



R&D FOCUS drugnews

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ivacaftor

**Vertex submitted for approval, USA
(cystic fibrosis)**

On 19 October 2011 Vertex announced that it has submitted an NDA to the US FDA for the approval of ivacaftor, under the trade name KALYDECO, as a treatment for cystic fibrosis. The application is based on results from two phase III trials of the agent (STRIVE and ENVISION) conducted in patients with cystic fibrosis who had at least one copy of the G551D mutation. The US filing includes a request for Priority Review.

Ivacaftor potentiates the function of the cystic fibrosis transmembrane conductance regulator (CFTR) protein, a cell membrane ion channel which is defective in cystic fibrosis. Vertex plans to file an MAA with the EMA by end October 2011; the agency has accepted Vertex's request for accelerated assessment.

Launches

belimumab

**Human Genome Sciences
marketed, Canada, Europe
(systemic lupus erythematosus)**

Belimumab (BENLYSTA) has been launched for the treatment of systemic lupus erythematosus (SLE) in Canada and a number of European countries, including Germany, Austria, Denmark,

Finland, Hungary, Sweden and Norway. Human Genome Sciences announced on 25 October 2011. A launch in Spain is planned by end 2011.

Human Genome Sciences and GlaxoSmithKline are developing belimumab, an anti-B-lymphocyte stimulator fully human monoclonal antibody (anti-BlyS MAb) for the treatment of SLE. The product was first launched in the USA in March 2011, and was approved in the EU for this indication in July 2011. The

LAUNCHES

APPROVALS

LICENSING

TECHNOLOGY

TRANSFER SPOTLIGHT

Opportunities with KUTLO-NITT

PRODUCTS & BIOTECHNOLOGY

CONFERENCES

AusBiotech 2011, 16-19
October 2011, Adelaide,
Australia

Offers from the Baker IDI
Heart & Diabetes Institute

Opportunities with Dimerix

Updates from Biosceptre

19th Annual BioPartnering
Europe, 9-11 October 2011,
London, UK

Opportunities with Addex

Offers from Cempra

News from Chelsea

Opportunities with MorphoSys

News from Pharnext

Opportunities with Resverlogix

Offers from Senexis

Opportunities with Transgene

The 51st Interscience
Conference on Antimicrobial
Agents and Chemotherapy
(ICAAC), 17-20 September
2011, Chicago, USA

COMPANY FOCUS

Focus on Delpor

NEWLY REPORTED DRUGS IN R&D FOCUS

PRODUCT PHASE CHANGES REPORTED IN R&D FOCUS

autoimmune diseases (such as rheumatoid arthritis). A series of compounds is under evaluation; lead optimization is ongoing. An IND filing for a lead compound in the NexVas AI program is expected in 2012, with phase I anticipated to start in early 2013. At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Kenneth Lebioda, Senior VP of Business and Corporate Development at Resverlogix, informed R&D Focus that the NexVas AI program is available for partnering.

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NexVas VI

Resverlogix partnering opportunity, Worldwide

Resverlogix has a program, designated NexVas VI (vascular inflammation), to develop small molecules that regulate pro-inflammatory mediators, for the treatment of systemic vascular inflammation. This program is at the discovery stage of development; however, it is currently on hold to focus on other pipeline priorities. At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Kenneth Lebioda, Senior VP of Business and Corporate Development at Resverlogix, informed R&D Focus that the NexVas VI program is available for partnering.

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Offers from Senexis

amylin aggregation inhibitors, Senexis

Senexis partnering opportunity, Worldwide

Senexis is conducting a program to develop small molecule amylin aggregation inhibitors for the treatment of type II diabetes. Discovery stage research is ongoing. This program is a lower priority for the company compared to its Alzheimer's disease programs. The amylin aggregation inhibitor program is available for partnering (collaboration), Mark Treherne, Chief Executive of Senexis, informed R&D Focus at the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK.

