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# SOTIO Biotech

April 2024

# SOTIO at a Glance

## Clinical-stage biotech company developing cancer immunotherapies

- Privately owned, clinical-stage immuno-oncology company
- Robust program pipeline leveraging multiple tumor-targeted platform technologies
  - Antibody-drug conjugates leveraging collaborations with three industry leaders, immunocytokines, CAR-T cell therapies
- Proven track record of translating preclinical research into clinic
- Headquartered in Amsterdam (NL)
  - R&D operations in Prague (CZ), Cambridge (US) and Basel (CH)
  - 160 employees

*Well positioned to initiate and advance innovative ADC programs and to generate clinical POC for the portfolio programs*

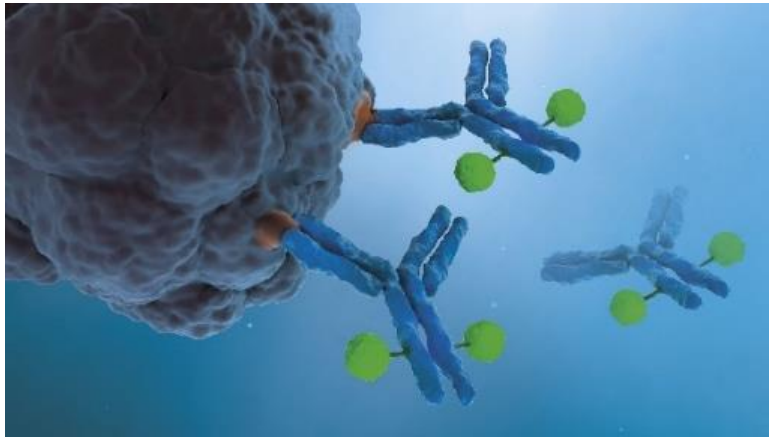
# Regulatory and Clinical development strategy
## General Concepts

- Internal regulatory department responsible for both EU and US activities
- Interactions with FDA and EMA from the earliest stages of clinical activities
- Ambition to have a fully synchronized clinical development plan in both geographies
- Analogical strategy for the selection of clinical sites
- Starting from the Phase I we include clinical sites in the US and Europe

# Key Programs
## Three clinical-stage technological platforms

### Antibody-drug conjugates

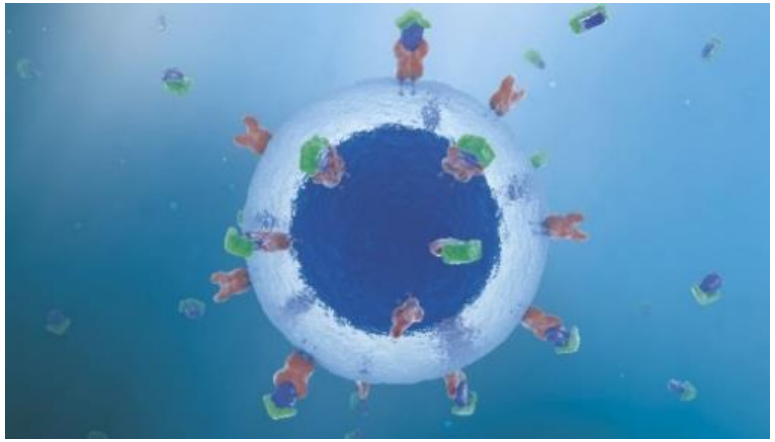
Access to multiple industry-leading ADC platforms



- Multi-target ADC collaborations with NBE-Therapeutics, LegoChem and Synaffix
- **SOT102**, Claudin18.2 ADC program in Phase I started Q1/2022
- **SOT106**, solid tumor ADC with IND filing in Q3 2025
- Three discovery stage programs

