Intensity Therapeutics looks to raise USD 7.5m to bring intratumoral chemo to clinical trials - exec

Seeking clinical CRO, CMO and FDA discussions expected in next few months

Financing will cover remaining preclinical work into Phase II

Intensity Therapeutics has raised USD 1.5m of its planned USD 9m target for its lead preclinical candidate, an intratumoral chemotherapy, said CEO Lewis Bender. By the end of 3Q14, the firm plans to finalize CMOs and CROs for clinical studies, he noted.

The Norwalk, Connecticut-based company is interested in raising the remaining capital through venture capitalists, angel investors and "anyone else," Bender said.

If the firm is able to raise the remaining financing over the next two months, then its focus over the next 12 to 15 months would be mainly on building the organization necessary for product development, the CEO added. For example, Bender would like to hire five or six additional employees. Currently, besides Bender, Robert Cooke serves as senior vice president.

But Bender added that the company needs to have more capital on hand before it can recruit a high-quality team. Until then, "we will keep using contractors and consultants," he said. Intensity Therapeutics has already identified a preclinical CMO to produce the API and a CRO to conduct preclinical testing.

The aim is to have enough funds to manufacture INT230-6's active ingredient under GMP, develop quality control and assurance testing protocols as well as bioassays, undertake toxicology and stability testing, submit an IND, conduct Phase Ia and IIa testing as well as for legal and IP costs, Bender said. Phase Ia will be a dose-escalation study, and the Phase IIa will be run as a follow-on trial with the maximum-tolerated dose.

The company has yet to file a development plan with the FDA and expects to do so in the next few months, Bender said.

The company is accepting pitches from CROs and CMOs for clinical work so that it can start the Phase Ia trial as soon as possible. It is looking for service providers that are "highly experienced with oncology studies and not too big and not too small," the CEO said.

INT230-6 is intended for all solid tumors except brain and lung and is aimed at patients who do not respond to other therapies. It contains three components: an amphiphilic penetration-enhancement molecule, cisplatin and 10µg of a vinca alkaloid compound.

Intensity Therapeutics' previous product, INT223-8, comprised the same components except the vinca alkaloid compound. Mice with colon cancer injected with INT223-8 showed a median overall survival (OS) of 56 days, while INT230-6 mice demonstrated a median OS of 77 days.

The company has filed for US and World Intellectual Property Organization patents.

by Kathleen Raven in New York