

ASCELIA PHARMA

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PRESENTATION OF Q1-2022 REPORT

Present from Ascelia Pharma:

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CMO Carl Bjartmar | CCO Julie Waras Brogren

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ASCELIA PHARMA – COMPANY HIGHLIGHTS



**TO IMPROVE THE LIFE
OF PEOPLE LIVING WITH CANCER
BY OFFERING BETTER
TREATMENT OPTIONS**

ADVANCING ORPHAN ONCOLOGY

- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
 - **ORVIGLANCE** – in global Phase 3; FDA Orphan Drug Designation
 - **ONCORAL** – ready for Phase 2

BUILDING GLOBAL CAPABILITIES

- Based in Malmö (Sweden), US affiliate in New Jersey (US)
- Solid balance sheet and financed into H2 2023
- Listed on NASDAQ Stockholm (Ticker: ACE)

BUILDING VALUE AND GROWTH TRAJECTORY



RECENT KEY EVENTS

Key events in Q1-2022

- Feb** Orviglance comparison study to gadolinium accepted to ESGAR conference
- Mar** Strong healthcare professional support to Orviglance from market research
- Mar** Suspension of Russian clinical activities for Orviglance
- Mar** Last patient visit in Orviglance Hepatic Impairment Study

Key events after Q1-2022

- May** Results from Orviglance Food Effect Study positively show that liver image enhancement is not influenced by intake of light meal





PORTFOLIO

ORVIGLANCE

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

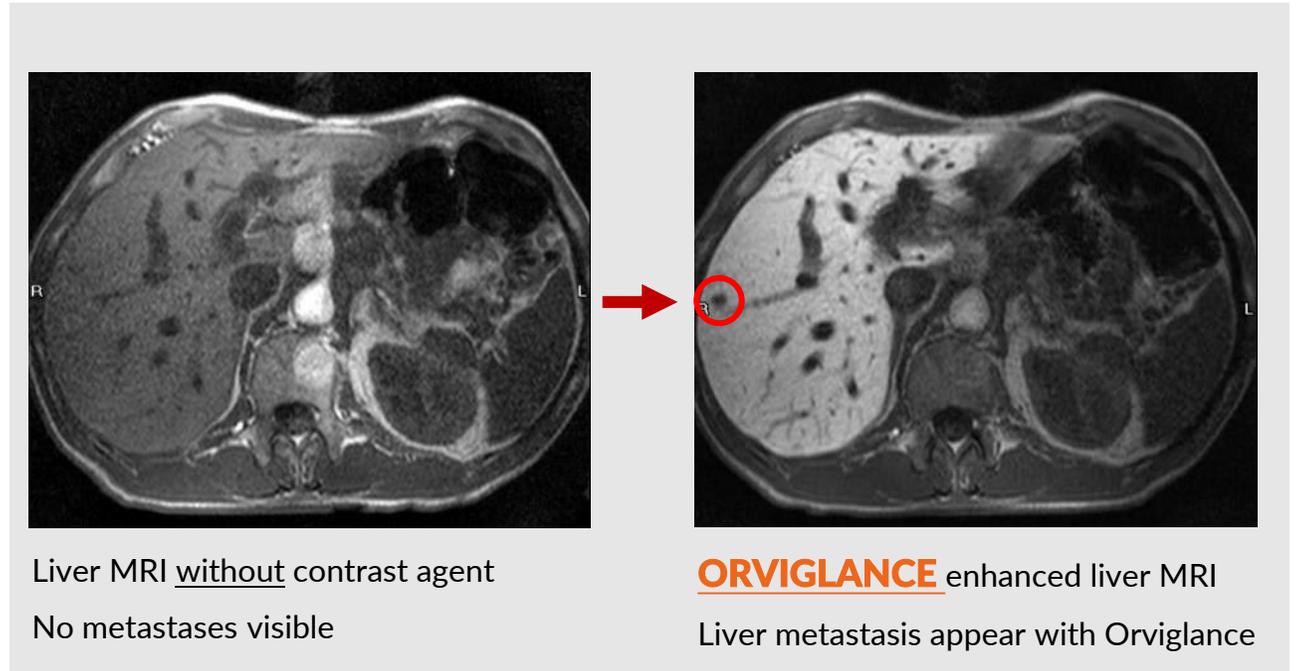
ORVIGLANCE – PHASE 3 LIVER MRI CONTRAST AGENT

NOVEL LIVER MRI CONTRAST AGENT

- Diagnostic drug for use in liver MRI scan to detect cancer
- Liver metastases common in many cancer types and often the cause of mortality
- Targeting patients at risk of potentially fatal side-effect from the current contrast agents on the market

SOLID PROGRESS

- Strong clinical Phase 2 results (p-values <0.0001)
- Ongoing Global Phase 3 study
- Orphan Drug Designation from FDA



ORVIGLANCE PHASE 1 & 2 RESULTS (6 STUDIES)

Consistent strong efficacy readout and safety profile

Blind read study of all images vs. unenhanced MRI (178 persons)

- Significantly improved MRI
- 33% more lesions
- Lesion visualization
 - Delineation (border sharpness): **p-value <0.0001**
 - Conspicuity (contrast vs. background): **p-value <0.0001**

Proceed to Phase 3

ORVIGLANCE ONGOING PHASE 3 STUDY – SPARKLE

<p>Patients</p> 	<ul style="list-style-type: none">• Global study, 200 patients• Known or suspected focal liver lesions and severe renal impairment	<ul style="list-style-type: none">• Around 50 sites in the US, Europe, Latin America• Working with active and new sites to accelerate enrollment
<p>Comparator</p> 	<p>Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI</p>	<p>No randomization – each patient as own control</p>
<p>Endpoint</p> 	<p>Lesion visualization</p> <ul style="list-style-type: none">• Lesion border delineation• Conspicuity	<ul style="list-style-type: none">• Same endpoints as in Phase 2• Same endpoints as for approved gadolinium agents
<p>Follow-up</p> 	<p>Less than a week</p>	<p>Expected pivotal study patient enrollment: 2022</p>

