
Lapatinib (<i>Tyverb</i>)	Oral tyrosine kinase inhibitor – adjuvant / first-line with paclitaxel / neoadjuvant [licence extension]	PIII / Filed / PIII
Lonafarnib (Sarasar)	Oral farnesyl transferase inhibitor	PII (None UK)
Motesanib	Oral VEGF receptor 3 antagonist	PII
Neratinib	Oral irreversible dual inhibitor of HER2 and EGFR kinases	PIII
Pazopanib (Votrient)	Oral VEGF receptor inhibitor	PIII
PEG-irinotecan	IV topoisomerase I inhibitor-polymer conjugate	PIII
Pertuzumab	IV HER dimerisation inhibitor – first-line / neoadjuvant	PIII / PII
Pixantrone (Pixuvri)	IV topoisomerase II inhibitor [licence extension]	PII
Ramucirumab	IV VEGF receptor 2 antagonist	PIII
Ridaforolimus	Oral mTOR inhibitor [licence extension]	PII
Sorafenib (Nexavar)	Oral multikinase inhibitor [licence extension]	PIII
Trastuzumab (Herceptin)	SC anti-HER2 monoclonal antibody [new formulation]	PIII
Trastuzumab + hyaluronidase	SC anti-HER2 monoclonal antibody co-formulated with recombinant human hyaluronidase	PIII
Trastuzumab emtansine	IV antibody-drug conjugate (DM1 cancer-cell killing agent linked to trastuzumab) – first-line / second- and third-line	PIII / PIII
Vinflunine (Javlor)	IV vinca-alkaloid [licence extension]	PIII
Zoledronate (Zometa)	IV bisphosphonate [licence extension]	Filing withdrawn

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