CT05 From preclinical models to first-in-human evaluation of STC-1010 immunotherapy in unresectable advanced colorectal cancer

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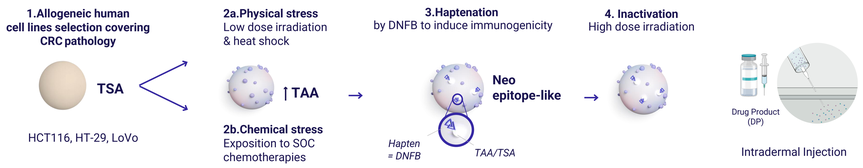
I. Addressing immune-resistant MSS CRC with SGC platform

- **Colorectal cancer** (CRC) is **the third most common cancer** and the **second leading cause of cancer death** worldwide. ~95% are MSS (micro satellite stable) tumors, largely **resistant to immunotherapy** due to **tumor plasticity** and **low immunogenicity**.
- **STC-1010 is a first-in-class allogeneic *in vivo* immunotherapy designed to restore immune responses by presenting clinically relevant tumor- and resistance-associated antigens** (TSA/TAA).
- STC-1010 is manufactured using **Brenus' Stimulated-Ghost-Cell platform (SGC)** that integrates **multi-omics characterization** to confirm stressed-induced antigen expression and their relevance using patient-derived datasets.
- This poster presents the **clinical translation** of STC-1010 through **BreAK CRC 001** (NCT06934538), a first-in-human Ph I/IIa study evaluating STC-1010 plus chemotherapy in MSS CRC.



CRC= Colorectal Cancer ; TSA= Tumor specific antigens ; SOC= Standard Of Care ; TAA= Tumor Associated Antigens ; DNFB= Dinitrofluorobenzene

Figure 1. STC-1010 manufacturing process enables to provide immunogenic TAA and TSA to patients.

II. Preclinical safety and anti-tumor immune activity of STC-1010

Safety and anti-tumor activity of murine STC-1010 surrogate in combination with FOLFOX in MC38

- mSTC-1010 demonstrated significant anti-tumor activity, both as a monotherapy and in combination with chemotherapies, with efficacy comparable to the standard of care.
- mSTC-1010 treatment improved safety compared with chemotherapies alone.
- The combination of FOLFOX and mSTC-1010 present similar tolerability profile to FOLFOX-treated group.

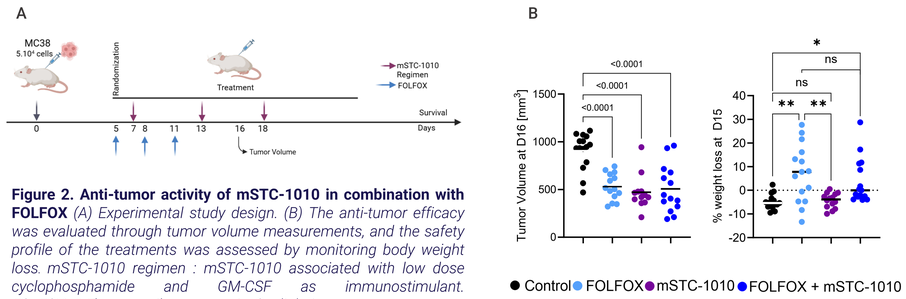


Figure 2. Anti-tumor activity of mSTC-1010 in combination with FOLFOX *(A) Experimental study design. (B) The anti-tumor efficacy was evaluated through tumor volume measurements, and the safety profile of the treatments was assessed by monitoring body weight loss. mSTC-1010 regimen : mSTC-1010 associated with low dose cyclophosphamide and GM-CSF as immunostimulant. FOLFOX: 5-Fluorouracile, Leucovorin, Oxaliplatin*

Anti-tumor immune activity of STC-1010 in HT29 CAM

- STC-1010 demonstrated significant anti-tumor activity with tumor size and metastasis reduction without toxicity.
- STC-1010 promoted the release of immune activating cytokines IL12 in peripheral blood and IFNγ within the TME.