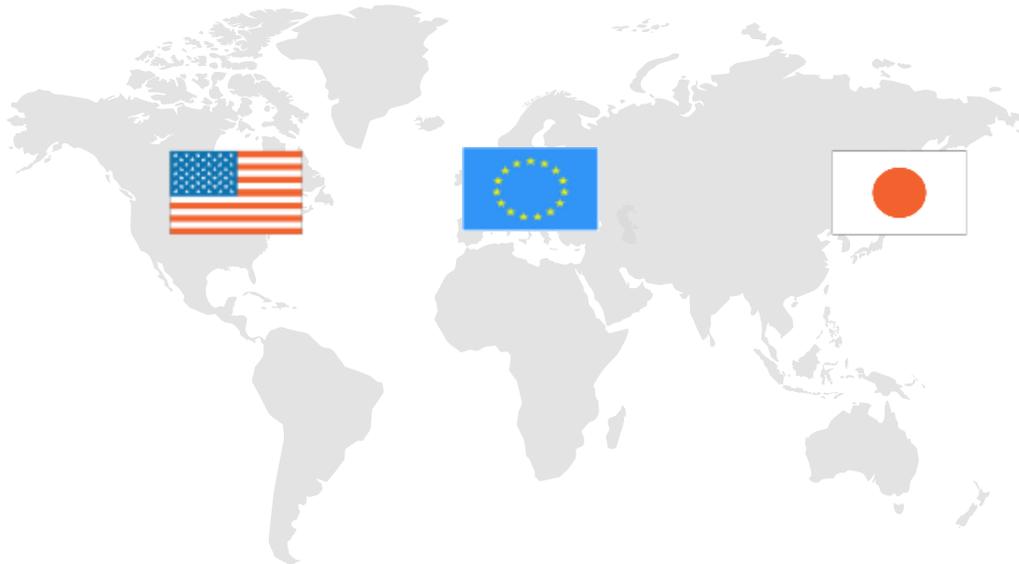
ORVIGLANCE PIVOTAL PROGRAM – SUPPORTING STUDIES

	Study design	Status and Results
Food Effect Study	<ul style="list-style-type: none">• Crossover study in healthy volunteers• Evaluate the impact of food intake on absorption and signal intensity of Orviglance (light meal or full meal vs. fasting condition)	<ul style="list-style-type: none">• Intake of light meal prior to Orviglance MRI provides similar liver image enhancement as Orviglance MRI on fasting condition• Robust image enhancement of the liver after Orviglance compared to an MRI without a contrast agent
Hepatic Impairment Study	<ul style="list-style-type: none">• Sequential cohort study in patients with different degrees of hepatic impairment• Evaluate the effect of liver impairment on the safety, pharmacokinetics and pharmacodynamics of Orviglance	<ul style="list-style-type: none">• Last patient visit completed in March 2022• No serious adverse events reported• Final results expected Q2/Q3 2022

ORVIGLANCE MARKET \$500-600 MILLION ANNUALLY

\$500-600M ADDRESSABLE MARKET IN US, EU AND JAPAN

- Ascelia Pharma to commercialize in the US
- RoW commercialization with partners



DRIVERS

- Patients with suspected primary liver cancer or liver metastases and severe kidney impairment (~4%)
- Actual imaging procedures (real-world data)¹
- Payer and expert input (+75 stakeholders)²

UPSIDES

- Other markets, e.g., China
- Annual growth of 4-5%

Sources:

1) Ascelia Pharma market research with Decision Resources Group, 2020

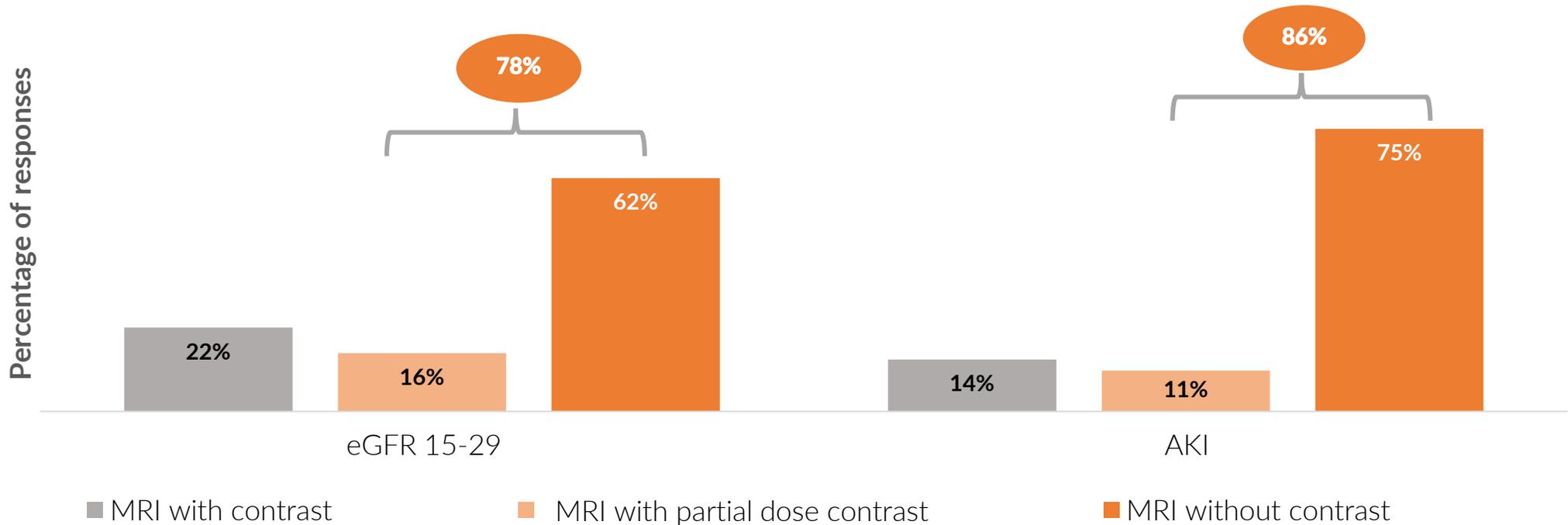
2) Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

