ADVANCING
ORPHAN
ONCOLOGY

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ASCELIA PHARMA

COMPANY PRESENTATION

December 2022

ASCELIA
PHARMA

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ASCELIA PHARMA – COMPANY HIGHLIGHTS

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 Q4 2023
- Listed on NASDAQ Stockholm (Ticker: ACE)

PORTFOLIO

ORVIGLANCE

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

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EARLY DETECTION OF LIVER METASTASES IS CRITICAL

LIVER METASTASES CRITICAL IN CANCER CARE

Liver metastases are common and often

- First site of metastases
- The cause of mortality

Incidence liver metastases per primary cancer [1-3]

* Metastatic breast cancer

CONTRAST ENHANCED MRI IS GOLD STANDARD

Contrast drug enhanced MRI enables

- Accurate detection and visualization
- Planning of surgery or drug treatment
- Post-treatment surveillance

1) Riihimäki, M. *et al.* Patterns of metastasis in colon and rectal cancer. *Sci. Rep.* 6, 29765; doi: 10.1038/srep29765 (2016); Journal of Pathology, 2014, 232:23-31
2) Guy diSibio and Samuel W. French (*2008*) Metastatic Patterns of Cancers: Results From a Large Autopsy Study. Archives of Pathology & Laboratory Medicine: June 2008, Vol. 132, No. 6, pp. 931-939
3) Rahbari et al. Metastatic Spread Emerging From Liver Metastases of Colorectal Cancer: Does the Seed Leave the Soil Again? Annals of Surgery: February 2016 - Volume 263 - Issue 2 - p 345–352

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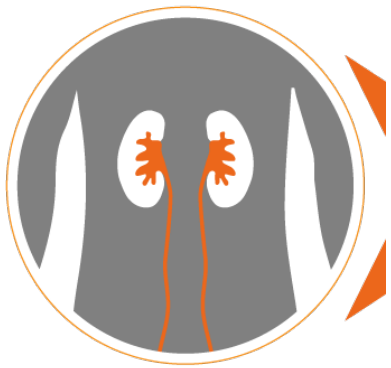
ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Suspected cancer in the liver | Test kidney function | MRI contrast agent decision | Liver MRI scan



A) Healthy kidneys

MRI with gadolinium contrast agent

B) Poor kidneys

- All gadolinium contrast agents have regulatory Black Box warnings
- Risk of severe and potentially fatal side-effect (Nephrogenic Systemic Fibrosis)

Solution:

MRI with **ORVIGLANCE** (manganese based)

ORVIGLANCE aims to be the standard of care liver MRI contrast agent for target patients

