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Proprietary Intelligence

Inspyr to decide on Phase III CRO for HCC in December, Phase II CRO for GBM in November – CEO

Phase III HCC to enrol 300-400 subjects in Asia

Two glioblastoma trials to enrol 75-100 subjects

Five to six companies in HCC partnership talks

Inspyr Therapeutics (OTCQB:NSPX) is likely to start looking for a CRO for its Phase III trial investigating oncology drug mipsagargin (G-202) for hepatocellular carcinoma (HCC) in October, with a final decision in December, CEO Chris Lowe said.

The San Antonio, Texas-based company is also likely to name a second CRO for two Phase II trials investigating mipsagargin for glioblastoma (GBM) in November, Lowe added. Inspyr is open to CRO pitches for the three trials, he said.

Inspyr will likely begin the Phase III HCC trial in mid-2017, Lowe said. The trial could enrol 300-400 subjects in China but could also expand to Singapore, Taiwan and Japan, he added.

For the Phase III, the CRO should have experience running HCC trials, with Asia expertise and existing relationships with local key opinion leaders, Lowe added. Asia is a focus for Phase III as the region has the largest HCC market in the world, with about 80-85% of the HCC commercial drug market, he said. China is an ideal country to run trials in as it has appropriate infrastructure, he added.

Whilst HCC is managed in hospitals, patients in Asia usually first present themselves in primary care so the CRO should have relationships there to be able to find subjects, he noted.

The Phase III trial is likely to be a randomised, double blind, placebo-controlled trial with the primary endpoint improving patient survival, with a potential completion date of mid-2019, Lowe said. The trial would be designed to allow interim analysis, which could then indicate if there's an opportunity for accelerated approval, he added, but did not comment on which territory.

A wide range of secondary endpoints would be used, investigating quality of life, biomarkers, overall safety, among others, he added. It is hoped Inspyr would file for approval by YE19, he added.

The cost of the trial is yet to be determined, Lowe said. The trial is likely to be funded with a yet-to-be named HCC partner, potentially via non-dilutive funds, he noted.

Inspyr is looking to finalise partnering/licensing decisions in the next month or two, but is still open to pitches, Lowe said. The company has already started due diligence and exchanged term sheets with potential development/commercialisation partners in the past month or two, he added. The company reached out to 10-12 companies - mostly large multinationals - with a presence in Asia, with about 5-6 companies going in to talks with Inspyr and having access to mipsagargin data, Lowe said.

Phase II glioblastoma CRO to help with trail design

The GBM trials are likely to have 75-100 subjects each and will begin enrolling in April or May next year, said Lowe. The successful CRO for the two Phase II glioblastoma trials would help hone the design of the protocols, Lowe added.

The first Phase II trial is an expansion of an ongoing 34-subject Phase II trial (NCT02067156), whereas the second Phase II will investigate mipsagargin as a combination therapy with different dosing levels, Lowe said. At present, mipsagargin is being investigated as a second or third line treatment option and combination use would help it improve its market chances, he said. He did not comment on what therapy mipsagargin would be investigated with.

The extension trial would likely to be based in the US, with the second Phase II trial possibly having sites in Europe like the UK and Germany, Lowe said.

Inspyr has already spoken to three CROs and is about to talk to a fourth CRO in a couple of weeks, Lowe said. Only one CRO will be chosen for both trials as Inspyr would like to leverage the CRO's experience in a specialised indication and relationships with trial sites, he added. Phase II trial sites could include specialty centres or academic centres with strong links to hospital facilities, Lowe said. Whilst there is no preference to CRO size, it should have experience in oncology, particularly GBM, he said. The CRO would manage day to day trial requirements as well as managing enrolments, among others, Lowe said.

Whilst costs are still unclear, the Phase II trials are likely be worth millions in the single-digit

Executives

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Company

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Drug(s)

*Mipsagargin

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range, Lowe said.

He noted that the ongoing Phase II does not have a CRO, with Inspyr working directly with an investigator. ClinicalTrials.gov shows the trial has two sites - University of California San Diego Moores Cancer Centre and John Wayne Cancer Institute, California - and has a primary completion date of December 2016.

Inspyr has a market cap of USD 5m.

by Reynald Castaneda in London

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