MARKET RESEARCH MARCH 2022

- FOR ORVIGLANCE TARGET PATIENTS, US HEALTHCARE PROFESSIONALS CURRENTLY PREFER UNENHANCED MRI

78% PREFER MRI WITHOUT OR WITH PARTIAL DOSE CONTRAST FOR PATIENTS WITH LOW eGFR

... EVEN MORE FOR AKI PATIENTS



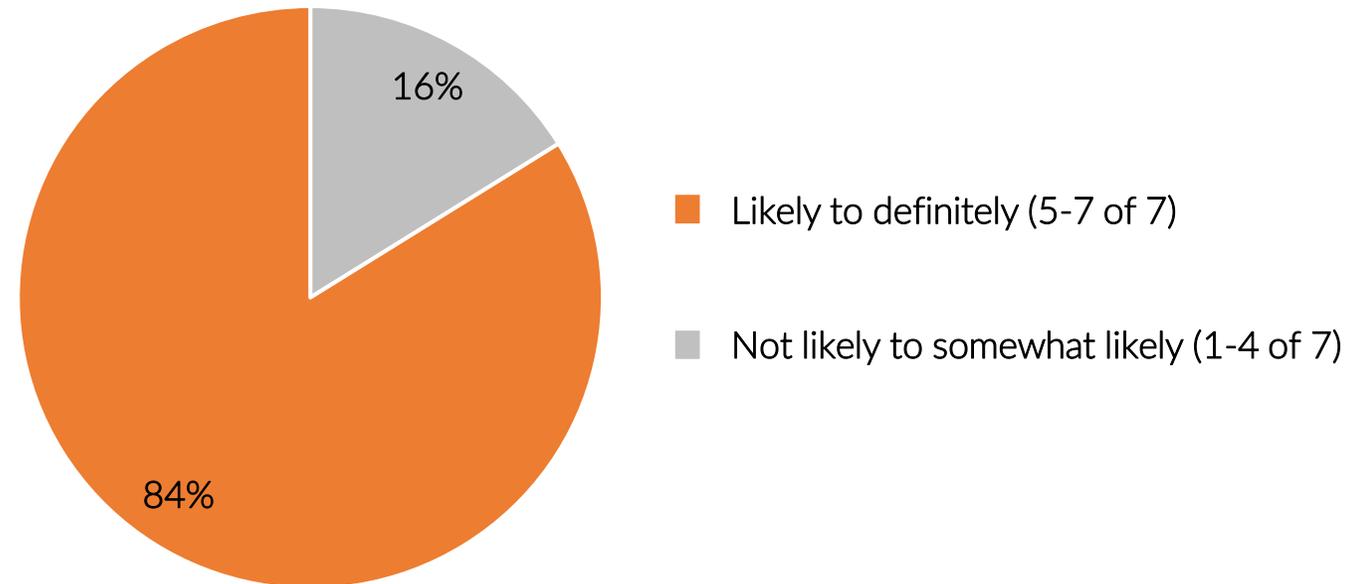
N=103 oncologist, nephrologist, and radiologist responses.

Q: Please assign priority to the imaging tests in the sequence or order in which you would recommend or perform them (shown as % split of first priority of MRI options)