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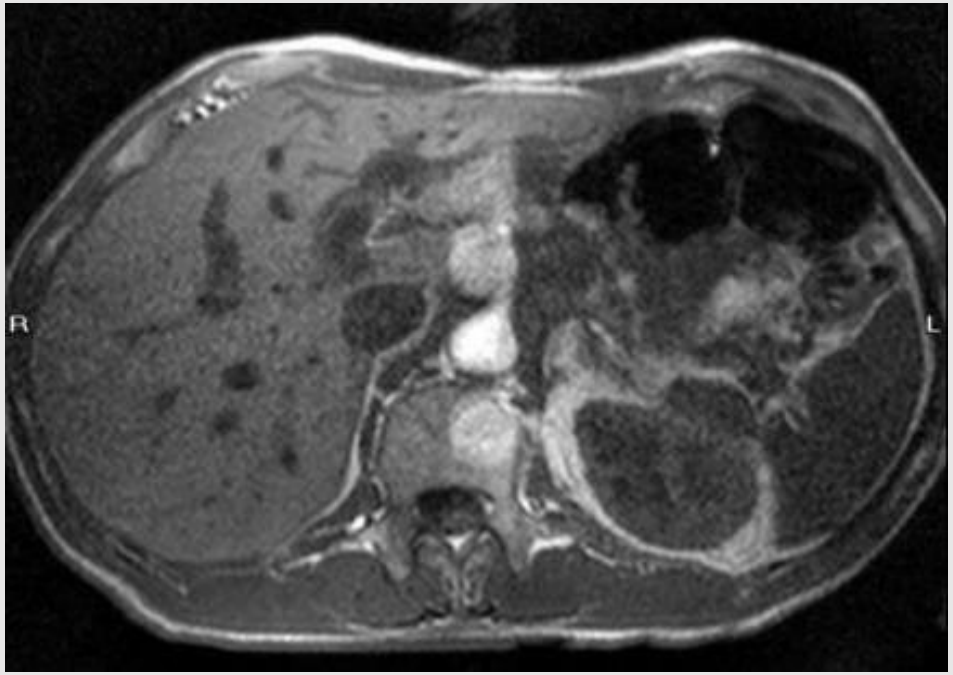
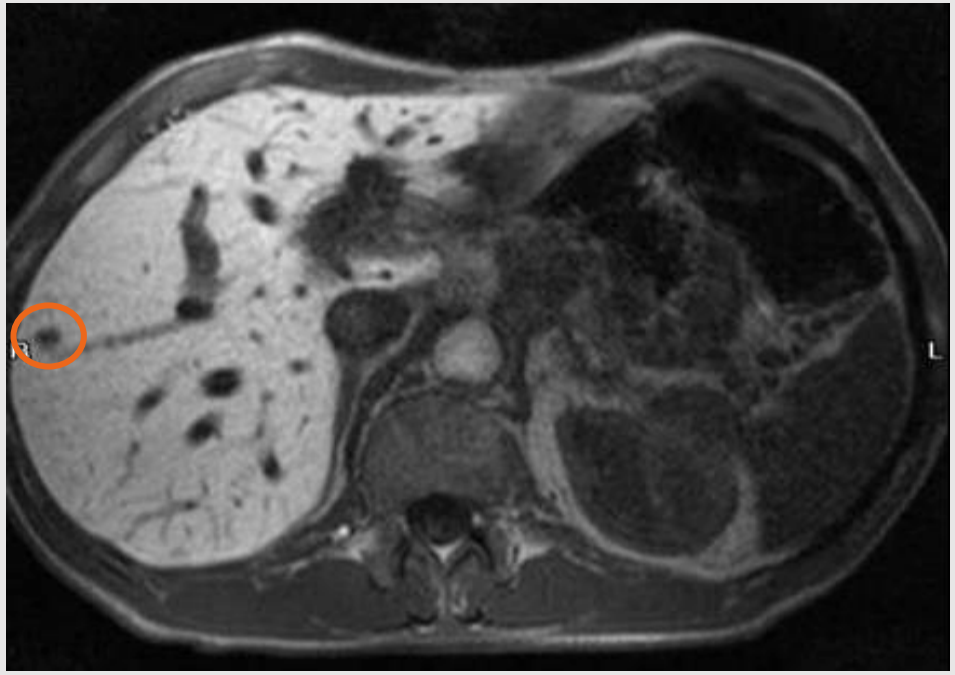
STRONG LIVER ENHANCEMENT WITH ORVIGLANCE

PATIENT EXAMPLE FROM PHASE 2 STUDY



UNENHANCED liver MRI (without contrast agent)



ORVIGLANCE contrast enhanced liver MRI

Liver metastasis appear with Orviglance

Source: Patient with colorectal cancer. (Study CMC-P002)

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EIGHT COMPLETED CLINICAL STUDIES

- Data presented at major radiology conferences

Phase 1 & 2	Completed (6 studies)	**BLINDED READ STUDY** Safety and efficacy vs. unenhanced in all phase 1 and 2 images (6 studies, including 178 persons and compassionate use)	**Consistent positive results, incl. 33% more lesions** **Delineation** (border sharpness) and **conspicuity** (contrast vs. background): p-value <0.0001
		ORVIGLANCE VS. GADOLINIUM CONTRAST AGENT Orviglance vs. gadolinium (Multihance) and vs. unenhanced (20 persons crossover with 3 independent readers)	**Number of lesions** (3 of 3 higher) **Smaller lesion** detection (3 of 3 higher) **Delineation and conspicuity** (2 of 3 higher)
Phase 3 Program	Completed (1 study)	**FOOD EFFECT STUDY** Evaluates the effect of food intake on absorption and signal intensity (23 healthy volunteers)	**Strong liver enhancement both in fasting condition and with light meal**, support intake of light meal
	Completed (1 study)	**HEPATIC IMPAIRMENT STUDY** Evaluates the effect of liver impairment on the safety, pharmacokinetics and pharmacodynamics	**Well tolerated in patients with liver impairment** Confirms excretion primarily via the liver and not the kidney
	Ongoing (1 study)	**SPARKLE PHASE 3 PIVOTAL STUDY** Evaluates the safety and efficacy in target patient population (enrollment not yet completed	Not yet complete

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New strong Orviglance data support successful SPARKLE completion with substantially fewer patients

