

# **CORIST Part 1 of Phase II - Interim Results**

**Audiocast June 24, 2021 at 10:00 am CEST**



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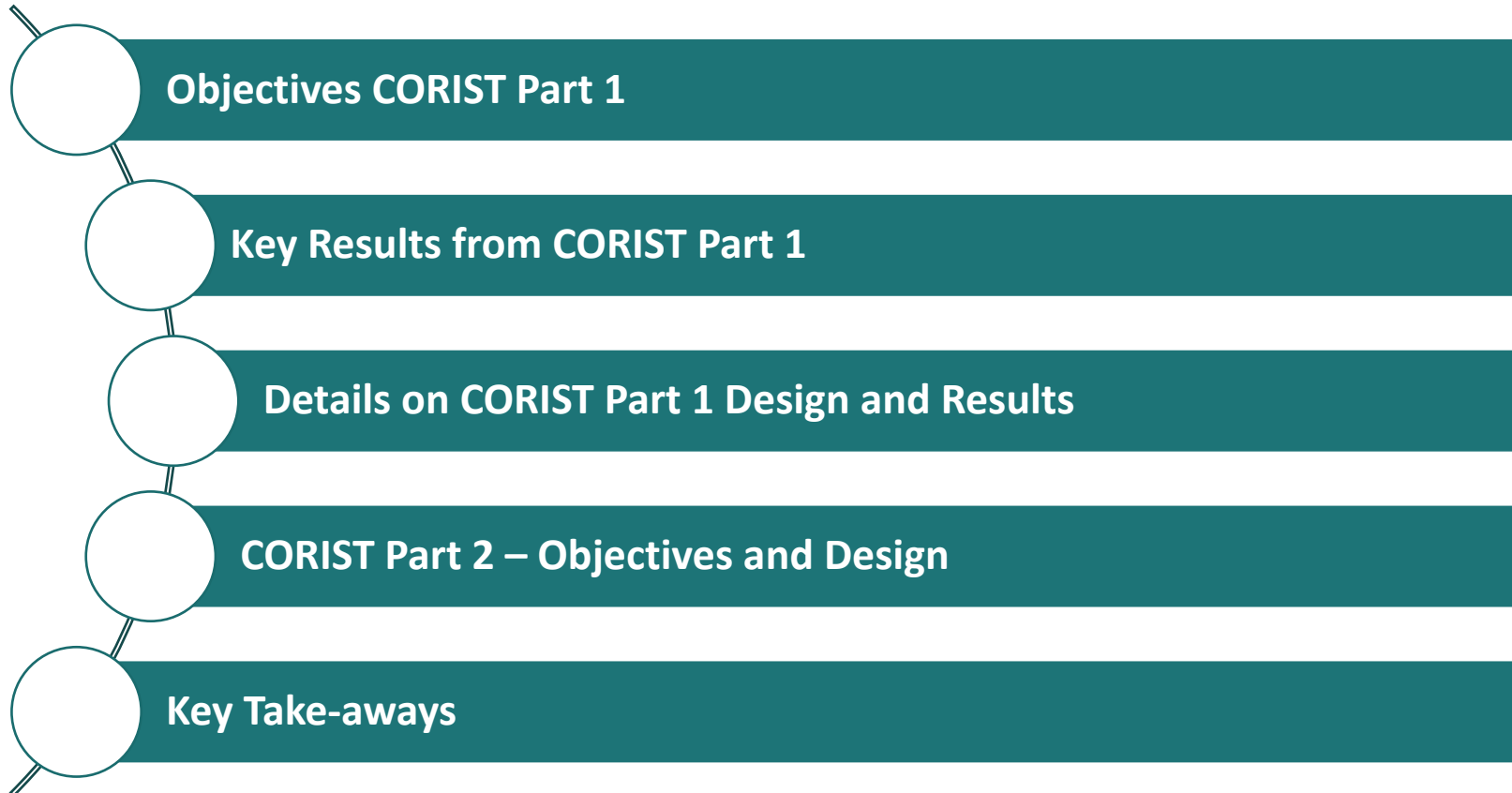
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# Agenda