### IL-15 superagonist platform

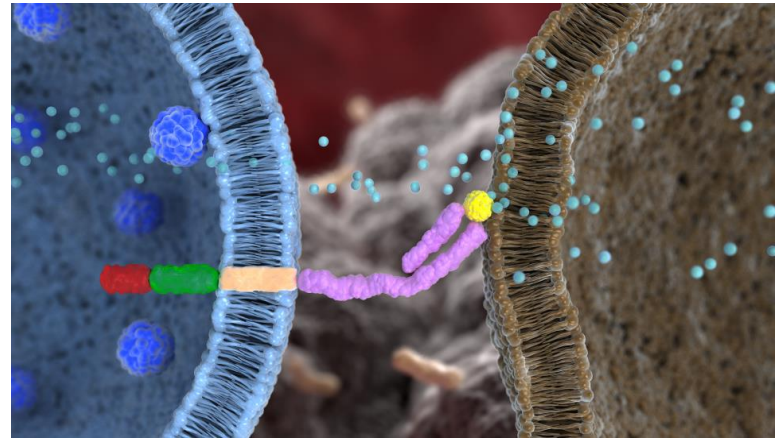
Differentiated agonist platform to stimulate NK and T cells



- **SOT201**, IL-15 x PD1 immunocytokine, IND/CTA filing 12/23

### T-cell therapies

Innovative CAR-T platform and programs in solid tumors



- **BOXR1030**, CAR-T in Phase I/II targeting GPC3 (HCC) with GOT2 transgene
- **BOXR platform** for enhanced metabolic profile of solid tumors CAR-T cells, MTAs with potential licensees ongoing

*Pipeline with strong focus on ADCs and immunocytokines*

# SOTIO Development Pipeline

## Diversified pipeline of differentiated product candidates

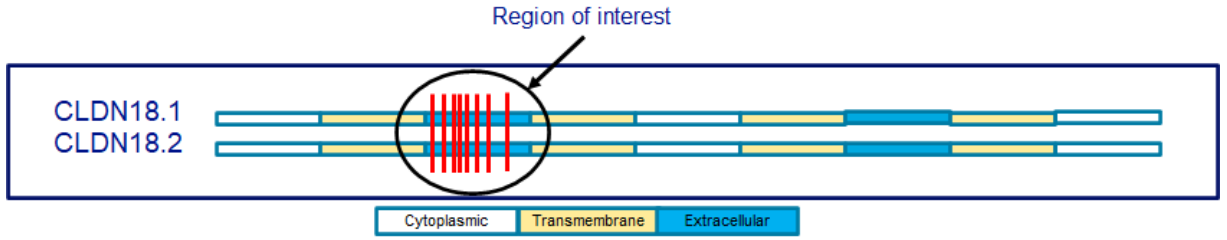
| Product | Target / Indications | Preclinical | Phase I | Phase II | Key Upcoming Milestone |
|---|---|---|---|---|---|
| **Antibody-drug conjugates** | | | | | |
| SOT102 | CLDN18.2 / PaCa, GaCa | | | | Q3 2024: complete dose escalation |
| SOT106 | not discl. / solid tumors | | | | Q3 2025: IND filing |
| SOT107 | not discl. | | | | H1 2024: initiate IND-enabling studies |
| SOT109 | not discl. | | | | |
| SOT110 | not discl. | | | | |
| **IL-15 superagonist based programs** | | | | | |
| SOT201 | IL-15mut x PD-1 / solid tumors | | | | Q2 2024: initiate Phase I |
| Nanril | Multiple solid tumors | | | | Preclinical combination studies |
| **T-cell therapies** | | | | | |
| BOXR1030 | GPC3 / HCC, SCCL, MCL | | | | Q1 2025: complete Phase I |