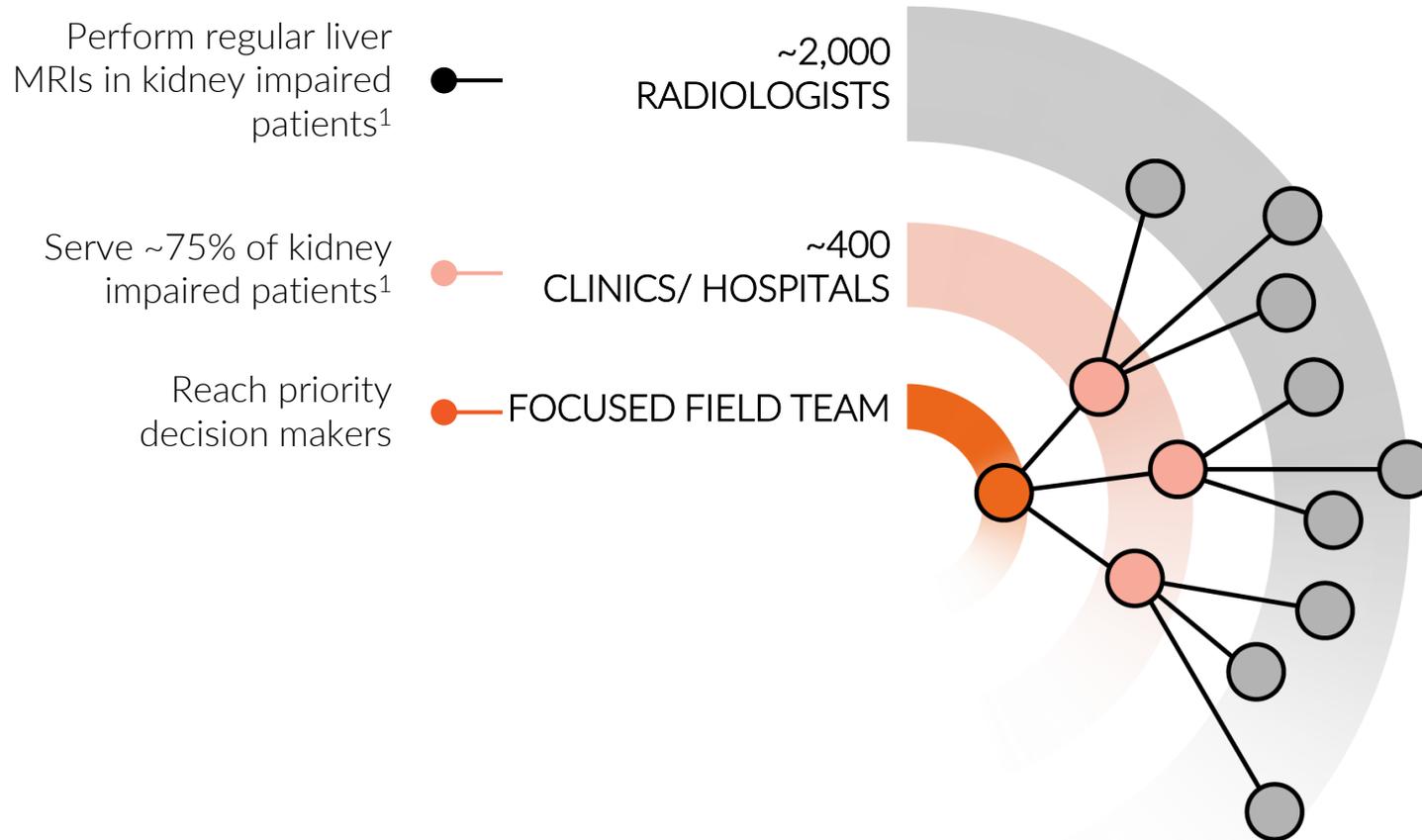
MARKET RESEARCH FROM MARCH 2022

– 84% US HEALTHCARE PROFESSIONALS SAY THEY WILL USE ORVIGLANCE

LIKELIHOOD OF USING ORVIGLANCE FOR TARGET PATIENTS



CAPTURING US MARKET VALUE WITH ASCELIA'S TEAM



BUILDING ASCELIA U.S. TEAM

New Jersey office (up to 40 FTEs at launch)

Cambrex manufacturing partner in New Jersey

BUILDING OUT U.S. FOOTPRINT

SPARKLE Phase 3 study at leading US Sites including Stanford, Mass. General, Duke University, UCLA Medical Center

Sources:

1) Ascelia Pharma analysis based on market research with Decision Resources Group, 2020



PORTFOLIO

ORVIGLANCE

Liver contrast agent in ongoing Phase 3

ONCORAL

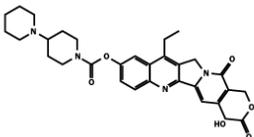
Daily oral chemotherapy ready for Phase 2

IMPROVING IRINOTECAN EFFICACY and TOLERABILITY

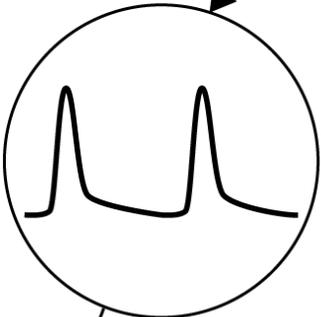
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing