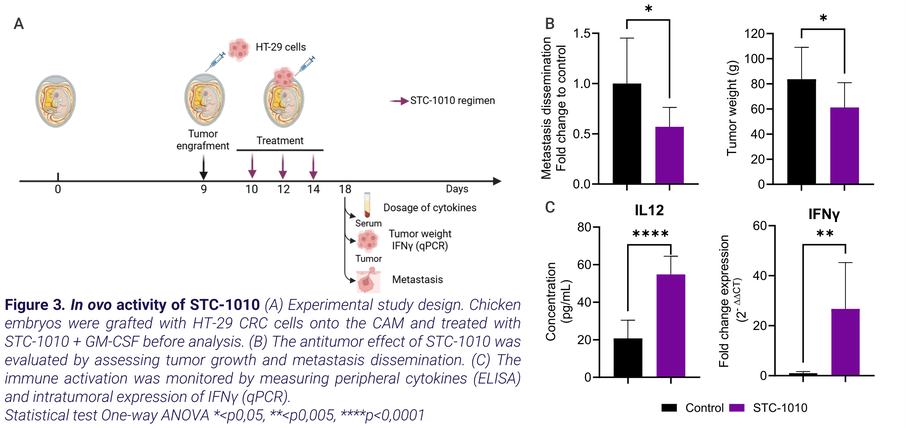
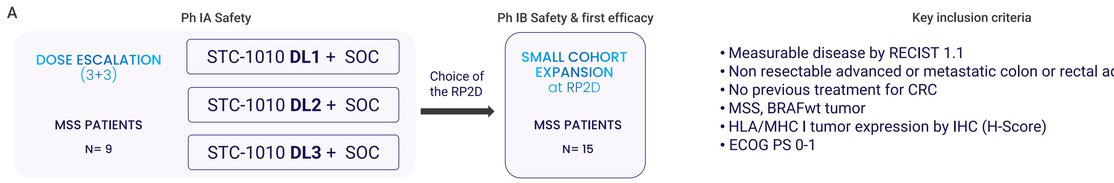
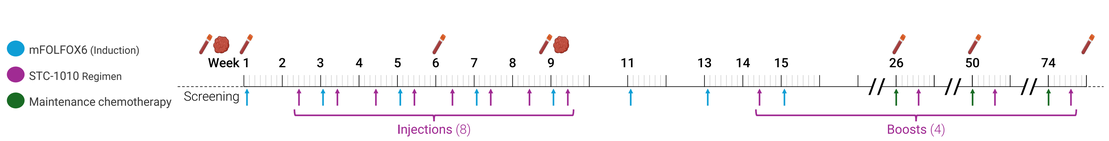
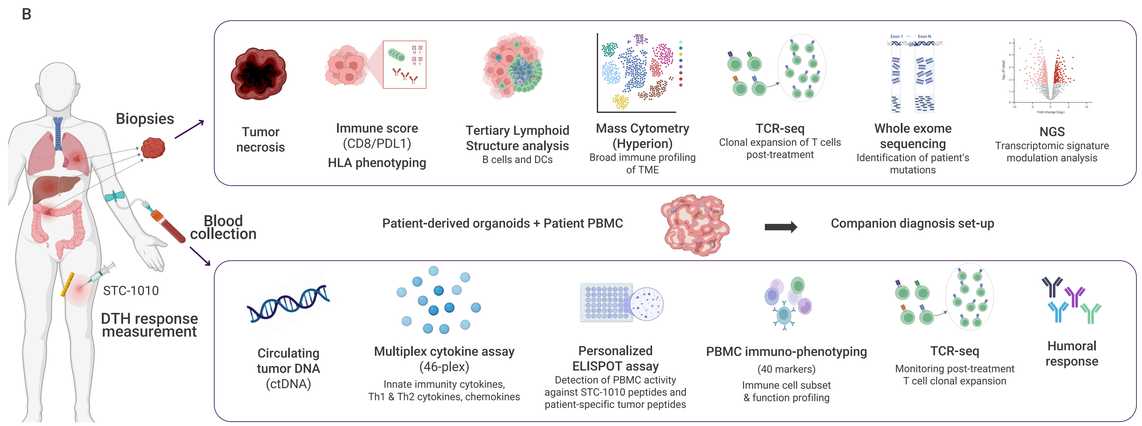


