

S05-7 **Generation of HPV therapeutic vaccine utilizing Lactobacillus display system**

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We present the development case with therapeutic vaccine to human papillomavirus (HPV). There is no therapeutic modality to the cervical intraepithelial neoplasia (CIN) patients, and it is a pressing need to develop the therapeutic modality to the CIN to defend woman's reproductive health. However, there is no clinical study which indicates definite clinical efficacy with immunological responses to the vaccine so far. We think that therapeutic vaccine to CIN should induce the cytotoxic T lymphocyte (CTL) to HPV protein at the cervical mucosa. Then, to develop the medicine that induces the mucosal cellular immunity, therapeutic HPV vaccine (Lac-E7) that expressing HPV16 E7 on the cell surface using the Lactobacillus is created, and it starts development that aims at the clinical application. The oral administration to the mice, the pharmacologic effect examination that confirms inducement of the mucosal cellular immunity, the nonclinical safety test of Lac-E7, and the GMP manufacturing for a clinical application are being executed now. The pharmacologic effect was examined, therefore high inducement of mucosal CTL not obtained with intramuscular inoculation was able to be confirmed, and abnormality that originated in Lac-E7 was not seen in the nonclinical safety test of Lac-E7. A clinical application of Lac-E7 is expected from these results as therapeutic vaccine to CIN patients.