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SEN 1176

Senexis partnering opportunity, Worldwide

Senexis is developing SEN 1176, a small molecule for the oral treatment of Alzheimer's disease. The agent suppresses beta-amyloid1-42-induced macrophage production of nitric oxide, TNF-alpha, IL-1 beta and IL-6. SEN 1176 is expected to be useful in the later stages of Alzheimer's disease to protect from chronic neuroinflammation damage as a result of brain amyloid-beta deposition. SEN 1176 showed favorable oral bioavailability and efficacy in an in vivo model of learning and memory. The agent also has potential in the treatment of inclusion body myositis. Preclinical studies are ongoing. At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Mark Treherne, Chief Executive of Senexis, informed R&D Focus that this program is available for partnering.

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SEN 1276

Senexis partnering opportunity, Worldwide

At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Mark Treherne, Chief Executive of Senexis, informed R&D Focus that SEN 1276 is available for partnering. The agent, a small molecule from the company's SEN 1100 series, is being developed for the oral treatment of Alzheimer's disease. The agent suppresses amyloid-beta 1-42-induced macrophage production of nitric oxide, TNF-alpha, IL-1 beta and IL-6. SEN 1276 is expected to be useful in the later stages of Alzheimer's disease to protect from chronic neuroinflammation damage as

a result of brain amyloid-beta deposition. The agent may also have potential in the treatment of inclusion body myositis. Preclinical studies are ongoing; an application to start clinical trials is expected to be submitted in 2013.

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SEN 1500

Senexis partnering opportunity, Worldwide

At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Mark Treherne, Chief Executive of Senexis, informed R&D Focus that SEN 1500 is available for partnering. The agent, a small molecule amyloid aggregation inhibitor from the company's SEN 1500 series, is being developed for the oral treatment of Alzheimer's disease and inclusion body myositis. The agent is expected to be useful in the early stages of Alzheimer's disease to protect nerve cells and treat mild cognitive impairment. Preclinical studies are ongoing.

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SEN 1576

Senexis partnering opportunity, Worldwide

Senexis is developing SEN 1576, a small molecule amyloid-beta aggregation inhibitor from the company's SEN 1500 series, for the oral treatment of Alzheimer's disease. SEN 1576 is a backup compound to SEN 1500. The agent is expected to be useful in the early stages of Alzheimer's disease to protect nerve cells and treat mild cognitive impairment. SEN 1576 also has potential in the treatment of inclusion body myositis. Preclinical studies are ongoing. At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Mark Treherne, Chief Executive of Senexis, informed R&D Focus that SEN 1576 is available for partnering.

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Opportunities with Transgene

TG 3003

Transgene licensing offer, Worldwide

At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Stephane Boissel, Executive VP and CFO at Transgene, informed R&D Focus that TG 3003, a humanized monoclonal antibody directed against colony stimulating factor 1 receptor (CSF1R;CD115), is available for licensing. The antibody is designed to have a cytotoxic effect on CSF1R-positive cells either directly or indirectly through CSF1R-positive tumor infiltrated activated macrophages (TAMs). Late preclinical studies are ongoing; phase I evaluation is expected to start in 2012 or 2013.

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TG 4023

Transgene partnering opportunity, Worldwide

Transgene is developing TG 4023 (MVA-FCU1), a virus-directed enzyme prodrug, for the treatment of patients with primary or secondary hepatic tumors mainly related to metastatic colorectal cancer or hepatocellular carcinoma. TG 4023 comprises a highly attenuated MVA vaccinia virus vector expressing a suicide gene, FCU1, which is a fusion of the yeast genes coding for cytosine deaminase and uracil phosphoribosyltransferase. The chimeric enzyme FCU1 transforms the non-toxic prodrug 5-fluorocytosine (5-FC) into 5-fluorouracil (5-FU). The company anticipates that intratumoral administration of the suicide gene followed by oral 5-FC therapy would result in the local production of 5-FU to kill cancer cells. TG 4023 is under phase I evaluation in patients with liver tumors. At the 19th Annual BioPartnering Europe, 9-11 October 2011, London, UK, Stephane Boissel, Executive VP and CFO at Transgene, informed R&D Focus that this program is available for partnering.

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