



# R&D FOCUS drugnews PART OF IMS LIFECYCLE

Volume 17 No 22

26 May 2008

## desvenlafaxine

**Wyeth marketed, USA (depression)**

On 15 May 2008 Wyeth announced that it has launched desvenlafaxine (PRISTIQ) in the USA for the treatment of major depressive disorder (MDD) in adults. The US FDA approved desvenlafaxine for this indication in March 2008 at a once-daily 50 mg dose. This approval was subject to post-marketing commitments to conduct and submit data for a long-term maintenance study, a sexual dysfunction study, pediatric studies, a study investigating low doses of the agent and a non-clinical toxicity study.

Wyeth is developing desvenlafaxine, a 5HT and noradrenaline reuptake inhibitor, for the treatment of depression and as a non-hormonal treatment for vasomotor symptoms associated with the menopause.

### Launches

#### REQUIP XL

**GlaxoSmithKline marketed, UK (once-daily extended-release formulation, Parkinson's disease)**

On 15 May 2008 GlaxoSmithKline reported that it has launched REQUIP XL, a once-daily controlled-released

oral tablet formulation of ropinirole, in the UK for the treatment of Parkinson's disease. In clinical trials REQUIP XL showed efficacy in the treatment of Parkinson's disease and was generally well tolerated in both early and advanced patients. REQUIP XL has been approved for the treatment of Parkinson's disease in the EU and USA.

GlaxoSmithKline is developing ropinirole, a specific dopamine D<sub>2</sub> receptor agonist, for the treatment of Parkinson's disease and restless leg

#### LAUNCHES

CIRCADIN Marketed in Germany

#### APPROVALS

PREPANDRIX Approved in the EU

YONDELIS Approved in South Korea

SUBLINOX Submitted for Approval in the USA

#### LICENSING

Agreements between Bristol-Myers Squibb & KAI Pharmaceuticals, Mymetics & Pevion, Medivir & Tibotec-Virco

#### TECHNOLOGY TRANSFER SPOTLIGHT

National Institutes of Health Stanford University

#### PIPELINE

DIREVO

#### PRODUCTS & BIOTECHNOLOGY

SGX 523 & TOLAMBA Discontinued  
CA9 SCAN Enters PIII  
P 1736 & CCX 354 Enter PI  
Clinical Data for XIENCE V, SPL 7013 and Everolimus

#### CONFERENCE

AACR 2008

#### COMPANY FOCUS

ViroStatics

#### TABLES

Newly reported drugs

Product phase changes

David Young  
President & CEO  
ARIUS Research Inc  
55 York Street  
15th Floor  
Toronto  
ON M5J 1R7  
Canada

Tel: +1 416 862 2323 ext. 222  
Fax: +1 416 862 9696  
Email: dyoung@ariusmabs.com

## AR 40A74623

### ARIUS Research partnering opportunity, Worldwide

#### ARIUS Research preclinical data

At the American Association for Cancer Research Annual Meeting 2008, 12-16 April 2008, San Diego, USA, ARIUS Research presented preclinical data for AR 40A74623, a monoclonal antibody directed against CD9. The antibody induced apoptosis in BxPC-3 pancreatic cancer cells through inhibition of the AKT pathway. AR 40A74623 demonstrated antitumor efficacy in xenograft mouse models of pancreatic, breast and acute myeloid leukemia (AML); the antibody caused a decrease in phosphorylation of several receptor tyrosine kinases. AR 40A74623 reduced the self-renewal capacity of AML cancer stem cells in secondary transplantation experiments. This program is available for partnering.

For further information on the partnering opportunities available, contact:

David Young  
President & CEO  
ARIUS Research Inc  
55 York Street  
15th Floor  
Toronto  
ON M5J 1R7  
Canada

Tel: +1 416 862 2323 ext. 222  
Fax: +1 416 862 9696  
Email: dyoung@ariusmabs.com

## Company Focus

### Focus on ViroStatics

ViroStatics is an Italian biopharmaceutical company created in June 2005 and located in Sassari. The company also has offices in Princeton, New Jersey (USA). ViroStatics is dedicated to the development of immunotherapeutic agents and virostatic drug combinations for the treatment of HIV/AIDS, viral infections and other global diseases. The company has developed a series of proprietary screening methodologies designed to select antiproliferative cytostatic agents for the treatment of HIV and AIDS. ViroStatics has currently one lead compound in a phase II trial for the treatment of HIV and is seeking to in-license additional agents for the treatment of HIV/AIDS.

