Abstract 2611: Primary efficacy and safety results of BAT1308, a PD-1 inhibitor, + chemotherapy ± bevacizumab in phase 2 trial for persistent, recurrent, or metastatic cervical cancer

NCT06123884

QingLei Gao[1], Meirong Liang [2], Gang Cheng[3], Junguo Bu[4], Yifeng Wang[4], Xiaojian Yan[5], Yinghua Ji[6], Chenchun Wu[7], Mei Feng[8], Hao Yu[9], Xulin Zhao[10], Haibo Liu[11], Shuqiang Song[11], Jin-Chen Yu[11], Shengfeng Li[11], Ding Ma[1]* *Corresponding author

1.Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China; 2. Jiangxi Maternal and Child Health Hospital, Nanchang, China; 3. The Affiliated Bozhou Hospital of Anhui Medical University, Bozhou, China; 4. Zhujiang Hospital of Southern Medical University, Guangzhou, China; 5. The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China; 6. The First Affiliated Hospital of Xinxiang Medical University, Xinxiang, China; 7. The First Affiliated Hospital of Henan University of Science & Technology, Luoyang, China; 8. Fujian Cancer Hospital, Fuzhou, China; 9. Shandong Cancer Hospital, Jinan, China; 10.Nanyang First People's Hospital, Nanyang, China; 11. Bio-Thera Solutions, Ltd, Guangzhou, China

Background

BAT1308 is a fully humanized and high-affinity anti-PD-

Previous phase 1 study demonstrated BAT1308 has a promising safety and efficacy profile in patients with advanced solid tumors.

A total of 59 participants were enrolled in that phase 1 study. After dose escalation of 100mg, 300mg, and 600mg, IV, Q3W of BAT1308, 300mg Q3W dose was expanded. The results demonstrated BAT1308 had low immunogenicity and exhibited long-lasting, high affinity to PD-1 receptor. No DLT events were observed. Common TRAEs included decreased white blood cell count, anemia, and hypothyroidism. The most common irAE were thyroid dysfunction. The ORR is 41.7% (5 of 12 patients) in NSCLC, 16.7% (2 of 12 patients) in cervical cancer, and 14.3% (2/14) in HCC.

Here we present the primary safety and efficacy results in phase 2 study for BAT1308 combined with platinum-based chemotherapy ± bevacizumab as first-line therapy for PD-L1 positive persistent, recurrent, or metastatic cervical cancer.

Objective

To investigate the safety and efficacy of BAT1308 + chemotherapy ± bevacizumab for patients with persistent, recurrent, or metastatic cervical cancer.

Methods

This is a multicenter, single-arm, open-labeled, phase 2 study.

Eligible patients received BAT1308 (300 mg Q3W for up to 24 months) plus platinum -based chemotherapy (paclitaxel 175 mg /m^2 + cisplatin 50 mg /m^2 or carboplatin AUC 5) and, per investigator discretion, with or without bevacizumab (15 mg /kg) for up to 6 cycles. The treatment will continue until disease progression, intolerable toxicity, the investigator determines that the participant is no longer benefiting from the treatment, the participant withdraws informed consent, or the treatment duration reaches 2 years.

Eligiblility

75 years of age;

PD-L1 1;

Have persistent, recurrent, or metastatic squamous cell carcinoma, adenosquamous carcinoma, adenocarcinoma, or clear cell carcinoma of the cervix which has not been treated with systemic chemotherapy and is not amenable to curative treatment (such as with surgery and/or radi1 0 0 1 515.9 1054.18(cJ5(ch)-o0003Gi)5(zuma>BQ40.000038624 0 2592 151 reW* nBT/F6 18 Tf1 0 0 1 254)-8(sol)5(id)5( )-8(tumo)3(rs.)]TJETQ EMC /P <</MCID 20/Lang (en-US)>BQq0.30.038624 0 2592 1512 rW* nBT/F4 18 Tf1 0 0 1 39.312 228.6

Patients

Adverse Events of

Summary of Adverse Events (n = 29)

Conclusion