# Objectives of CORIST Part 1 of Phase II



## Primary Objective

Establish Maximum Tolerated Dose (MTD) of SCO-101 in combination with FOLFIRI



## Secondary Objective

Evaluate PK profile of SCO-101 in combination with FOLFIRI



# Objectives of CORIST Part 1 of Phase II and New Knowledge



## Primary Objective

Establish Maximum Tolerated Dose (MTD) of SCO-101 in combination with FOLFIRI



## Secondary Objective

Evaluate PK profile of SCO-101 in combination with FOLFIRI



## New Knowledge

RAS identified as predictive biomarker



# Key Results from CORIST Part 1

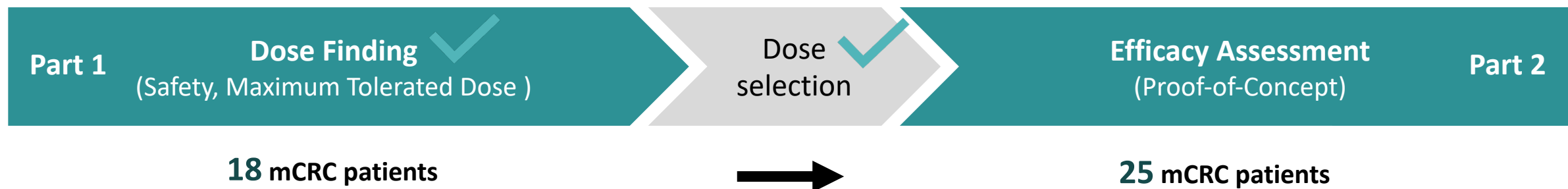


- Well tolerated dose of SCO-101 in combination with FOLFIRI established
- SCO-101 notably potentiated the biological effect of FOLFIRI in patients
- Identification of the predictive biomarker (RAS wild-type), which can guide patient selection for optimal treatment response and de-risk part 2 of CORIST
- **Preliminary effect measure**
  - Five of the 8 RAS wild-type patients in the study have shown stable disease for more than 8 weeks
  - Two of the 5 patients experienced a reduction in tumor volume (<30%)
  - One patient has been on trial for more than 24 weeks and is still on therapy as part of the study

**We are now ready to advance to the proof-of-concept study (part 2) of CORIST**

# CORIST Phase II - Study Design

**Patient population:** Patients with metastatic colorectal cancer (mCRC) with acquired resistance to FOLFIRI (with no other treatment options)



## Aim of CORIST Part 1:

Establish a well tolerated dose of SCO-101 in combination with FOLFIRI to be used in part 2



# Treatment Design for Combination of SCO-101 and FOLFIRI



Treatment Cycle														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
SCO-101														
FOLFIRI														

- Tumor evaluation performed after every 4 treatment cycles (8 weeks) by CT-scan
- Patients continue on treatment until progression of disease or withdrawal from study



# Dosing in Cohort 1 and Cohort 2



Treatment Cycle														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14
SCO-101														
FOLFIRI														

**Two cohorts were treated in CORIST part 1**

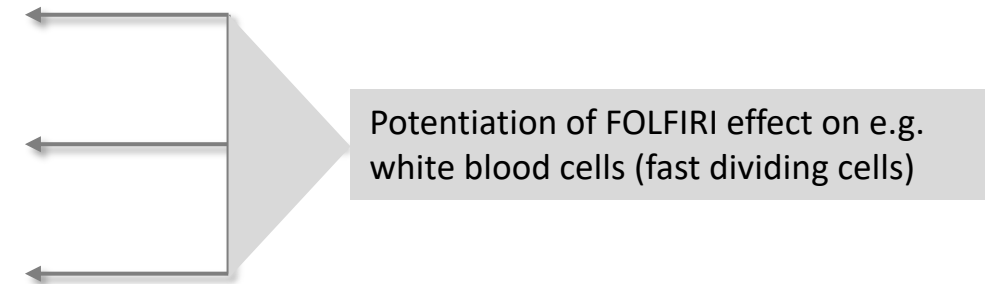
**Cohort 1:** Fixed dose of SCO-101 with varying doses of FOLFIRI (12 patients)