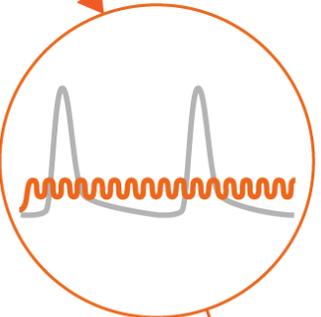
irinotecan



High-dose IV infusion every 3 weeks



Oncoral low-dosing daily tablet

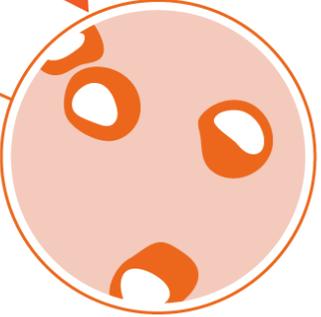


Serious side-effects limit efficacy



Tumor cells

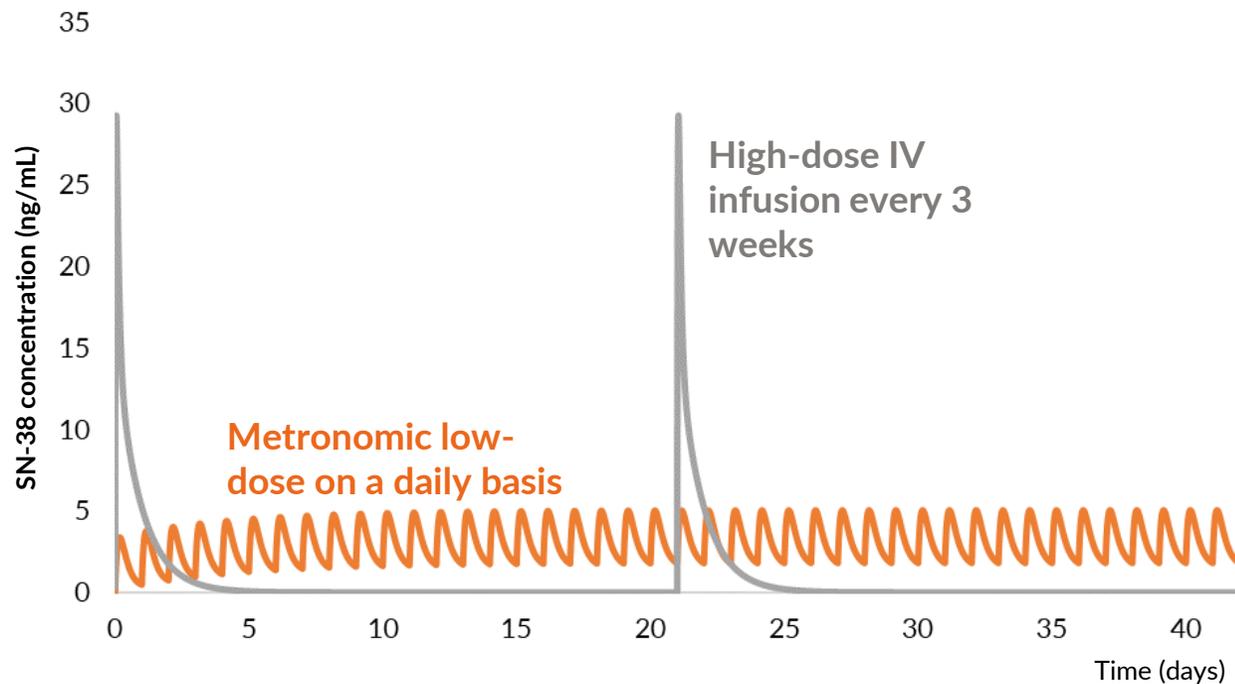
Potential for improved efficacy with reduced side-effects



Tumor cells

ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar performed by Pkxpert AB

Oncoral Phase 1 results

- Well tolerated, no unexpected side-effects
- Hematological toxicities mild-moderate (grade 1 or 2)⁴
- Efficacy: Stable disease even in patients previously treated with IV irinotecan

Infrequent high-dose IV irinotecan

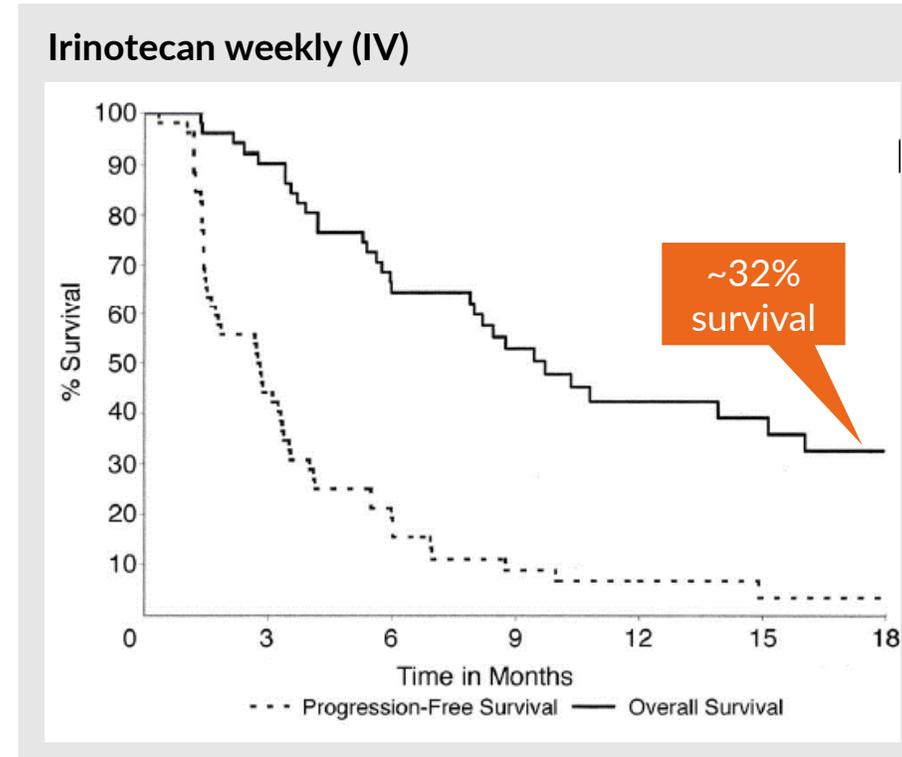
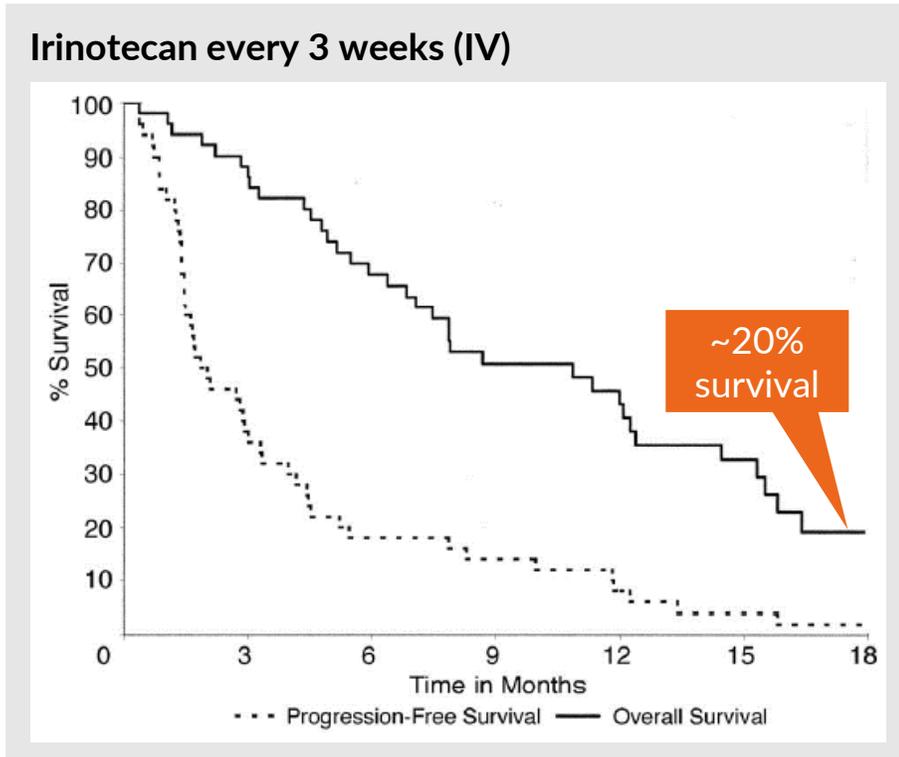
Gastrointestinal and hematological side effects, ~30% severe or life-threatening (grade 3 or 4)¹