Figure 3. *In ovo* activity of STC-1010 *(A) Experimental study design. Chicken embryos were grafted with HT-29 CRC cells onto the CAM and treated with STC-1010 + GM-CSF before analysis. (B) The antitumor effect of STC-1010 was evaluated by assessing tumor growth and metastasis dissemination. (C) The immune activation was monitored by measuring peripheral cytokines (ELISA) and intratumoral expression of IFNγ (qPCR).*
*Statistical test One-way ANOVA *<p0,05, **<p0,005, ****p<0,0001*

III. First-in-human evaluation of STC-1010 in advanced metastatic MSS CRC : BreAK CRC 001 Phase I/IIa







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Gender		
	Men	3
	Women	3
Age (years)		
	Median	58.5
	Range	40 - 75
Stage		
	III	0
	IV	6
Primary tumor		
	Colon	4
	Right colon	1
	Left colon	3
	Rectum	2
Site of metastases		
	Lymph nodes	3
	Lung	2
	Liver	5
	Peritoneum	3
Mutational profile		
	KRAS	6
	TP53	5
	APC	4
	PIK3CA	3

Favorable safety and early immune activation

- STC-1010 is well tolerated, with no serious adverse events related to experimental treatment identified and no dose-limiting toxicities (DLTs) observed.
- At the data cutoff date, the disease control rate (DCR) was 100%.
- A DTH was induced (>5mm) post 4th injection compared with 1st injection in 83,3% of patients.

D

	DTH response (in mm) **Median** (Range)	**%>5mm**	**%>20mm**
After 1st injection	0 (0-10)	16,7%	0%
After 4th injection	17,5 (0-50)	83,3%	50%

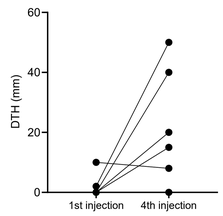

Figure 4. Overview of Phase I BreAK CRC 001 Clinical trial and first preliminary results. *(A) Study design showing treatment administration schedule and timing of blood and tumor sample collection. mFOLFOX6 : 5-FU, Leucovorin, Oxaliplatin ± bevacizumab (B) Overview of exploratory analyses performed on tumor and peripheral blood samples to characterize STC-1010-induced anti-tumor immune responses and identify potential predictive biomarkers. (C) Baseline characteristics of the first six patients enrolled in the Phase Ia cohort (D) Delayed-type hypersensitivity (DTH) is a T-cell–mediated immune response that occurs after exposure to a specific antigen and reflects activation of antigen-specific T cells. DTH responses were assessed 48 hours after the first and fourth injections. Each point represents DTH value for each patient.*

IV. CONCLUSION

- The Stimulated-Ghost-Cell (SGC) platform introduces a novel **allogeneic, in vivo approach to target immune-resistant MSS CRC,** by providing immunogenic and clinically relevant TAA and TSA to patients.
- STC-1010 demonstrates **a favorable safety profile (no DLTs), early and promising signs of efficacy** (100% DCR) **and immune engagement** (DTH responses) in a frontline metastatic setting, at a median follow-up of 6 months (n=6).
- Exploratory analyses are expected to elucidate underlying **tumor–immune mechanisms and identify predictive biomarkers**.
- **These results support translational bridging from preclinical models to clinical outcomes for the off-the-shelf SGC platform.**

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Figures were created using biorender.com

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