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H3 Biomedicine in active discussions for co-developing its cancer genomics programs - CEO

H3 Biomedicine is in talks with pharma companies to co-develop one or more of its Phase I drugs that are based on its cancer genomics platform, said CEO Markus Warmuth.

The goal is to find a partner by in 2018, the CEO noted, though stressed that H3 wants to gain a strategic partner that will help them impact the specific space and will not enter into a partnership if they don't find the right deal. Warmuth declined to elaborate on the status of discussions, but added that they are beyond very early talks.

Cambridge, Massachusetts-based H3 was recently in discussions with **Eisai** (TYO:4523), the company from which it had spun out in 2011, to explore other routes to further advance H3's clinical program, said Warmuth. H3 Biomedicine was launched in 2011 with a USD 200m funding commitment from Eisai.

H3's ongoing clinical programs include three Phase I studies: H3B-6545, an estrogen receptor modulator in a recently initiated Phase I study (NCT03250676); H3B-6527, a fibroblast growth factor receptor 4 inhibitor in a Phase I hepatocellular carcinoma study (NCT02834780); and H3B-8800, an orally bioavailable small molecule modulator of wild-type and mutant splicing factor 3b complex in a Phase I (NCT02841540) for patients with myelodysplastic syndromes, acute myeloid leukemia and chronic myelomonocytic leukemia.

All three investigational drugs have been found to be well tolerated and are still in the dose-escalation stage since they have not reached a maximum tolerated doses, said Warmuth. The trials are expected to have a recommended Phase II dose for expansion cohorts in 3-6 months, he added.

The company is most interested in a co-development partnership, or one that allows it to be involved in the program in the future, said Warmuth. A potential pharma partner will ideally have expertise in hematological malignancies, breast cancer or hepatocellular carcinoma, and have a complementary portfolio to H3.

While the company is not focused on partnering a specific program, H3 is not thinking of partnering all of them, said Warmuth. If there is a larger pharma company interested in co-developing two of H3's assets it would entertain those discussions, he added.

The company has built a data bank of genomic and transcriptomic information of over 100,000 patients, which it is using in different stages of drug discovery, said Warmuth. H3's cancer genomics-based platform leverages genomic and transcriptomic information that relates to alternate and aberrant splicing, he added. For example, H3B-8800 attacks the core spliceosome in case of an aberrant splicing event, leading to a death spiral, said Warmuth.

In the first half of the dose-escalation study, the company plans to use a DNA sequencing panel to stratify patients on the basis of mutations that lead to these aberrant splicing events, he added. The dose-expansion arms will be selecting patients on the basis of a positive diagnostic test, said Warmuth. In some indications, he added, these mutations could be frequent enough to allow for an all-comer trial, and a decision will be taken as the dose-expansion cohorts start enrolling.

by Manasi Vaidya in New York

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Drug(s)

*H3B-6527

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