**Cohort 2:** Reduced dose of SCO-101 with fixed dose of FOLFIRI (6 patients)

# Safety and Dose Finding – Complete Patient Population



mCRC patients			Worst level of AE (treatment related)	
	SCO-101	FOLFIRI	Non-hematological	Hematological
Cohort 1	150 mg	Level 1		
		Level 2		
		Level 3 FOLFIRI (+G-CSF)		
Cohort 2	Reduced dose	Level 3 FOLFIRI (+G-CSF)		



## Explanation of AE severity

Grade 1 and grade 2:	Mild or moderate symptoms (Acceptable)
Grade 3:	Severe (Acceptable if treatable)
Grade 4:	Unacceptable

# Safety and Dose Finding - Stratification by RAS Biomarker



mCRC mixed population RAS mut & RAS wild-type			Worst level of AE (treatment related)	
SCO-101		FOLFIRI	Non-hematological	Hematological
Cohort 1	150 mg	Level 1		
		Level 2		
		Level 3 FOLFIRI (+G-CSF)		
Cohort 2	Reduced dose	Level 3 FOLFIRI (+G-CSF)		

mCRC with RAS wild-type			Worst level of AE (treatment related)	
SCO-101		FOLFIRI	Non-hematological	Hematological
Cohort 1	150 mg	Level 1		
		Level 2		
		Level 3 FOLFIRI (+G-CSF)		
Cohort 2	Reduced dose	Level 3 FOLFIRI (+G-CSF)		

