



FDA AND EUROPEAN COMMISSION GRANT NOSCIRA (GRUPO ZELTIA) ORPHAN DRUG STATUS FOR NYPTA[®] TO TREAT A TYPE OF DEMENTIA

- **Health authorities in both the European Union and the US have granted Noscira, a Grupo Zeltia subsidiary, orphan drug status for Nypta[®] (NP-12) to treat Progressive Supranuclear Palsy (PSP), a type of dementia.**
- **Nypta[®] is one of the compounds with the greatest potential for treating neurodegenerative disorders due to the way it modifies disease progression. It is also undergoing Phase II clinical trials on Alzheimer's disease.**

Madrid, 3 November, 2009: The European Commission and the US Food and Drug Administration (FDA) have granted Noscira, a biotechnology subsidiary of Grupo Zeltia (ZEL.MC), orphan drug status for Nypta[®] (NP-12) for treating Progressive Supranuclear Palsy (PSP), a neurodegenerative disease.

Orphan drug designation is awarded to drugs that offer potential therapeutic value in the treatment of **rare diseases and conditions**.

In Europe, this designation affords the drug developer certain advantages, such as fee exemption in requests for scientific advice, marketing authorisation and other procedures. Designation also provides developers with access to specific scientific advice from European Medicines Agency (EMA) experts in orphan diseases. The authorisation to market orphan drugs follows the centralised process. In the event that an orphan drug obtains marketing authorisation, it is granted market exclusivity for 10 years in the European Union for the designated therapeutic indication. Various member states offer tax benefits, systems to facilitate accelerated entry into the market, automatic reimbursement by the government, and favourable conditions when establishing the drug's price.

In the US, orphan drugs benefit directly from the advantages contained in the Orphan Drug Act, including: regulatory advice and incentives to develop and approve the orphan drug, plus seven years of market exclusivity if marketing authorisation is obtained; exemption from registration fees; tax credits for clinical development costs, and aid for research into treatment of the rare disease.

Nypta[®] inhibits the GSK-3 enzyme; this is an innovative approach for treating neurodegenerative diseases such as Alzheimer's and PSP. Nypta[®] is the only GSK-3 inhibitor under clinical development and the only compound capable of acting on all of the histopathological lesions associated with the disease.

From 2006 to 2008, Nypta[®] was administered to more than 150 healthy volunteers, both young and old, in three double-blind Phase I trials. The first Phase II trial for



Alzheimer's was approved in the last quarter of 2008; 30 patients have already been treated, and the results are being processed.

Noscira expects the first Phase II clinical trial in PSP to begin in 2009.

For more information

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This press release is also available in the pressroom section on www.noscira.com

Zeltia

Zeltia, S.A. is a pioneering biotechnology company ranked first in Spain. The Zeltia Group comprises the following companies: PharmaMar, a world-leading biotechnology firm focused on advancing cancer therapy by discovering and developing innovative drugs of marine origin; Noscira, a biotechnology company focused on discovering and developing new drugs against Alzheimer's disease and other neurodegenerative diseases; Genómica, Spain's leading molecular diagnostics company; Sylentis, established recently to research therapeutic applications of gene silencing (RNAi); and Zelnova and Xylazel, two long-standing, highly-profitable chemical companies that are leaders in their respective markets.

Noscira

Noscira, which is headquartered in Madrid (Spain), is a biopharmaceutical company which researches and develops innovative drugs for treating and preventing diseases of the nervous system. Since its inception, the company has specialised in Alzheimer's disease. Noscira's search strategy combines a unique, highly-specialised primary screening platform for marine samples and a strong focus on chemical optimisation.

The company has two clinical compounds (NP-12 and NP-61) which are well-positioned in the pipeline for treating Alzheimer's disease. It also has a solid pipeline of products in the pre-clinical phases.

Noscira is a subsidiary of Grupo Zeltia (Madrid stock exchange: ZEL.MC; Bloomberg: ZEL SM; Reuters: ZEL.MC), Spain's leading biotechnology and chemical company.

For more information, visit www.noscira.com



Nypta[®] (NP-12)

Overexpression of GSK-3 leads to hyperphosphorylation of the tau protein, an anomaly which occurs in a number of neurodegenerative diseases known collectively as tauopathies, which include Alzheimer's disease, PSP, Pick disease, etc.

NP-12 is a GSK-3 inhibitor with oral bioavailability and great therapeutic potential as a disease-modifying treatment for Alzheimer's. NP-12 is currently undergoing Phase II clinical trials for Alzheimer's disease in the EU.

NP-12 is the only GSK-3 inhibitor under clinical development and the only compound capable of acting on all of the histopathological lesions associated with the disease: it reduces phosphorylation of the tau protein and hippocampal and entorhinal cortex neuron loss, improves spatial deficits and significantly reduces the accumulation of amyloid plaques in the brain. NP-12 also provides neuroprotection in vivo and has a potent anti-inflammatory effect in a range of animal models.

Progressive Supranuclear Palsy

PSP is a neurodegenerative disease characterised by oculomotor disturbances, specifically difficulties in moving the eye vertically, falling down and Parkinsonian symptoms. The disease affects an estimated 5-6.4 out of every 100,000 people.

There is currently no treatment capable of delaying or altering the progression of the illness.

Rare disease

A rare disease is one that arises infrequently in the population. To be classified as rare, the disease must affect less than a specific threshold of total population, defined in Europe as less than 1 per 2,000 people (EC Regulation on Orphan Medicinal Products).