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PMDA REGULATORY UPDATE

PMDA regulatory update on approval and revision of the precautions for use of anticancer drugs: approval of nivolumab for unresectable advanced or recurrent epithelial skin malignancies in Japan

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Approval of anticancer drugs

After completion of the review by Pharmaceuticals and Medical Devices Agency (PMDA), nivolumab was approved in Japan in February 9, 2024 for unresectable advanced or recurrent epithelial skin malignancies [1].

Summary of the approval

Nivolumab is an anti-human PD-1 monoclonal antibody. An investigator-initiated trial (NMSC-PD1 trial: KCTR-D014) [2] was conducted in Japan to evaluate nivolumab in 31 patients with epithelial skin malignancies. The trial met its primary endpoint with a response rate of 19.4% (6/31 patients, 95% CI 7.5–37.5%). The safety profile of nivolumab in this trial was consistent with that observed in previously reported clinical trials of nivolumab.

Revisions to anticancer drug precautions

Based on the results of post marketing safety assessment by PMDA, Ministry of Health, Labour and Welfare directed that the package inserts for vascular endothelial growth factor (VEGF) or its receptor (VEGFR) inhibitors be revised to include the risk of arterial dissection as a serious adverse event [3, 4].

References

1. Pharmaceuticals and Medical Devices Agency (2024) Review report for nivolumab. https://www.pmda.go.jp/drugs/2024/P20240219002/180188000_22600AMX00768_A100_1.pdf. Accessed 13 Mar 2024 (**in Japanese**)
2. Ishii M, Hirai I, Tanese K et al (2020) Anti-PD-1 antibody therapy for epithelial skin malignancies: An investigator-initiated, open-label, single-arm, multicenter, phase II clinical trial (NMSC-PD1 Study). Medicine (Baltimore) 99:e22913. https://doi.org/10.1097/MD.0000000000022913
3. Pharmaceuticals and Medical Devices Agency (2024) Revision of PRECAUTIONS; Nintedanib ethanesulfonate, Axitinib, Aflibercept beta (geneticalrecombination), Cabozantinib malate, Sunitinib malate, Sorafenib tosilate, Pazopanib hydrochloride, Vandetanib, Ponatinib hydrochloride, Ramucirumab (genetical recombination), Regorafenib hydrate, Lenvatinib mesilate. https://www.pmda.go.jp/files/000266902.pdf
4. Pharmaceuticals and Medical Devices Agency (2024) Evaluation of the risk of artery dissection due to systemic exposure to VEGF/VEGFR inhibitors. https://www.pmda.go.jp/files/000266522.pdf Accessed 13 Mar 2024

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