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Chugai's SAIL66, under Development for CLDN6 Positive Solid Tumors, Non-Clinical Research Results Published in the Journal for ImmunoTherapy of Cancer

- A renowned academic journal in the field of cancer immunotherapy has accepted the non-clinical research results of SAIL66, which applies Dual-Ig technology, Chugai's proprietary antibody engineering technology
- Non-clinical studies suggest that SAIL66 has high selectivity for CLDN6 and may demonstrate superior anti-tumor effects compared to conventional T-cell engagers through CD3 and CD137 co-stimulation
- A Phase I clinical study to investigate SAIL66 in CLDN6-positive solid tumors is ongoing

TOKYO, October 24, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the results of non-clinical research on SAIL66, a Chugai's in-house project under Phase I clinical development for CLDN6 positive solid tumors, have been published in the Journal for ImmunoTherapy of Cancer. The journal is a renowned academic journal in the field of cancer immunotherapy, published by the Society for Immunotherapy of Cancer (SITC) in the United States.

"SAIL66, a next generation CLDN6-targeting T-cell engager, demonstrates potent antitumor efficacy through dual binding to CD3/CD137"
(https://doi.org/10.1136/jitc-2024-009563)

The following findings were demonstrated in this research, which suggest that SAIL66 may be useful as a treatment for CLDN6 positive solid tumors.

- Creation of SAIL66, which is a novel tri-specific T-cell engager* (TCE) for Claudin-6 (CLDN6), CD3, and CD137, applying Dual-Ig® technology, Chugai's proprietary antibody engineering technology
  *T-cell engager: A therapeutic agent that exerts anti-tumor effects by bringing T cells, which are immune cells, closer to tumor cells
- SAIL66 binds to CLDN6, which is specifically expressed on tumor tissue, and does not bind to other CLDN family proteins (CLDN3, 4, or 9) with similar amino sequences
- *in vitro*, SAIL66 was shown to strongly activate T cells and exert cancer cell cytotoxicity by not only triggering CD3 signaling like conventional TCEs, but also by providing CD137 co-stimulation
- In experiments using mice, SAIL66 was shown to increase intratumor T-cells and decrease the number of exhausted T cells, leading to enhanced antitumor efficacy compared to conventional TCEs

About SAIL66

SAIL66 is an anti-CLDN6/CD3/CD137 trispecific antibody and one of the next-generation T-cell engagers (TCEs) applying Chugai's proprietary Dual-Ig® technology. Conventional TCEs are designed to guide T

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cells to the target cancer cells by activating and engaging T cells through its binding to CD3 on T cells. Dual-Ig technology is a novel technology providing antibodies with the ability to induce CD137 signaling, a co-stimulating molecule, in addition to CD3 signaling. This property enables to maintain T cell activity, potentially inducing more potent antitumor effects than conventional T-cell engagers.[1]

Sources

1. Hirofumi Mikami et al. Engineering CD3/CD137 Dual Specificity into a DLL3-Targeted T-Cell Engager Enhances T-Cell Infiltration and Efficacy against Small-Cell Lung Cancer. Cancer Immunol Res June 2024; 12 (6): 719–730.

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