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ZUCERO:

FDA CANCER TRIAL OK

DELAYS $30m IPO

ZUCERO THERAPEUTICS

Zucero says that the US Food and Drug Administration approval of a 61-patient, phase II cancer trial has contributed to delaying a proposed $30 million initial public offer.

Melbourne's Zucero said the FDA had approved its investigational new drug application for a phase II 'basket' trial of its PG545, or pixatimod, in combination with Bristol Myers Squibb's PD-1 inhibitor nivolumab, or Opvido, in patients with PD-1 relapsed and/or refractory metastatic melanoma and non-small cell lung cancer (NSCLC) and micro-satellite stable metastatic colorectal cancer (MSS mCRC).

The company said its phase Ib study showed that the combination of pixatimod and Nivolumab induced meaningful anti-cancer activity in patients with micro-satellite stable metastatic colorectal cancer (BD: Jul 29, 2019).

Today, Zucero said that the phase II, open-label, single-centre basket study would be conducted by the University of Pittsburgh Medical Centre, with Dr Diwakar Davar as the principal investigator.

The company said that 31 subjects would be enrolled in stage 1 of the trial, 13 with metastatic colorectal cancer, nine with melanoma and nine with non-small cell lung cancer, with the potential to enrol a further 30 subjects in stage 2, 14 with metastatic colorectal cancer, eight with melanoma and eight with non-small cell lung cancer.

Zucero said that for PD-1 relapsed and/or refractory metastatic melanoma and NSCLC subjects, intravenous pixatimod would be dosed at 25mg weekly with intravenous nivolumab dosed at 480mg every 4 weeks.

The company said that the metastatic colorectal cancer would also receive a metronomic or low-dose dose of 50mg cyclophosphamide.

Zucero said the primary end point was the objective response rate with secondary endpoints including duration of response, progressive free survival and overall survival.

Zucero chief scientific and operations officer Dr Keith Dredge said the phase Ib preliminary data "showed meaningful anti-cancer activity in patients with MSS mCRC who traditionally have not responded to immune checkpoint inhibitors in a monotherapy setting".

"These data demonstrate that by providing an extra signal to the immune system, in addition to checkpoint blockade, pixatimod may boost the effectiveness of immune checkpoint inhibitors not only for MSS mCRC but for other cancers where immune checkpoint inhibition alone has limited or no benefit," Dr Dredge said.

Zucero managing director Chris Burrell said the company had been hoping to raise up to $30 million at 30 cents a share.

Mr Burrell said that although the institutional and broker firm offer was oversubscribed the company could not complete the listing in the time frame required.

Mr Burrell said that the time when it could list was dependent on not having to re-issue the prospectus as material events relating to our business occurred.

Mr Burrell said that the FDA approval was a factor that might have required a re-issue of the prospectus.

Mr Burrell said that pixatimod and ZUC002 appeared to be "coronavirus agnostic and offer broad anti-viral activity based on their mechanism as heparan sulfate (HS) mimetics".

He said that Zucero was continuing to refine its anti-viral clinical development plan reflecting a 'pandemic preparedness' approach and was considering the best time for the company to list.

Last year, Zucero said that in-vitro studies of ZU545, or pixatimod, had shown it had "potent antiviral activity" against Covid-19 (BD: Jun 26, 2021).

Zucero is a public unlisted company.