Press Release 06 Dec 2022

Assumptions for original SPARKLE sample size estimate were conservative

New data with the same image reading methodology as in SPARKLE demonstrate

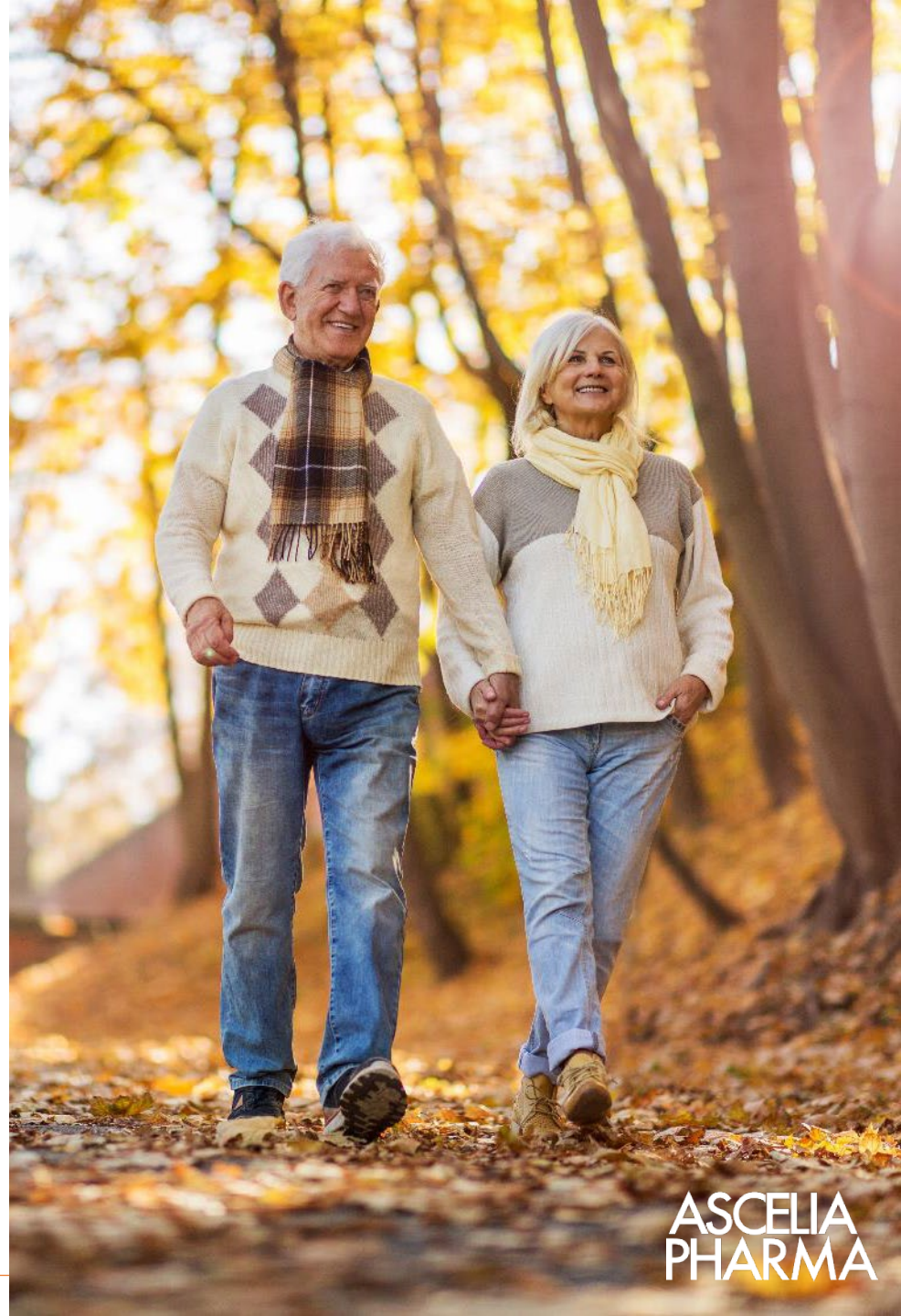
- Successful re-read study ($p<0.009$) based on 20 patients for lesion visualization (primary endpoint in SPARKLE)
- Two to three times higher effect than originally assumed

Statistically significant results can be obtained with substantially fewer patients and strong likelihood of success, while maintaining conservative assumptions

We have thoroughly analyzed the new data and original assumptions with statisticians and regulatory experts to validate this important finding

Based on discussions with the FDA, Ascelia Pharma has decided to change the patient enrolment target of SPARKLE to 80 patients

