

Headline

Marina retains Numoda for Phase Ib/IIa trial of lead compound; open to contact from other CROs for pivotal Phase IIb - CEO

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Intelligence Details

Marina Biotech (NASDAQ:MRNA) will work with the CRO Numoda Corp for the Phase Ib/IIa trial of its lead compound, CEQ508, in familial adenomatous polyposis (FAP), CEO J. Michael French said.

The Phase Ib/IIa trial will begin within the next few weeks, French said, noting that enrollment will begin soon after local approval from the clinical trial site, Massachusetts General Hospital, is attained.

The company will work with Numoda for the 30 patient trial that will assess the knock-down of beta-catenin in the epithelial cells of the small and large intestine—regions where beta-catenin is known to be dysregulated in FAP. Results from the 28 day study and subsequent dose escalation portion are expected by 3Q11, with interim results in between, French said.

FAP is predominantly a genetic condition in which individuals develop colon polyps in their teens and colon cancer by their early 40s, often requiring colon resection, French said. Since FAP is an orphan disease that afflicts approximately one in 10,000 individuals, Marina will consider filing for orphan drug status, the CEO said, noting that the timing and strategy on doing so is currently undetermined.

CEQ508, an oral agent, utilizes the TransKingdom RNA interference platform. The agent is comprised of attenuated bacteria that are engineered to enter into dysplastic tissue and release short-hairpin RNA, which targets the mRNA of beta-catenin, French explained, adding that he is "confident" in the safety profile of the agent as there have been no safety concerns seen to date in long-term toxicology studies.

Company:

Mdrna, Inc (FKA: Nastech Pharmaceuticals)

Pfizer, Inc.

Company

Numoda Corporation

Drug(s)

[Celebrex](#)

Intelligence Type(s)

Product Development

Topic

CROs, CMOs, EDC

Intelligence Grade

Confirmed

Sub-sectors

Drug development

Country

USA

Pfizer's (NYSE:PFE) Celebrex is the only available treatment option for FAP patients; however, its dosage remains "outside the cardiac safe zone," French said. Celebrex was approved in FAP based on a pivotal Phase II study, he noted.

According to French, a pivotal, 80-patient Phase IIb study assessing delay of polyp formation may be sufficient to file for approval with the FDA. Although Numoda has the capability to take CEQ508 to market, the company is open to contact from other CROs to aid in the pivotal Phase IIb study, he added.

French said he anticipates CEQ508 will reach the market within three years, with total development costs totaling about USD 10m. The compound is "ready made" for a small biotech to take it to market by itself, he noted.

Marina obtained its RNAi platform through the acquisition of Cequent Pharmaceuticals this past July.

Marina has a current market cap of USD 49m.

by Anusha Kambhampaty

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