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Tunitas shops Australian CROs and CMOs for preclinical and Phase I work with fusion protein – CEO

Tunitas Therapeutics is seeking service vendors for preclinical and Phase I work with its GE2 compound in moderate-to-severe asthma, said CEO Nolan Sigal. It plans to conduct the Phase I study in mid-2014, he added.

The San Francisco, California-based company is looking to raise USD 2m to 3m, in addition to obtaining grants, to support the company until it has initial clinical results, the CEO noted.

The firm's plan is to run the Phase I trial in Australia, so it has a preference for Australian vendors as it selects contract research organizations (CROs) and contract manufacturing organizations (CMOs), he said.

Tunitas intends to work with Australian groups on all preclinical work including animal studies, GLP toxicology and formulation work as well as to take the drug candidate into a Phase I trial that will likely be run at Australian sites, Sigal explained. The firm will also consider non-Australian vendors, but the goal will be to do everything in one country, he said.

The company will talk to a number of US-based CMOs as well, Sigal added. If manufacturing does not work out in Australia and shipping of material from nation to nation is necessary, Tunitas would lean toward a US-based manufacturer to be closer to home, he noted.

The firm's preliminary Phase I plans would test GE2 in healthy allergy patients and would analyze biomarkers to assess the candidate's mechanism of action, the CEO said. Because the Phase I trial would not need to enroll serious allergy patients, Sigal added that the company would be able to work with a broad range of CROs and does not require an allergy-specialized vendor.

For Phase I, GE2 will likely be formulated as an IV therapy to have greater flexibility altering the dose, but the ultimate goal will be to have a subcutaneous formulation, Sigal explained. Tunitas is open to working with the same vendor on IV and subcutaneous formulations or separate CMOs, he noted.

The firm has heard from a number of service providers and remains open to contact, he added.

GE2 is a fusion protein that directly inhibits basophil and mast cell function and suppresses allergic antibody production by interacting with IgE-producing lymphocytes, according to a 4 June press release.

Tunitas intends to return to US markets for later trials, but for preclinical and Phase I, the company will take advantage of tax credits in Australia, Sigal explained. Tunitas is in the process of establishing an Australian subsidiary to carry out preclinical and clinical work with Australian vendors, he said.

Studies carried out in Australia will be high quality at major institutions and will be very translatable to filing for later trials with the US Food and Drug Administration, he noted.

Tunitas received a three-year USD 3m small business innovation research grant, according to the press release. The company has raised a total USD 10m in grants, added Sigal.

In addition to pursuing further grants, Tunitas has met with institutional VCs and angel

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investors and has ongoing talks with four or five major biotech and pharmaceutical companies, he said.

Potential partners likely will want to see some data before partnering, but interaction is still helpful, he added.

by Casey McDonald in New York

Email the journalist team at editorialfeedback@biopharminsight.com