Frequent (metronomic) low-dose irinotecan

- Several studies show improved tolerability^{2,3}
- Daily dosing – adjust quickly if acute toxicity

IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

Overall survival: Improved from 20% (dosing every third week) to 32% (weekly dosing)¹



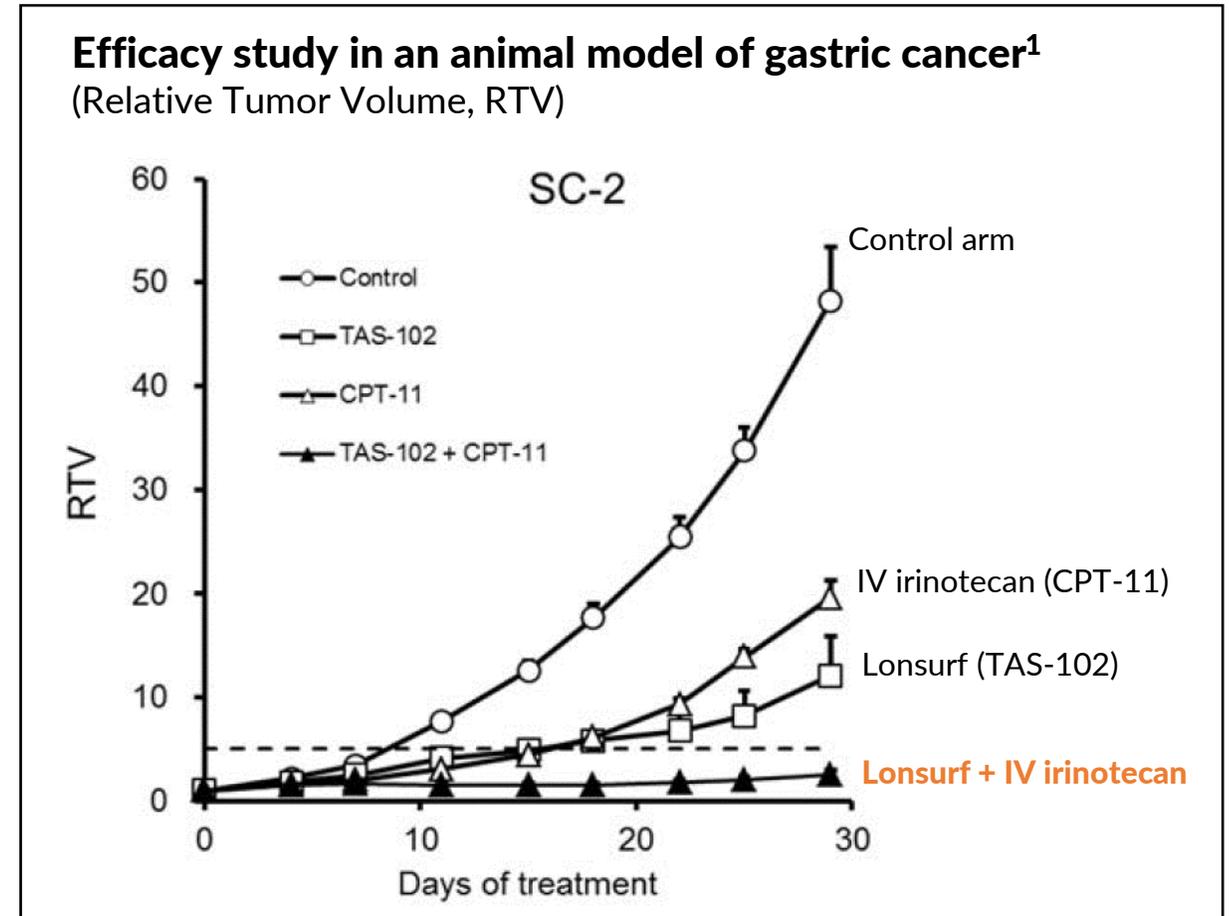
Study in patients with metastatic refractory breast cancer, N=103

1) Perez et al. J Clin Oncol 2004: Randomized Phase II Study of Two Irinotecan Schedules for Patients With Metastatic Breast Cancer Refractory to an Anthracycline, a Taxane, or Both

ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

- Clinical guidelines support efficacy of irinotecan
- Potential for Orphan Drug Designation
- Potential for synergistic effect between Lonsurf and irinotecan



PHASE 2 STUDY DESIGN

STUDY DESIGN (ALL-ORAL COMBINATION STUDY)

Patients 	<ul style="list-style-type: none">• Around 100 patients• Metastatic gastric cancer• Randomized controlled, multicenter/multinational
Comparator 	Oncoral + Lonsurf vs. Lonsurf
Endpoints 	Primary: Progression Free Survival Secondary: Response rate, PK, Safety and Overall Survival data in a follow up analysis

