

Best Oral (BO4)  
Cervical Cancer

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# Newly developed adoptive cell therapy using autologous tumor-infiltrating lymphocytes in cervical cancer

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**Objective:** Adoptive cell therapy using tumor-infiltrating lymphocytes (TIL-ACT) is a promising immunotherapy using autologous lymphocytes ex vivo expanded from patient's tumor. We are performing a phase I study for malignant melanoma and then perform a phase II study for recurrent cervical cancer as to evaluate the safety and efficacy of TIL-ACT.

**Methods:** Three patients with malignant melanoma received TIL-ACT. Tumor fragments were cultured in outgrowth medium to produce TIL. Then T cell populations with tumor reactivity were selected for rapid expansion, generating over 1,000-fold TILs within 2 weeks and finally reinfused into the patient who received preparative lymphodepleting. IL-2 regimens after cell transfer were conducted to promote TIL growth and antitumor activity. The primary endpoint was to define treatment feasibility as completion of TIL-ACT without early cessation due to unacceptable adverse events. The secondary endpoints were safety assessed using CTCAE v. 4.0, clinical response; objective response rate based on the RECIST v.1.1.

**Results:** Three cases of TIL-ACT treated melanoma patients were successfully completed without unacceptable adverse events including one partial response, one stable disease and one progression disease case. Next, we manufactured a TIL products from specimens of three cervical cancer patient, and succeeded in producing TIL that meets the standards of TIL-ACT. Based on this result, TIL-ACT for cervical cancer was approved by the Japanese Ministry of Health, Labour and Welfare as advanced medical treatment.

**Conclusion:** TIL-ACT could be safely performed for Japanese patients with malignant melanoma. Currently, we are implementing TIL-ACT for recurrent cervical cancer.