## Explanation of AE severity

Grade 1 and grade 2:	Mild or moderate symptoms (Acceptable)
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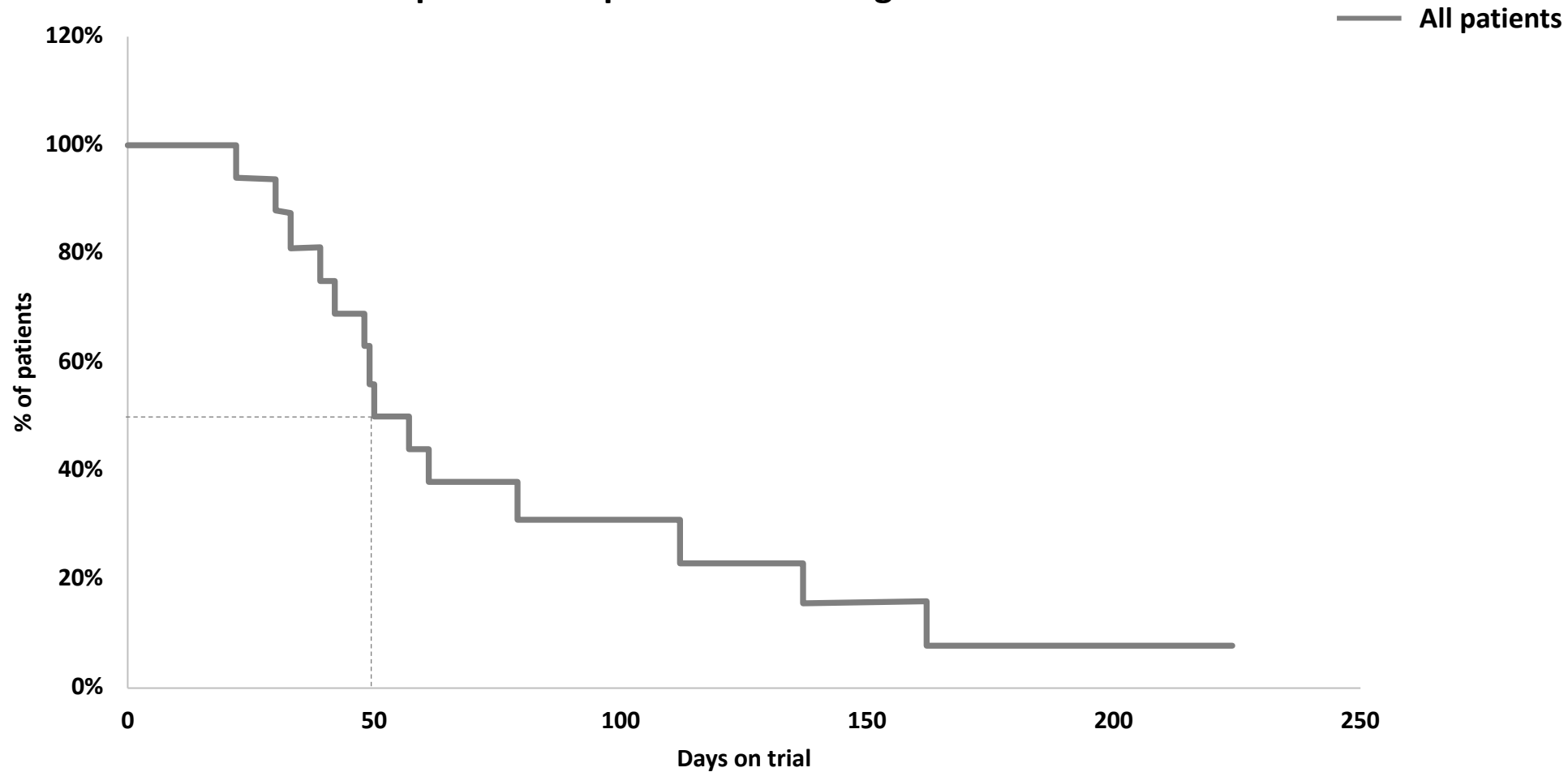
## What is RAS?

RAS is a known oncogene in tumors where mutations are observed to impact disease prognosis

