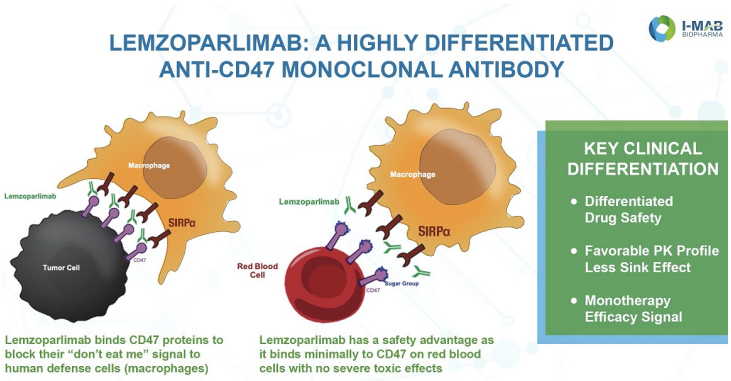
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

I-Mab reports efficacy of Anti-CD47 monoclonal Ab on relapsed/refractory malignancy

25 November 2020 | Company results

Initial monotherapy results at Ph 1 clinical trial data demonstrate differentiated safety and PK profile and efficacy signal of lemzoparlimab (Highly Differentiated Anti-CD47 Monoclonal Antibody)



I-Mab, a global clinical-stage biopharmaceutical company based in China and the US and committed to the discovery, development and commercialization of novel biologics, announced initial results from its U.S. phase 1 clinical trial (NCT03934814) evaluating lemzoparlimab (also known as TJC4) for the treatment of relapsed or refractory solid tumors and lymphoma. The results were released in a poster entitled *"A first-in-patient study of lemzoparlimab, a differentiated anti-CD47 antibody, in subjects with relapsed/refractory malignancy: initial monotherapy results"* at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting, on November 9, 2020 (Abstract #385).

Lemzoparlimab is a unique CD47 antibody that exerts strong anti-tumor activity while exhibiting a minimal binding to red blood cells. It is designed to avoid severe anemia -- common toxicity of CD47 antibodies of the same class.

"Lemzoparlimab was originally discovered and developed by I-Mab as a globally competitive CD47 antibody and has been uniquely designed to overcome the toxicity associated with this drug target," said Jingwu Zang, M.D., Ph.D., Founder, Honorary Chairman and Director of I-Mab. "The initial clinical results are consistent with the key differentiation of lemzoparlimab in terms of drug safety and the PK profile. These clinical advantages put lemzoparlimab in a highly competitive position among CD47 antibodies of the same class."

The phase 1 study is an open-label, multi-center, multiple dose study conducted in two parts. The first part is comprised of a single agent dose escalation followed by two separate combination regimens in an escalating dose range (Part 1b with pembrolizumab; Part 1c with rituximab). The second part is a dose expansion study in the combination therapies.

The data to be presented at SITC include the initial results from the single agent therapy (N=20), which is designed to determine the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and anti-tumor activity of lemzoparlimab. The key findings include:

- Lemzoparlimab was well tolerated up to 30 mg/kg on a weekly basis without priming dosing strategy. No dose-limiting toxicity and no clinical or laboratory evidence of hemolytic anemia were observed throughout.
- Lemzoparlimab PK appears to be linear at mid to high dose levels following a single dose with no significant "sink

effect".

- One confirmed Partial Response (PR) was observed in the 30 mg/kg monotherapy cohort (N=3). The patient had failed prior treatments with checkpoint inhibitors.

"We are very encouraged by the safety and tolerability data that have emerged from the phase 1 trial," said Jordan Berlin, M.D. from Vanderbilt University, the principal investigator of the trial. "It shows the promise of lemzoparlimab as a differentiated CD47 antibody for multiple cancers, and we look forward to advancing the development of lemzoparlimab for patients with advanced solid tumors and hematologic malignancies." Dr. Berlin presented the data during the virtual poster sessions on November 11, 2020 5:15-5:45 p.m. EST and November 13, 2020 4:40-5:10 p.m. EST.

Recruitment of patients for the dose escalation study of lemzoparlimab in combination with pembrolizumab or rituximab is ongoing. Additional information on the clinical trial (NCT03934814) is available on www.clinicaltrials.gov.

In September 2020, I-Mab and AbbVie entered into a global strategic partnership to develop and commercialize lemzoparlimab. Subject to pre-closing conditions, both companies will be collaborating to further advance the clinical development of lemzoparlimab for the treatment of multiple cancers globally and in China.