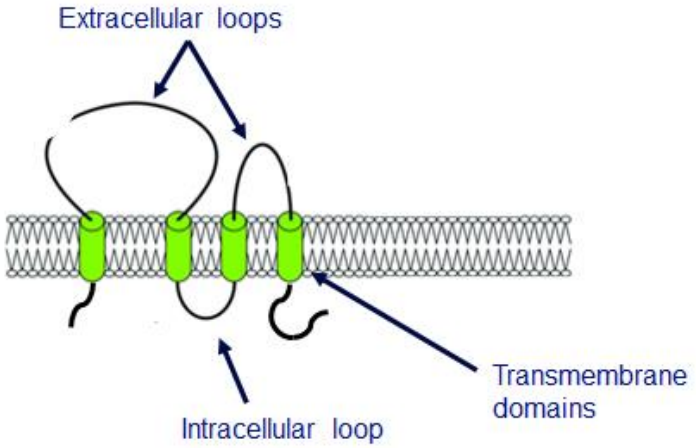
# SOT102

## Claudin 18.2-targeting ADC in Phase I

# CLDN18.2 Target Biology
## Uniquely cancer-expressed and clinically-validated antigen

- Tight junction protein, 4 transmembrane domains, 2 extracellular (EC) loops
- Isoform CLDN18.1 expressed on normal lung
- Isoform CLDN18.2 expressed on differentiated normal gastric cells and tumors
- CLDN18.1 and CLDN18.2 sequences differ only within EC 1
- High cross-species homology of CLDN18.2
  - 100% amino acid identity of the targeted EC 1 loop between mouse, rat, cynomolgus monkey and human
  - High relevance of rodent and NHP animal species to study safety and efficacy

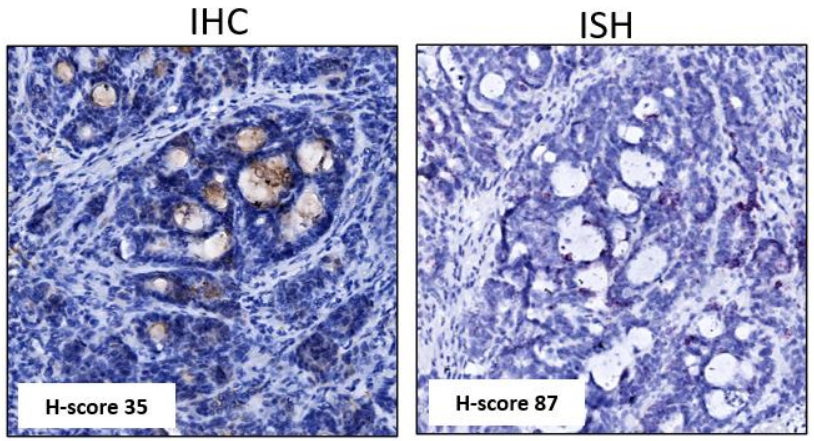


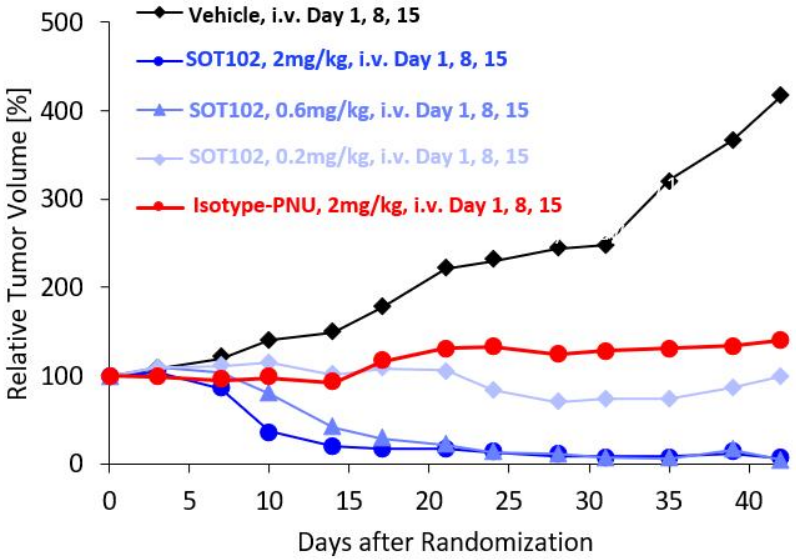



# SOT102 is Highly Active in CLDN18.2 Expressing Tumors

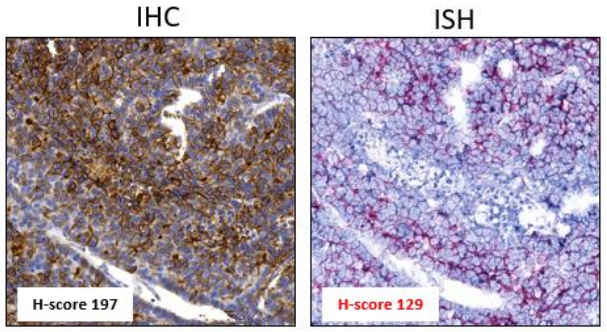
## Complete regression in gastric, pancreatic, colon and liver cancer PDXs

