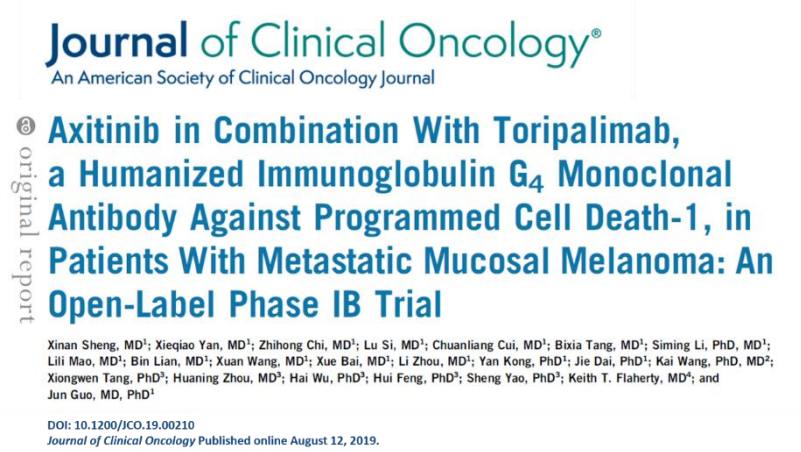
新闻稿

Junshi Biosciences Toripalimab’s Breakthrough in Advanced Mucinous Melanoma Treatment Published on JCO

Junshi Biosciences, a leading biopharmaceutical enterprise, has recently taken the lead in the combination therapy of its domestically developed anti-PD-1 mAb toripalimab (trade name: Tuoyi) and anti-angiogenic drug axitinib, which has made breakthrough and **provided new solutions for first-line treatment of advanced mucinous melanoma.** It is also expected to become **the new standard for first-line treatment**.

It was an open-label, phase IB clinical trial in patients with advanced melanoma conducted by Professor Guo Jun’ team from the Peking University Cancer Hospital and was published in the Journal of Clinical Oncology (IF: 28.245) recently.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original report

Axitinib in Combination With Toripalimab, a Humanized Immunoglobulin G_4 Monoclonal Antibody Against Programmed Cell Death-1, in Patients With Metastatic Mucosal Melanoma: An Open-Label Phase IB Trial

Xinan Sheng, MD[1]; Xieqiao Yan, MD[1]; Zhihong Chi, MD[1]; Lu Si, MD[1]; Chuanliang Cui, MD[1]; Bixia Tang, MD[1]; Siming Li, PhD, MD[1]; Lili Mao, MD[1]; Bin Lian, MD[1]; Xuan Wang, MD[1]; Xue Bai, MD[1]; Li Zhou, MD[1]; Yan Kong, PhD[1]; Jie Dai, PhD[1]; Kai Wang, PhD, MD[2]; Xiongwen Tang, PhD[3]; Huaning Zhou, MD[3]; Hai Wu, PhD[3]; Hui Feng, PhD[3]; Sheng Yao, PhD[3]; Keith T. Flaherty, MD[4]; and Jun Guo, MD, PhD[1]

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In recent years, the incidence of malignant melanoma in China is on the rise, with an annual growth rate of 3% to 5%, which has become the fastest growing type among all malignant tumors. Mucosal melanoma is one of the main subtypes in China, accounting for 22%~25%, but it is rare in white race. This subtype is prone to visceral metastasis with poor prognosis and poor responses to traditional chemotherapy , the response rate to mono-immunotherapy is also extremely limited.

Previous clinical studies demonstrated that vascular endothelial growth factor (VEGF) expression level was associated with poor outcomes in patients with mucosal melanoma which may be due to its biological characteristics such as hypervascularity. Axitinib is a tyrosine kinase inhibitor against VEGFR1-3 (vascular endothelial growth factor receptor 1-3), which could increase the efficacy of anti-PD-1 mAb via downregulating immunosuppressive factors when combines with anti-PD-1 mAb.

Professor Guo Jun's team aimed at the clinical unmet needs of Chinese patients and initiated the first combination therapy of toripalimab and axitinib, which brought unprecedented breakthrough in the first-line treatment of mucosal melanoma.

The study showed that the combination therapy of toripalimab and axitinib in patients with chemotherapy-naive advanced mucinous melanoma, the **ORR was 48.3% (irRECIST criteria: ORR 51.7%), DCR was 86.2% and median progression-free survival(mPFS) was 7.5 months (The median OS was not reached by the cutoff date).**

As the leader of this study, **Professor Guo Jun** said: "The immunotherapy combination regimen of mucosal melanoma developed by Chinese experts has been internationally recognized for the first time. The safety data was better than the overseas researches, which may even rewrite the international guidelines. I am proud of our research team and China's domestic innovative drugs! Toripalimab gives Chinese experts more opportunities to conduct some innovative, Asia-specific studies. In the field of melanoma, a number of studies on neoadjuvant therapies and combination therapies of toripalimab are currently in full swing. I believe that the vast majority of evidence-based medical evidence in the future guidelines of acral and mucosal melanoma will come from China."

Junshi Biosciences attaches great importance to the treatment of China's unique tumors, constantly explores new ways brought by combination therapy, and seeks safer and more effective combination therapy in cooperation with researchers and pharmaceutical companies in China and

abroad to improve the efficacy of tumor treatment and overcome the drug resistance of anti PD-1 monotherapy hoping to benefit more patients.

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Official Website：www.junshipharma.com

Should you have any questions, please contact:

厉智 | Zhi LI

E-mail: zhi_li@junshipharma.com

Corporate Communications Dept.