Download our mobile app!

BPI IS NOW MOBILE

receive breaking investigative news the second it happens!

Related Articles by Company

CRO report - 20 July 2015

Related Articles by Topic

Syngenta predicted to enter into talks with Monsanto as shareholders urge change

Published 2015-07-10

Proprietary Intelligence

TheraSource seeks pharma partner, CMO for acute kidney injury drug – executives

Pharmaceutical partner preferred, CMO would be the fallback strategy

TheraSource is seeking a development and commercialization partner for its acute kidney injury (AKI) drug rhMFG-E8, said President Ping Wang and Chief Science Officer Weng-Lang Yang.

As part of a fallback plan, the company is also welcoming bids for a CMO that would manufacture samples to be used in clinical studies, they said.

The Manhasset, New York-based firm has already spoken to half a dozen large drug companies, with two or three expressing strong interest, though these partnership discussions are still in early stages, Wang said while on the sidelines of New York Bio's first New York-Beijing BioForum. Ideally, he said, a partnership contract would be in place as soon as possible.

The company prefers a co-development partnership under which a mid-sized or large pharmaceutical company would help fund preclinical and early clinical development of rhMFG-E8 and manufacture the product, while TheraSource would lead the preclinical and early clinical development itself, Yang said. TheraSource hopes to move the drug into clinical trials within the next one or two years, Wang added. Remaining preclinical work and early clinical studies are expected to cost around USD 8m, he added.

The co-development arrangement would continue through the end of Phase II proof-of-concept studies, Wang said, after which TheraSource would out-license the drug to the partner, which would take over further development and commercialization, in exchange for milestone payments to TheraSource and royalties. TheraSource's patent for rhMFG-E8 is global, so a partner with global capabilities is preferred, they said.

If TheraSource fails to find a partner in the aforementioned time frame, its fallback plan is to find a CMO and preclinical CRO, they said. That plan would probably result in the drug entering the clinic in two to four years rather than one to two, Wang added, though it would also allow the company to collect more data that could make it more attractive to potential partners. It would also prompt the company to continue seeking National Institutes of Health (NIH) funding, from which it has already raised USD 12m, Wang said.

In case that scenario happens, the company is already looking for a CMO and hopes to have a contract in place in the next six months, Wang said. The company is currently in an early-stage dialogue with one CMO that had asked for a CDA, though none had been signed, he added, with Yang adding the company has spoken with four or five CMOs in total. In particular, Wang said, the company prefers a large-sized CMO with experience in protein production and a lot of experience with IND submissions, though there is no preference in terms of geography for the CMO.

After securing a CMO, the company would then begin CRO discussions, in 2Q16, with an eye on having one in place a year from now. The CRO preferably would be one that can do immunogenicity and monkey studies, Wang added, and along with the CMO would be helping TheraSource with IND-enabling studies. While the company itself does have flexibility in terms of working with an international CRO, receiving funding from the NIH would require using a US-based CRO, he noted. The company is not currently open to CRO bids, but if a larger pharmaceutical partner is found, then the partnering company will likely be using its own CRO, they said.

The fallback plan would probably prompt TheraSource to seek VC funding as well, Yang said. The company would probably start talking to VC investors in two years, targeting at least USD 2.5m - USD 3m, Wang said. The current funding should last the company about 18 months, assuming a USD 1.25m monthly burn rate, noted Wang, who is the majority shareholder.

The company may nevertheless seek VC funding even if it finds a partner, but the partner is unable or unwilling to put up enough funding to cover the USD 8m cost, Wang said.

The rhMFG-E8 product is a milk fat globule-epidermal growth factor-factor VIII secretory protein produced by the human body, which the company says has anti-inflammatory properties through enhanced clearing of dying cells and thereby protecting the kidneys from ischemic injury, according to a company brochure. AKI occurs when there is insufficient blood flow to provide oxygen to the kidneys and is frequently observed after major surgical procedures such as cardiac surgery. However, no FDA-approved drugs are available to treat or prevent AKI.

by Alaric DeArment in New York

About Alaric DeArment

Email the journalist team at editorialfeedback@biopharminsight.com

Company

THERASOURCE LLC
View Contacts

Topic

CROs, CMOs, EDC
Financing
Partnerships/Licensing

Indications

Kidney Disease

Country

USA

Key Opinion Leaders

Ping Wang
Weng-Lang Yang

Intelligence Grade

Confirmed

Email Analyst

© Infinata 2014 Site Map