Clinical collaboration with



TAIHO ONCOLOGY

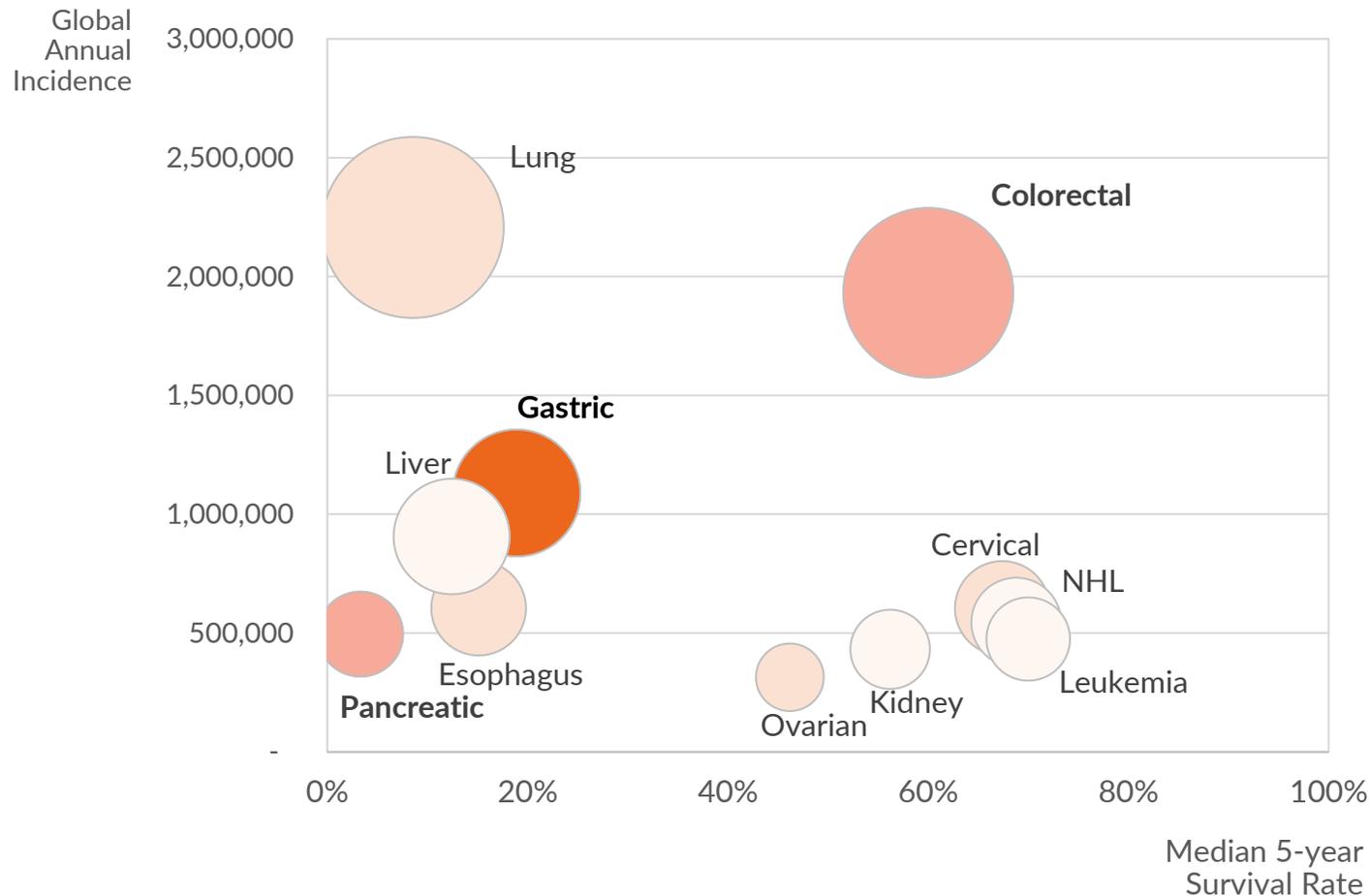
LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

POSTPONING START OF PHASE 2 TO FOCUS ON ORVIGLANCE

- Continued very strong belief in Oncoral as a novel oral chemotherapy
- Study start approval (IND) gained in the US in December 2021
- Study start approval gained in the UK and Spain in H1 2022
- To focus all resources on Orviglance, patient enrollment is not initiated until it can be done effectively (was planned to start Q2/Q3 2022)

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN³



- **Current focus: Gastric cancer**
 - 3rd highest cancer deaths¹
 - Orphan opportunity (U.S. and EU)
 - \$3-4bn market²
- Approved indications for IV irinotecan infusions
- Indications for which IV irinotecan infusions are clinically demonstrated & NCCN recognized
- Indications for which IV irinotecan infusions are clinically demonstrated

1) International Agency for Research on Cancer (IARC, 2021)
 2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024
 3) Globocan 2020, WHO, Cancer Research UK