- 58 patients completed; significantly impacted by Covid, CRO change and Russian sites closing
- Growing and sizeable pool of identified eligible patients for enrollment



ORVIGLANCE ONGOING PHASE 3 STUDY – SPARKLE

Patients 	• Global study, 80 patients • Known or suspected focal liver lesions and severe renal impairment	• Around 50 sites in the US, Europe, Latin America • Enrolled 58 patients as of Dec 6 2023
Comparator 	Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI	No randomization – each patient as own control
Endpoint 	Lesion visualization • Lesion border delineation • Conspicuity	• Same endpoints as in Phase 2 • Same endpoints as for approved gadolinium agents
Follow-up 	Less than a week	Expected complete patient enrollment: Feb-Mar 2023

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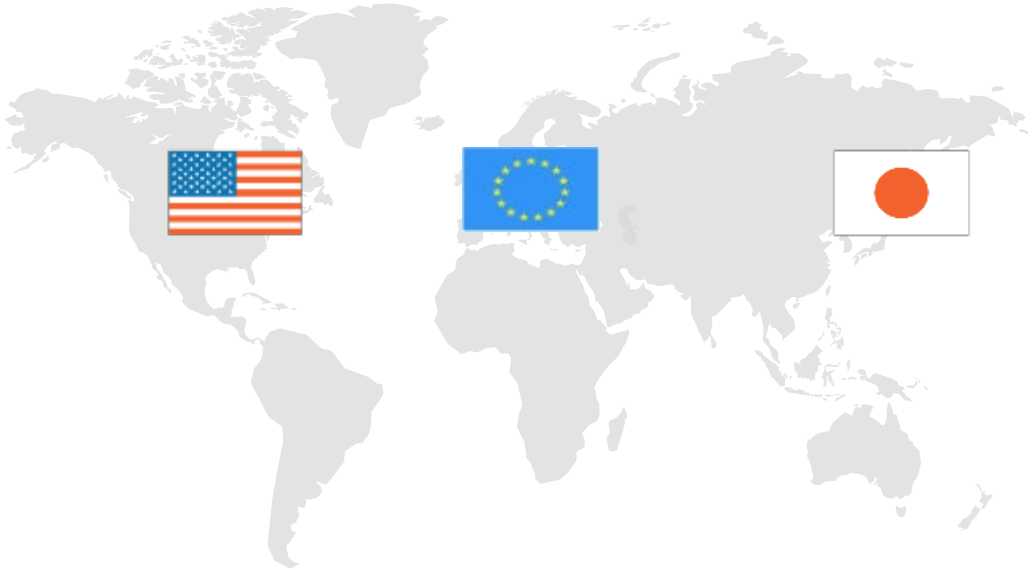
ORVIGLANCE MARKET $500-600 MILLION ANNUALLY

$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%

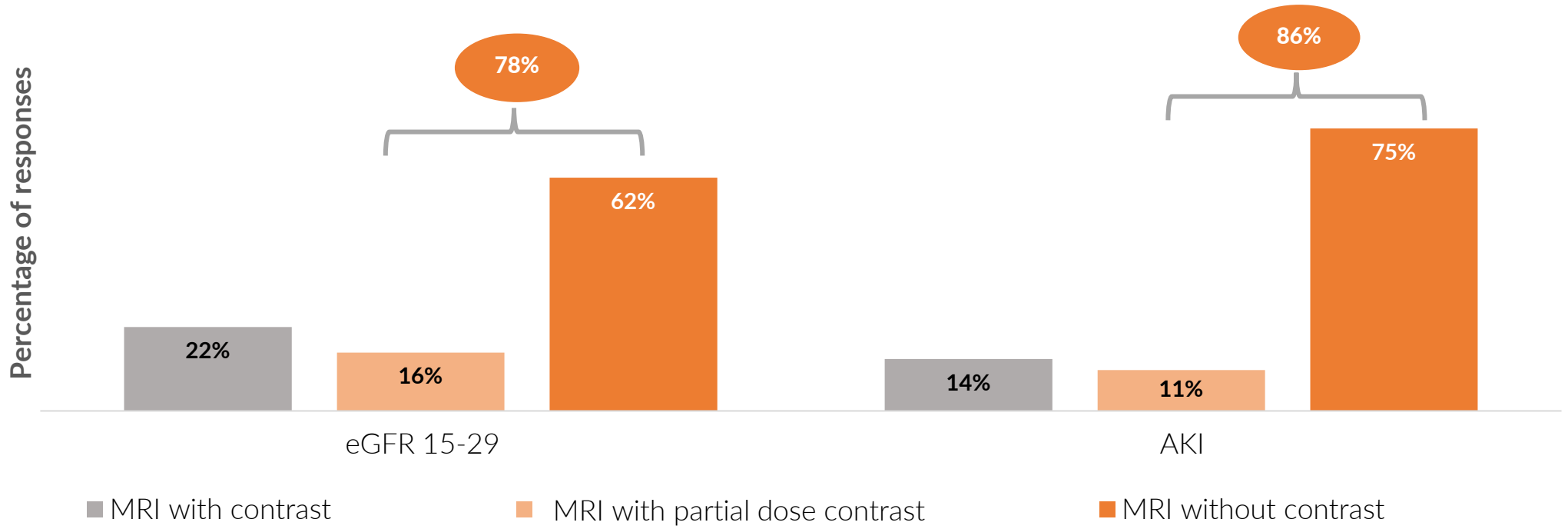
Sources:
1) Ascelia Pharma market research with Decision Resources Group, 2020
2) Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

