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# Santhera holds talks with potential Eastern European distribution partners for Raxone in LHON – CEO

Reimbursement discussions ongoing in multiple countries

DMD regulatory filings expected before YE15

Santhera Pharmaceuticals (SWX:SANN) is in ongoing discussions with potential distributors in Eastern Europe for Raxone (idebenone) in Leber's hereditary optic neuropathy (LHON), said CEO Thomas Meier. There is a reasonable chance the company will have selected a partner by the end of this year, he said.

The company received EMA marketing authorisation for Raxone in LHON on 9 September, according to a company press release.

The company has built an infrastructure for Western European countries; however, in Eastern European territories it needs logistical help, Meier said.

In terms of deal structure it is likely Santhera would pay a fee to the distribution partner and it may receive a percentage of the sales within those territories, Meier said, adding the exact arrangement is still under evaluation. However, Santhera will retain the license for Raxone in these regions, he noted. The company's preferred scenario is to find one partner for the entire bloc of Eastern European countries rather than multiple partners for several territories, he explained.

Santhera is hiring a team of in-house experts to help commercialise Raxone within Western European territories and is hoping to launch the product in an undisclosed European country shortly, Meier said. Payer discussions are ongoing in multiple countries, he added. When asked about potential pricing, Meier declined to provide a figure however pointed to a recent analyst report which may provide an estimate. The analyst report noted an estimated net price of USD 7,373 per treatment month in 2016 and USD 7,005 for 2017 and beyond.

LHON is a heritable genetic disease causing blindness. The disease typically presents in young, otherwise healthy adults, mostly men, as rapid, painless loss of central vision in one eye, followed by visual loss in the other eye within a few months of the onset of symptoms, leading to blindness, according to a company press release.

The company will file for FDA approval for Raxone in LHON at a later date.

Additional indications

The company's cash position at the end of August was CHF 37m, which will cover the full European launch of Raxone, Meier said. Additional financing may be required to continue development of Raxone in other indications, he noted, declining to comment on further financing details.

The company may consider similar LHON distribution agreements for Duchenne Muscular Dystrophy (DMD) in specific territories necessary, he said.

Santhera is preparing regulatory filings for Raxone in the EU and the US for DMD before the year's end, Meier noted. On the back of the EMA approval in LHON, the company believes it may be able to apply for a line extension for Raxone in DMD which is under discussion internally. The company will initiate discussions with the Committee for Medicinal Products for Human Use (CHMP) shortly. According to the aforementioned analyst report, the LHON approval may allow for a six-month review of Raxone in DMD within Europe. The company anticipates filing its NDA to the FDA as well.

Meier declined to comment on any speculation with regards to a sale of the company and noted the management's current preference is to stand alone and build value through obtaining additional approvals and pipeline development. Santhera is also considering additional indications for Raxone and is in discussions internally and with key opinion leaders as it believes that the drug may be beneficial for additional mitochondrial diseases, Meier said. However, he declined to name any specific indications under consideration. Within the next 12 months the company will have a clearly defined strategy for other indications, he added.

The company will not out-license Raxone in either LHON or DMD and will market alone in both the US and EU, Meier said. However, Santhera has set aside certain capital resources for in-licensing activities.

Raxone was the first approval for a mitochondrial disease and the company will consider licensing additional molecules for mitochondrial disease, neuromuscular diseases or paediatric diseases, he noted. The company could take part in co-development arrangements or license from a US company looking for a European partner.

Santhera also has a fully recruited Phase II trial ongoing in primary progressive multiple sclerosis, he added.

Santhera's market cap is CHF 697m.

by Hamish McDougall in London

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**Company**

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**Drug(s)**

*Catena

**Topic**

Partnerships/Licensing

**Country**

Switzerland

**Mechanism(s)**

Oxidative Stress Suppressor

**Intelligence Grade**

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Email Analyst

*Email the journalist team at editorialfeedback@biopharminsight.com*