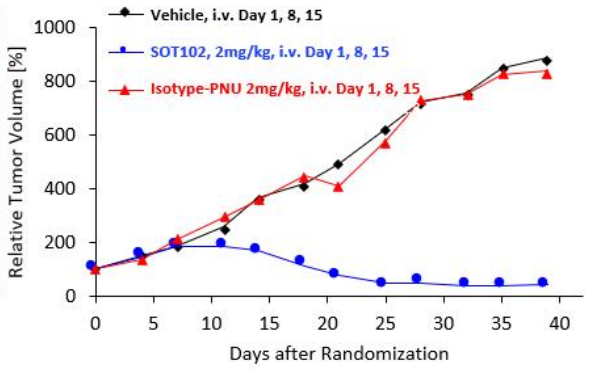
### GXA 3037– Gastric Cancer



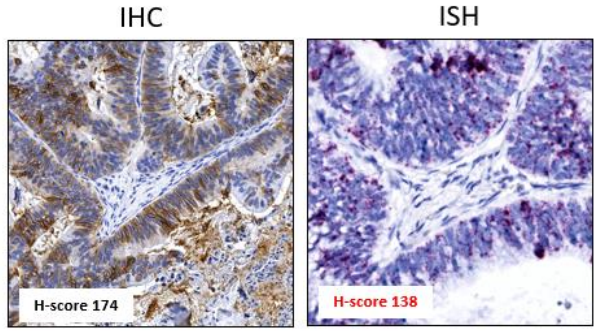



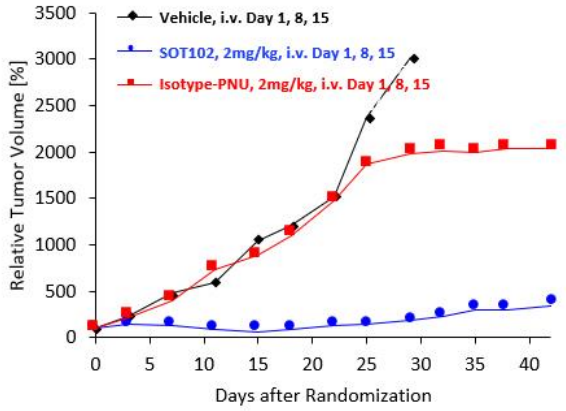

### CXF 742 – Colon Cancer




### LIXF 3109 – Lung Cancer



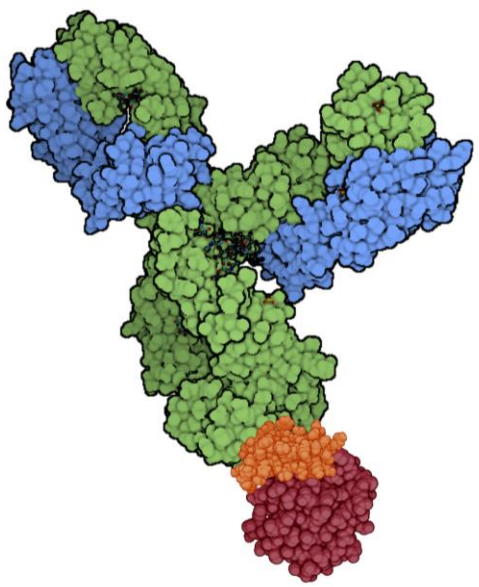



# SOT201

## PD-1 Targeted IL-15 Superagonistic Immunocytokine

# SOT201 Unique Proposition
## PD-1-targeted *cis*-acting IL-15 agonist at IND stage

**SOT201**

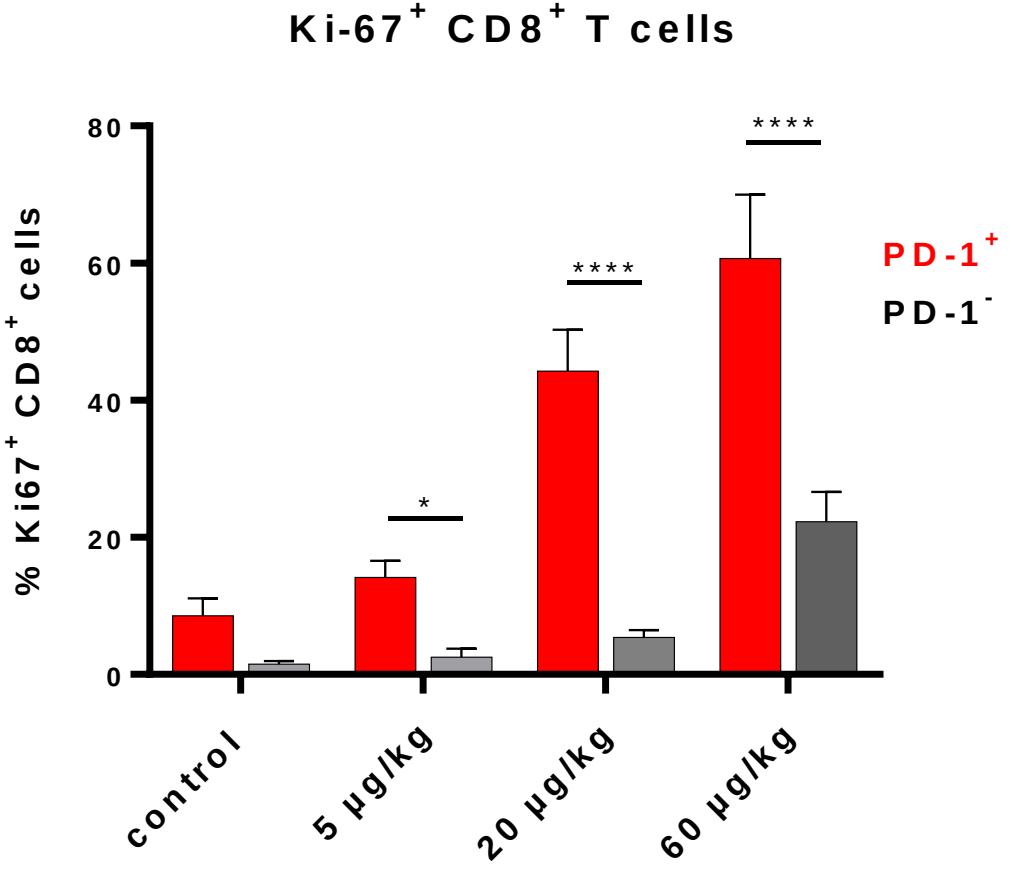



- Optimally-balanced bi-functionality between PD-1 blockade and cytokine co-stimulatory signal provides a clear mechanistic rational and superior therapeutic index than individual combination
- Two synergistic MoAs exploiting *cis*-activation to combine different signaling pathways in one molecule
- Preferential and selective activation of several key PD-1 expressing T-cell populations may provide superior response rates
- Multi-optional clinical development with several strategic opportunities
  - Increased chance of response to anti-PD(L)1-based therapies at the population level, e.g., PD-L1 and tumor mutational burden (TMB)
  - Various attractive combination opportunities to increase success rate
- IND filing year end, start of phase I in Q2 2024

