ZELTIA NEWS

Sylentis participates in the 7th Spanish Conference on Glaucoma (SEG)

- ***Sylentis presented the results of its Phase I clinical trialwith SYL040012 for treating ocular hypertension associated with glaucoma.***
- ***The presentation, entitled "Phase I Trial with SYL040012: New RNAi-based treatment for glaucoma" was given by Dr Ana I. Jiménez in Session III—Medical Therapies, on 9 March.***
- ***The trial evidenced excellent ocular and systemic tolerance of the first glaucoma drug based on gene silencing (interference RNA, RNAi) that is administered topically.***
- ***Sylentis is one of only five companies in the world with RNAi-based products undergoing clinical trials.***

Madrid, 9 March 2011: Sylentis (MC:ZEL) presented the main results of its Phase I trial on safety and tolerance of its product SYL040012; the compound proved to be safe in the trial conditions. These results were presented in an oral communication entitled "Phase I Trial with SYL040012: New RNAi-based treatment for glaucoma" at the 7thConference on Glaucoma, organised by the Spanish Society for Glaucoma in Alicante from 8 to 10 March, 2012.

The presentation was given by Dr Ana I. Jiménez in Session III—Medical Therapies, on 9 March.

The trial, performed at the Navarra University Clinic, sought to establish the tolerance and effect of SYL040012 on intraocular pressure.

This is the first time in Spain that an RNAi-based product is undergoing a clinical trial in humans.

In this trial, 30 healthy volunteers were treated in two phases: acute treatment (single dose) and, subsequently, continuous treatment for 7 days, during which time two dosage patterns of SYL040012 were evaluated.

Phase I clinical trials primarily seek to determine a drug's safety. In view of the results of the Phase I trial, Sylentis is continuing with Phases IB and II in expectation of further progress with the compound's clinical development.

About SYL040012

In preclinical trials with SYL040012, the siRNAs administered topically to treat ocular hypertension associated with open angle glaucoma have proven effective in vivo. These trials concluded that the model of transient hypertension induced by fluid overload is a good model for evaluating the effectiveness of drugs against glaucoma, since it does not produce alterations in the various ocular structures. Additionally, in these trials it was observed that pre-treatment with SYL040012 prevents the induced increase in intraocular pressure in this ocular hypertension model. The prophylactic effect of this compound is greater than described previously in this model for the drugs currently used for treating glaucoma, such as Timolol and Xalatan.

About Sylentis

Founded in 2006 as a spin-off from Grupo Zeltia subsidiary Genómica, S.A.U., Sylentis is a subsidiary of Grupo Zeltia and a key player in the search for new therapies based on interference RNA (RNAi).Its strategy focuses on the efficient design of siRNAs using proprietary technology: SIRFINDER®, which finds small fragments of RNAi (short interfering RNAs, siRNAs) with pharmaceutical potential by searching the appropriate sequences using bioinformatics; once the disease's target gene has been identified, SYLENTIS develops a quick and economical solution for siRNAs to silence that gene.

About interference RNA (RNAi)

Interference RNA (RNAi) has arisen in recent years as a promising technology with therapeutic applications. Discovered in plants in the 1990s, RNAi consists of highly efficient selective and specific inhibition of gene expression (Fire et al., 1998). Interference RNA is mediated by small RNAi, consisting of 19-23 nucleotides, which promote degradation of mRNA, thus inhibiting synthesis of the proteins for which they code. As this mechanism is used naturally by cells to regulate gene expression in a way that is both non-toxic and highly effective, RNAi has great therapeutic potential.

About open-angle glaucoma

Primary open-angle glaucoma (POAG) is the most prevalent form of glaucoma, accounting for approximately two-thirds of all diagnosed cases of glaucoma. It is defined as a multifactorial optic neuropathy consisting of a loss of retinal ganglion cells and characteristic atrophy of the optical nerve leading to progressive, irreversible blindness. The risk factors of POAG include high intraocular pressure (IOP), a family history of the disease, and old age (Marquis and Wilson, 2005). Although the physiopathological mechanisms by which higher pressure leads to neuron damage are not known, most current therapies include medicine or surgery to reduce IOP to a level that safely halts progressive loss of vision.

About eye pain associated with dry eye syndrome

Eye pain can be described as a burning, throbbing or stabbing sensation in the eye or around it, or the feeling that there is a foreign body in the eye. Chronic eye pain is generally associated with eye pathologies such as dry eye syndrome. Easing this symptom is essential for improving patients' quality of life. There are currently no drugs approved specifically for reducing chronic eye pain.

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(*) This note is also available on the Sylentis website: www.sylentis.com and on the Zeltia website: www.zeltia.com