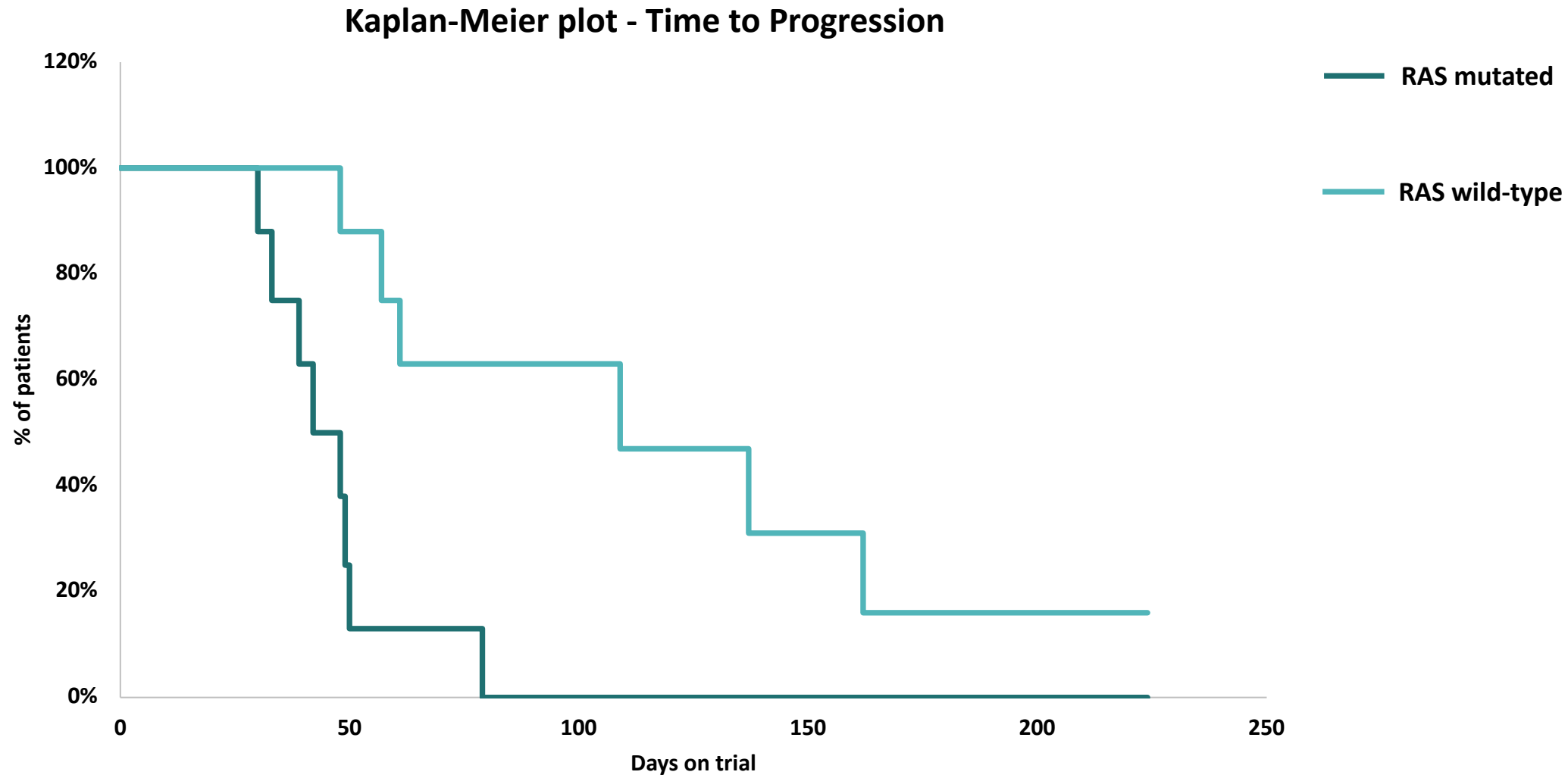
# Time on Trial – All Patients, CORIST Part 1