# SOT201-Mediated Activation of CD8+ T Cells

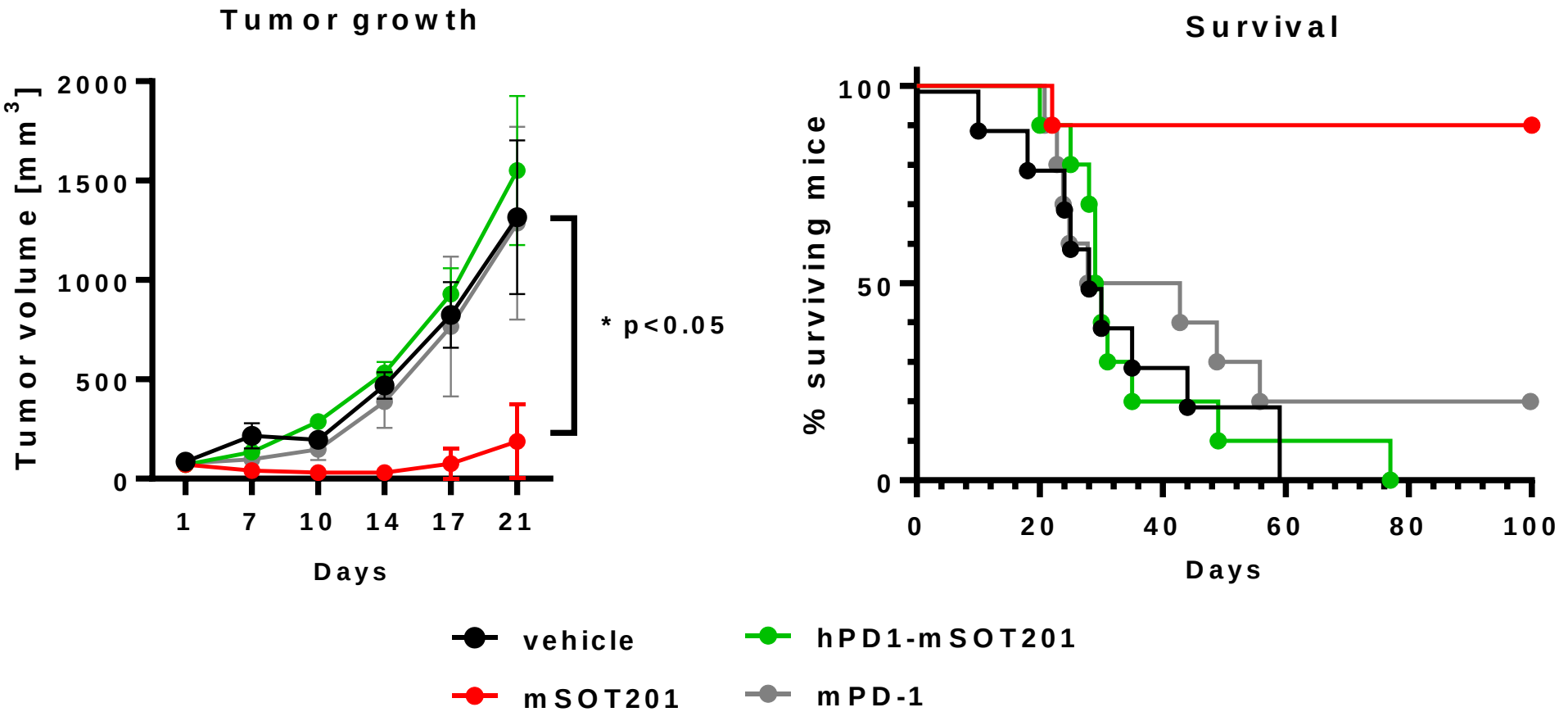
## T-cell activation in Cynomolgus monkeys depends on PD-1 expression

- PD-1 expression determines the activation of CD8+ T cells
- SOT201 mediated *cis*-acting MoA confirmed *in vivo* in Cynomolgus monkeys
- Treg counts substantially less modulated by SOT201




8 animals/group, IV administration of SOT201. Blood drawn 5 days after SOT201 administration in Cynomolgus monkeys. Proliferation of PD-1+ and PD-1- CD8+ T cells detected by flow cytometry.

# Mouse SOT201 Induces Tumor Regression and Long-lasting Responses in Syngeneic MC38 Tumor-bearing Mice




10 mice/group, D0 = 100 mm³, dosing with mSOT201 or hPD-1-mSOT201 at 5 mg/kg IV and mPD-1 at 4.5 mg/kg (equimolar to mSOT201) IP.
**All compounds dosed only once at D0**. Mouse surrogate molecules based on RMP1-14 mouse anti-PD-1 antibody and human RLI-$15_{AQA}$ mutein

# SOT201

## Ready to start enrollment in the US, advanced status of the regulatory review in EU

- FDA approved the Phase I protocol
  - Recruitment to start at MD Anderson

- EMA process slower
  - Review process at its final stages
  - Recruitment in Europe to start with aprox.2-3 months delay compared to the US