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Street cheering Immuneering's phase IIa pancreatic data

By Randy Osborne, Staff Writer

Immuneering Corp. CEO Benjamin Zeskind said he is "pleased with enrollment across the full trial" that's ongoing with IMM-1-104 in cancer, and 30 subjects are due per arm in five arms that the phase IIa experiment includes.

Meanwhile, shares of Cambridge, Mass.-based Immuneering (NASDAQ:IMRX) closed Sept. 13 at $2.02, up 59 cents, or 41%, on word of positive initial response data from the first five subjects treated with the drug in first-line pancreatic cancer. The MEK1/2 inhibitor is being tested against melanoma and non-small-cell lung cancer as well.

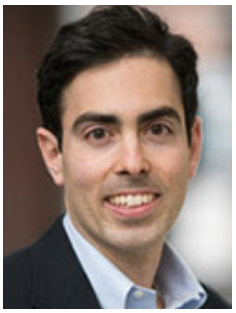
Paired with modified gemcitabine/nab-paclitaxel, IMM-1-104 yielded results in five patients, showing an overall response rate of 40% (2/5), including one complete response (CR), and a disease control rate of 80% (4/5). Mizuho analyst Graig Suvannavejh said in a report that although development is "still in the early innings, we're highly encouraged by these initial data." More results are coming from at least one of the other arms of the study by the end of this year. Zeskind declined to comment on regulatory actions until later. All five subjects remain on treatment.

"Uncertainty on [the drug's] efficacy has been a major overhang on Immuneering's stock," Suvannavejh observed. "Phase I data disclosed in March in a heavily pretreated all-RAS cancer population suggested little/limited activity," but the effort "predominantly consisted of tougher-to-treat patients, and thus, responses seen from today's first-line patients, provides, in our view, critical validation for IMM-1-104 that was not previously seen." The initial patients were all treated at the 240-mg once-daily safety lead-in dose. "As such, we believe this leaves room for even greater efficacy in the upcoming patients dosed at the recommended 320-mg once-daily phase II amount.

So far, the combo has proved well-tolerated, with an emerging safety profile in line with known data for both therapies, respectively. The trial's data and safety monitoring board has approved enrolling additional patients into this arm at the 320-mg once-daily dose, with the first of those already dosed and awaiting scans.

Earlier this year at the American Association for Cancer Research (AACR) meeting, Immuneering shared preclinical data that raised hope, as pancreatic cancer has remained a particularly stubborn tumor type – aggressive and often diagnosed late in the course of disease. "On the other hand, it's also a cancer that's typically very reliant on the MAP kinase pathway, and that's one of the reasons that we came to prioritize it."

The AACR data pointed to synergies between IMM-1-104 and chemotherapeutics, too. If the combo data for IMM-1-104 continue to be positive, and taking into account the excellent emerging safety profile, the company is moving toward potential inclusion in various vertical drug combinations, immune-modifying combos, and orthogonal matching with therapeutics with non-overlapping mechanisms of action, developed by the company alone or in partnership. Zeskind said Immuneering "has a bunch of opportunities in front of us. Anytime you see a CR in pancreatic cancer, that's exciting and worth paying attention to."



Benjamin Zeskind, CEO, Immuneering

With regard to collaborations, "we certainly keep all options on the table" and have maintained "a robust and active dialogue" on setups that could "expand the reach of [the drug], whether it's geographically [or] being able to try more combinations in more types of cancer. There's no fire to do a deal right away."

Which other indication in the trial might report next? "We haven't got into that yet," Zeskind told *BioWorld*. It just depends which arm becomes ready, "and that's something hard to predict." The pancreatic data were "pretty mature, to be able to see a CR that holds across four scans and the patient continues on treatment and the unconfirmed partial response in the second patient and good disease control in two of the others."

Pancreatic cancer has seen more than its share of clinical casualties over the years. A recent flameout came at the end of July when Fibrogen Inc. terminated work on its once-promising anti-CTGF monoclonal antibody, pamrevlumab, after the San Francisco-based firm reported missed endpoints in two late-stage pancreatic cancer studies, and made known plans to cut its workforce by about 75%.

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The push continues apace, though, and some Wall Street speculators are placing chips on other developers. Cytomx Therapeutics Inc., of South San Francisco, is expected to make a decision (influenced by partner Amgen Inc.) around the end of this year on phase I-stage CX-904, a T-cell-engaging bispecific antibody targeting EGFR on tumor cells and the CD3 receptor on T cells. Included in the go/no-go decision could be the start of phase Ib expansion cohorts in specific EGFR-positive tumor types. "We expect pancreatic cancer to be a core component of this expansion," Wainwright analyst Mitchell Kapoor said in a Sept. 13 report. Phase Ia data provided cause for optimism, but "we await more evidence" in the difficult disease. "We would like to see a broader dataset to become more comfortable in this indication," he said.