### didanosine + hydroxyurea

#### ViroStatics phase change IIa, Russia, Argentina, Italy, Uganda (HIV infection)

On 12 May 2008 ViroStatics announced the initiation of a phase IIa trial (VS411-C201) of VS 411, a fixed combination of didanosine and hydroxyurea for the treatment of HIV infection. The five-arm, dose-ranging, proof-of-principle trial has been initiated in Russia, Argentina, Italy and Uganda in 60 patients with HIV infection. Dosing of the first subject has been initiated in Italy. The randomized, double-blind, dose-finding study will investigate hydroxyurea doses between 300 and 900 mg/day in combination with 200 mg or 400 mg of enterically-coated didanosine administered over a four-week period. Efficacy, pharmacokinetic parameters, safety and tolerability will be assessed. Intense intracellular pharmacokinetics will be performed to investigate interaction between low dose hydroxyurea and the conversion of didanosine to its active form, dideoxyadenosine triphosphate, within CD4 T-cells, and novel immunological tests will assess the conservation of immune system cells with high proliferative capacity.

VS 411 aims to target HIV replication and modulate the hyper-proliferation of CD4 T-cells. The drug combination has been designed to yield low peak plasma concentrations of didanosine with improved dosing flexibility to investigate low doses of hydroxyurea in order to reduce toxicity and enhance efficacy. A phase I trial has completed in Spain

<b>NEWLY REPORTED DRUGS IN R&amp;D FOCUS</b>				
<b>Company</b>	<b>Product</b>	<b>Therapeutic Class</b>	<b>Indication</b>	<b>Phase</b>
Upstream Biosciences	malaria therapeutics, Upstream Biosciences	P1D	malaria	Discovery
ViroStatics	didanosine + hydroxyurea	J5C1	HIV infection	Phase II
Wilex	CA9 SCAN	T1G	diagnosis	Phase III

PRODUCT PHASE CHANGES REPORTED IN R&D FOCUS						
Company	Product	Therapeutic Class*	Indication	New Phase	Region of Phase Change	Highest Phase
ChemoCentryx	CCX 354	L4A	inflammation	Phase I	USA	Phase I
Critical Biologics	rhu-pGSN, Critical Biologics	V3X	all other therapeutics	Phase II	Hong Kong	Phase II
Crucell	MAb, rabies virus, Crucell	J5B	rabies	Phase II	Philippines	Phase II
GlaxoSmithKline	PREPANDRIX	J7A1	influenza	Registered	EU	Registered
ImClone Systems	IMC A12	L1X3	hepatocellular carcinoma	Phase II	USA	Phase II
Lundbeck	CIRCADIN	H4V	insomnia	Marketed	Germany	Marketed
Orexo	OX 22	N5B; V7A	insomnia	Pre-registration	USA	Pre-registration
PharmaMar	trabectedin	L1A	soft tissue sarcoma	Registered	South Korea	Marketed
Piramal Life Sciences	P 1736	A10B9	diabetes	Phase I	Netherlands	Phase I
Sunesis	SNS 595	L1X9	AML	Phase II	USA	Phase II
Trophos	TRO 19622	A5B	liver disease	Phase II	France	Phase II
ViroStatics	didanosine + hydroxyurea	J5C1	HIV infection	Phase II	Russia; Argentina; Italy; Uganda	Phase II
Wilex	CA9 SCAN	T1G	diagnosis	Phase III	USA	Phase III
Wyeth	desvenlafaxine	N6A5	depression	Marketed	USA	Marketed
* A change in phase may not apply to all therapeutic classes and indications						