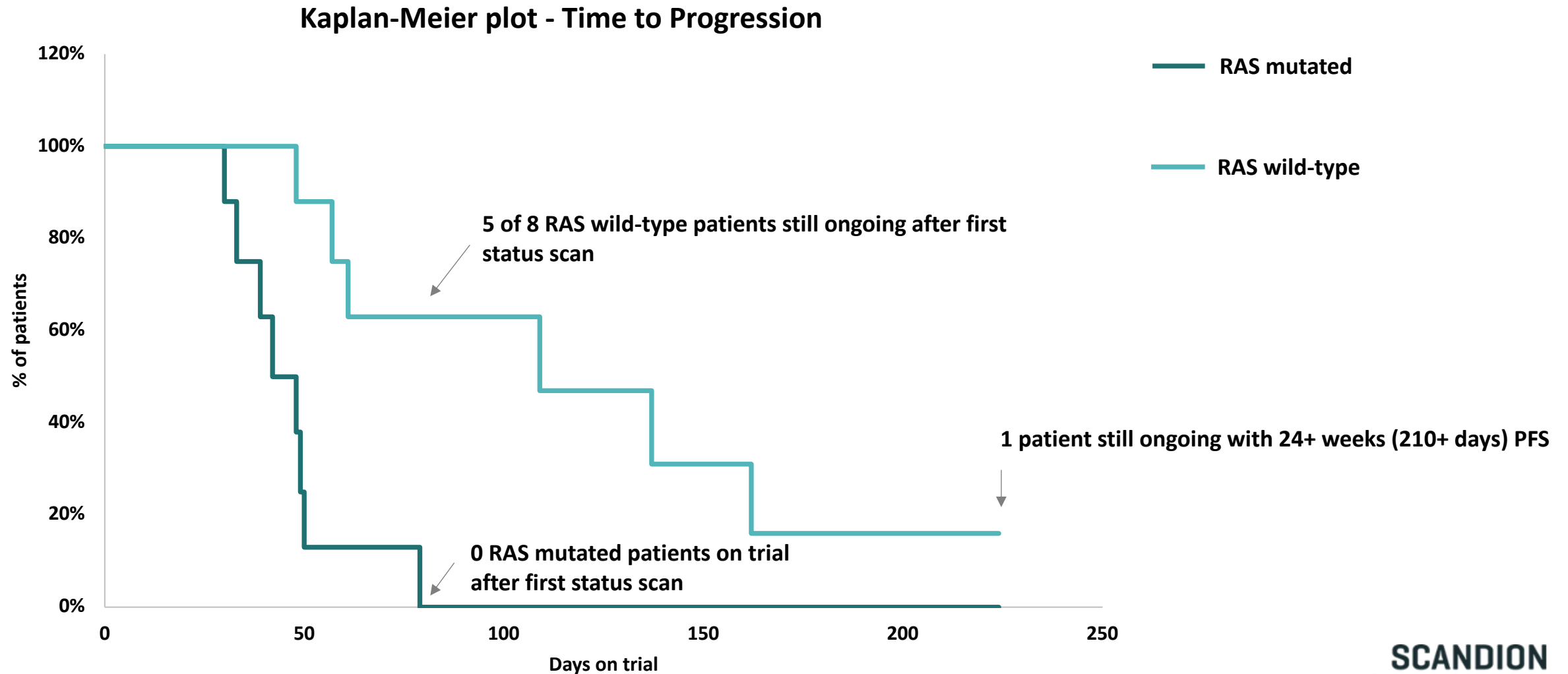
Kaplan-Meier plot: Time to Progression



# Stratification by RAS Biomarker (Time on Trial)



# Stratification by RAS Biomarker (Time on Trial)



# The RAS Biomarker Will Be Used for Patient Selection in CORIST Part 2





# Objectives of the CORIST Part 2 Study



## Primary Objectives

Safety and Tolerability

Objective Response Rate (ORR)

## Secondary Objectives

Clinical Benefit Rate (CBR), Progression Free Survival (PFS) and Overall Survival (OS)

Duration of Response (DOR)

Clinical biomarkers to predict response to SCO-101 in combination with FOLFIRI

# CORIST Phase II Part 2

**Aim:** Evaluate efficacy of well tolerated dose of SCO-101 and FOLFIRI

**Patient population:** Patients with **RAS wild-type** metastatic colorectal cancer with acquired resistance to FOLFIRI (with no other treatment options)

## Updated plan following finalization of CORIST part 1:

- 25 patients
- Focus on mCRC patients with RAS wild-type tumors
- Treat with well tolerated dose for RAS wild-type

## Timelines and acceleration plan

- Expected data readout may extend into Q3, 2022
- Additional sites to be initiated to increase recruitment rate

Submission of amendment to study protocol in July 2021 (approval expected 1 to 2 months following submission)

# Key Take-aways



**All objectives met for Part 1 of the CORIST Phase II study**

**Well tolerated dose of SCO-101 in combination with FOLFIRI established**

**Identification of RAS biomarker enables de-risking of the CORIST Part 2 study**

**Scandion Oncology is ready to advance to the Part 2 proof-of-concept study**



***“There is a need for new ways of thinking treatment of solid cancers.  
With the introduction of SCO-101 there is a unique possibility to  
modulate the metabolism and pharmacokinetics of chemotherapy.***

***This could be the beginning of a paradigm shift in overcoming  
resistance to chemotherapy.”***

**BENNY VITTRUP, MD**

Chief Physician, Department of Oncology, Herlev & Gentofte Hospital, University of Copenhagen