FINANCIALS AND PRIORITIES

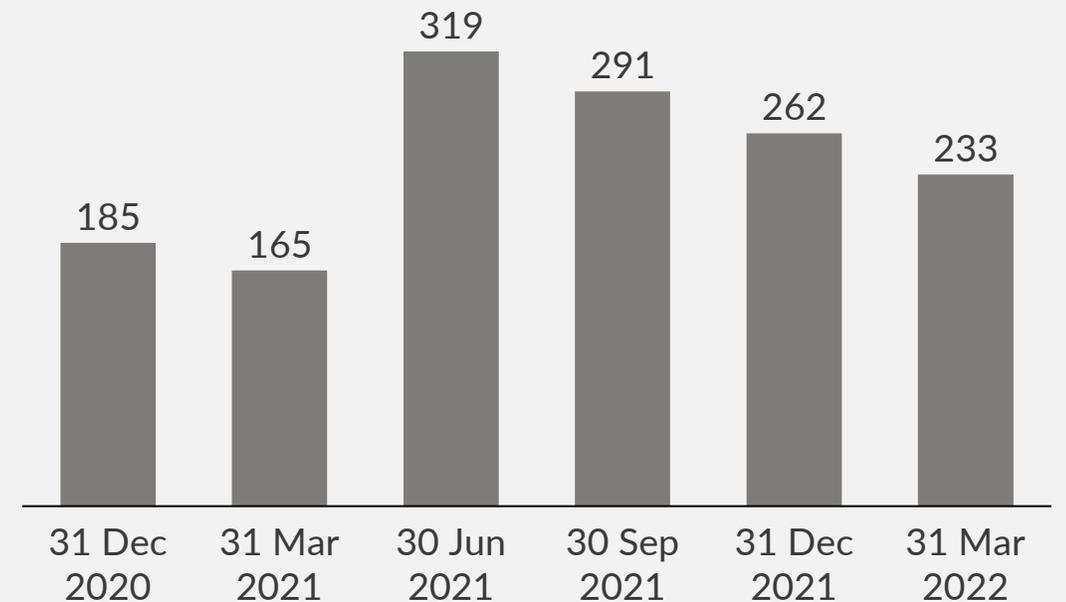


FINANCIAL HIGHLIGHTS Q1 2022 – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets of 233 MSEK (\$25 million) by 31 Mar 2022
- Current cash position provides financing into H2 2023

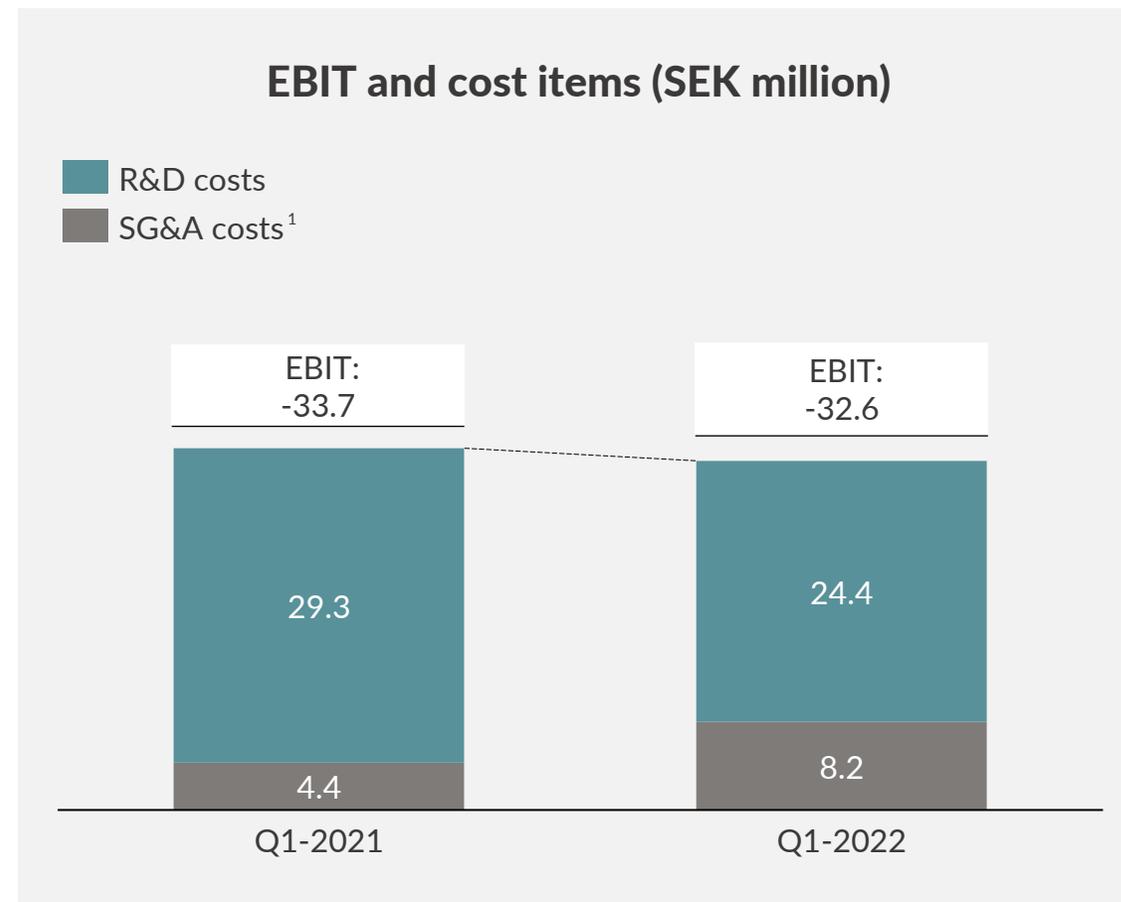
Liquid assets including marketable securities
(SEK million)



FINANCIAL HIGHLIGHTS Q1 2022 – OPERATING RESULTS

Largely unchanged operating loss y/y:

- Reduced R&D costs y/y due to timing of expenses for Orvigance Phase 3 study, which caused higher cost recognition in Q1 2021 compared to Q1 2022
- Higher SG&A costs y/y driven by increased launch preparations costs for Orvigance in Q1 2022



Notes:

1) Other operating income and other operating costs added to SG&A



PRIORITIES 2022

 Complete Orvigance Phase 3 patient enrollment

 Prepare Orvigance launch

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