



## SYMPOSIUM: DEVELOPMENTS IN THE TREATMENT OF SOFT TISSUE SARCOMA

SY24-1

MASTER KEY Project: A platform study for rare cancers in Japan and Asia

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MASTER KEY Project (Japan) launched in 2017, for driving research and development for rare cancers and for promoting genomic medicine, a successful collaboration between industry and academia. Clinical trials targeting rare cancers, including sarcomas, are limited since most global clinical trials are aimed for drug approval for common cancers.

MASTER KEY consists of two major arms. The first is a registry study, and the second comprises multiple clinical trials. With the collaboration between 6 Japanese academia institutes and 12 pharmaceutical companies, we have enrolled over 2000 patients in the registry, making it one of the largest rare cancer databases worldwide, and are simultaneously conducting 19 independent registration-directed clinical trials. With the collected genomic information, treatment outcomes, and prognosis, the data will be used as research purpose as well as for drug approval applications as historical control data. In November 2021, ASTER KEY Asia was launched to include Asian countries in the registry to accelerate clinical development and genomic medicine throughout Asia.

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Possibility of immune checkpoint inhibitor as the new treatment strategy in the management of cutaneous angiosarcoma

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Prognosis of primary cutaneous angiosarcoma in Japan is dismal, the median overall survival of patients without metastasis and treated with surgery reported to be less than 20 months. We recently proposed a new treatment strategy using concurrent chemoradiotherapy with taxane, and this therapy became one of the first-line treatment. However, the long-term outcome still needed to be improved. After immune checkpoint inhibitors (ICI) first introduced for advanced melanoma in 2011, ICI shown to be effective in various cancer types. On the other hand, ICI did not show clinical benefit among sarcomas in the clinical trials. The efficacy of ICI reported to be correlate with tumor mutational burden (TMB), but sarcoma is known to have low TMB. Thus, sarcoma in general considered to be less sensitive to ICI. However, according to our study, cutaneous angiosarcoma with high PD-1 and PD-L1 expression in the tumor microenvironment had statistically better overall survival compared with those without. This suggests that PD-1/L1 pathway might have some role in cutaneous angiosarcoma. Moreover, the recent study has shown that cutaneous angiosarcoma had higher TMB compared with angiosarcoma developed in other sites. Indeed, many successful cases of cutaneous angiosarcoma treated with ICI have been published. In 2020, we started physician-led clinical trial evaluating the efficacy of anti-PD-1 antibody, nivolumab, for cutaneous angiosarcoma who had prior taxanecontaining regimen. This study has potential to bring dramatic change in the management of advanced cutaneous angiosarcoma.

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