

## BIOPHARM INSIGHT FEBRUARY 2013

Gene Signal to start two Phase II ophthalmology trials by 4Q13, lowers partner priority – CEO

### BioPharm Insight

- Works with CMOs Girindus, Amatsi for angiogenesis candidates

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**Gene Signal**, a private Swiss biotech company, will start a Phase II neovascular glaucoma (NVG) trial before summer-2013, and a large age-related macular degeneration (AMD) Phase II study in 4Q13, said CEO Eric Viaud. The firm has lowered its partnership priority after completing its latest capital raise which will fund three years of clinical development, he noted.

The company announced last week it had completed a private financing round with undisclosed private investors. This undisclosed amount will allow the company to aggressively develop a number of Phase II programs for its lead drug in Aganirsen (GS-101) in several back-of-the-eye angiogenesis-related diseases until 2015.

Gene signal will start the orphan indicated NVG trial in more than 300 patients across 30-35 European sites before summer 2013, said Viaud. The company is already starting first discussions with the European Medicines Authority (EMA) for provisional marketing authorisation if the results are positive. The study is expected to last around two to three years and more details will be formally announced next quarter.

The non-orphan AMD study will be significantly larger than the NVG program. The patient size of this trial is still being finalised and will be established before the summer, he said. Gene Signal will also start a diabetic retinopathy Phase II trial which will follow the initiation of the AMD study and is yet to be announced, he said.

CROs will be contracted and the company has already shortlisted around two to three candidates. These are all new candidates and the successful CRO will be selected in the next few weeks, said Viaud.

The company uses US-based contract manufacturing organisation (CMO) **Girindus** to produce the powder of Aganirsen. The drug is then finished by French manufacturer **Amatsi**, which is responsible for mixing the dry powder and saline solution and conditioning of the final product, said Viaud. Gene Signal plans to use these CMO partners through its development period and is not looking for additional providers, he said.

Gene signal's lead orphan indication neovascular-associated corneal graft rejection (NV-CGR) will have Phase III results announced by mid-2013, he said.

The company will work towards putting its marketing authorisation application with the EMA, said Viaud. The company will commercialise the drug itself due to the small size of the population. Should the drug get approved (end 2014 at the earliest), Gene Signal may hire a contract sales force; however, it is now focussing on the results and approval package, said Viaud.

Gene Signal is ready to reach 150 physicians in Europe and already has a direct key opinion network through its compassionate-use program, said Viaud. For the NV-CGR indication, targeted sales countries would be Germany, UK, France, Spain, Italy, Portugal and some eastern European countries, he said.

Gene Signal is developing a pipeline of novel antisense oligonucleotides, proteins and monoclonal antibodies to treat a range of angiogenesis-based diseases (diseases affecting the growth of new capillary blood vessels), according to the company website.

In May last year, Gene Signal told this news service it could partner or be acquired by late 2012. Since then the company has re-prioritised and decided it would like to hold more control over the destiny of its clinical programs, said a company spokesperson. Raising funds at this stage gives the company more flexibility on its partnering needs, he said.

The company is not actively looking for partners at this stage, but expects expressions of interest and partner discussions to take place as its clinical pipeline unfolds over the next three years, said Viaud. Sale and IPO options are still kept open during this period, he added. Gene Signal has not hired an investment bank for sale advice, although it does work with UBS as its commercial bank, Viaud.

Gene Signal works with PwC as its auditor, Cabinet ICOSA as its patent lawyer, and Cabinet BMP as its commercial law firm.

by Surani Fernando in London