New Drugs Online Newsletter

Highlights of updates to *NDO* in August 2012

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Regulatory changes in the EU		*in Prescribing Outlook 2011*
Launched in the UK		
Pazopanib (*Votrient*)	Soft tissue sarcoma, advanced – second-line [licence extension]	✓
Strontium ranelate (*Protelos*)	Osteoporosis, in men [licence extension]	
Approved in the EU		
Ceftaroline (*Zinforo*)	Complicated skin and soft tissue infections / Community-acquired pneumonia	✓
Ruxolitinib (*Jakavi*)	Myelofibrosis	✓
Filed for approval in the EU		
Dabrafenib	Malignant melanoma, advanced or metastatic BRAF^{V600}-positive	
Delamanid	Tuberculosis, multidrug-resistant	
Everolimus (*Votubia*)	Angiomyolipoma [licence extension]	
Imatinib (*Ruvise*)	Pulmonary arterial hypertension [licence extension]	✓
Infliximab biosimilar	Rheumatoid arthritis	
Other EU developments		
Bapineuzumab	Alzheimer's disease – development of IV formulation discontinued	
Cholic acid	Inborn error of metabolism, primary bile acid synthesis – not approved	
Ganitumab	Pancreatic cancer, metastatic – development discontinued	
Insulin glargine (*Lantus*)	Cardiovascular disease, prevention in patients with type 2 diabetes mellitus or impaired glucose tolerance – development discontinued	
Pomaglumetad methionil	Schizophrenia – development discontinued	
Telavancin (*Vibativ*)	Nosocomial pneumonia, including ventilator-associated, known or suspected to be caused by MRSA – licence suspended	✓

New monographs added (15)		*Phase in EU*
Aripiprazole	Schizophrenia – acute treatment, IM injection	PIII
Aztreonam lysine (*Cayston*)	Bronchiectasis	PIII
Belimumab	Vasculitis (Wegeners granulomatosis and microscopic polyangiitis)	PIII
Bevacizumab (*Avastin*)	Breast cancer, metastatic HER2-negative – first-line with a taxane	PIII
Everolimus (*Afinitor*)	Breast cancer, estrogen receptor-positive, HER2-negative – with adjuvant endocrine therapy	None (PIII US)
GS-7977	Hepatitis C, co-infected with HIV	PIII
Ixazomib	Systemic light chain amyloidosis , relapsed or refractory	PIII
Lanreotide (*Somatuline Autogel*)	Gastroenteropancreatic neuroendocrine tumours	PIII
Nivolumab	Non-small cell lung cancer, non-squamous – second-line	PIII
Onartuzumab	Gastric or gastroesophageal cancer	PIII
Patiromer	Hyperkalaemia	PII (None UK)
Pazopanib (*Votrient*)	Bladder cancer, relapsed or refractory	PII
Rivaroxaban (*Xarelto*)	Cardiovascular disease – prevention in patients undergoing cardioversion	PIII

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 August 2012 | 334 monographs updated | 36 evidence-based evaluations added | 2,793 registered NDO users

New monographs added (continued)		Phase in EU
Tofacitinib	Rheumatoid arthritis, moderate-to-severe, methotrexate-naive	PIII
Vemurafenib (*Zelboraf*)	Malignant melanoma, BRAF^{V600}-positive, resected, at high recurrence risk	PIII

Focus: Drugs in development for malignant melanoma		Phase in EU
Astuprotimut-R	IM antigen-specific cancer immunotherapeutic	PIII
Dabrafenib	Oral proto oncogene protein BRAF inhibitor	Filed
Dabrafenib + trametinib	Oral proto oncogene protein BRAF inhibitor plus MEK inhibitor	PIII
Elesclomol	IV apoptosis stimulant	Suspended
Ipilimumab (*Yervoy*)	IV human antibody against CTLA-4 (first-line adjuvant therapy / first-line with dacarbazine /new dose regimen)	All PIII
Masitinib	Oral tyrosine kinase inhibitor	PIII
Nilotinib (*Tasigna*)	Oral tyrosine kinase inhibitor	PIII
Paclitaxel albumin bound (*Abraxane*)	IV nanoparticle albumin-bound formulation of paclitaxel	PIII
POL 103A	Intradermal polyvalent melanoma vaccine using a combination of shed antigens produced by three proprietary melanoma cell lines	PIII
PV 10	Intralesional cell death stimulant and cell membrane modulator	None (PII US)
Sorafenib (*Nexavar*)	Oral Raf kinase and vascular endothelial growth factor receptor inhibitor	Suspended
Talimogene laherparepvec	Intratumoural oncolytic virus immunostimulant	PIII
Tasisulam	IV apoptosis stimulant	Discontinued
Trametinib	Oral MEK inhibitor	PIII
Velimogene (*Allovectin-7*)	Intratumoural gene-based immunotherapeutic	PIII
Vemurafenib (*Zelboraf*)	Oral BRAF inhibitor (resected melanoma, at high recurrence risk)	PIII

Focus: Drugs in development for pancreatic cancer		Phase in EU
AGS-1C4D4	IV fully human IgG1 antibody that targets the Prostate Stem Cell Antigen (PSCA) on the surface of tumour cells	PII (None UK)
Algenpantucel-L (*HyperAcute Pancreas*)	Intradermal immunostimulant vaccine	None (PIII US)
Bevacizumab (*Avastin*)	IV vascular endothelial growth factor antagonist	Discontinued
Ganitumab	IV human monoclonal antibody that binds to and inhibits insulin-like growth factor-1 receptor	Discontinued
Glufosfamide	IV glucose conjugate of ifosfamide	PII (None UK)
Irinotecan nanoliposomal	IV DNA topoisomerase I inhibitor	PIII
Masitinib	Oral tyrosine kinase inhibitor which targets c-kit, platelet-derived growth factor receptors and fibroblast growth factor receptor 3	PIII (None UK)
Nimotuzumab (*Theraloc*)	IV epidermal growth factor receptor-targeting monoclonal antibody	PIII (None UK)
Paclitaxel albumin bound (*Abraxane*)	IV nanoparticle albumin-bound formulation of paclitaxel	PIII
Tertomotide	Intradermal anti-telomerase therapeutic cancer vaccine	None (PIII UK)
TH-302	IV hypoxia-targeted drug	PII
Virulizin (*Virulizin*)	IM biological response modifier that induces IL-17E expression	None (PIII US)

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