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)

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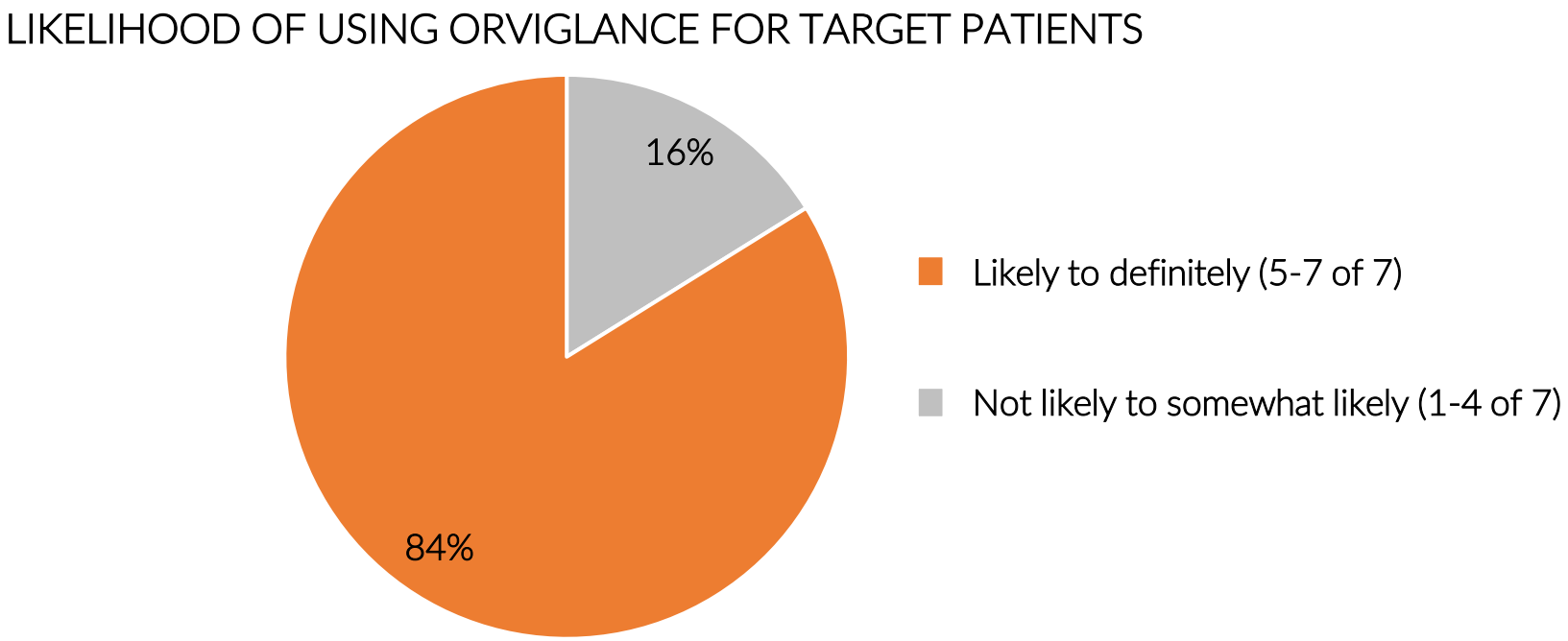
MARKET RESEARCH FROM MARCH 2022
– 84% US HEALTHCARE PROFESSIONALS SAY THEY WILL USE ORVIGLANCE



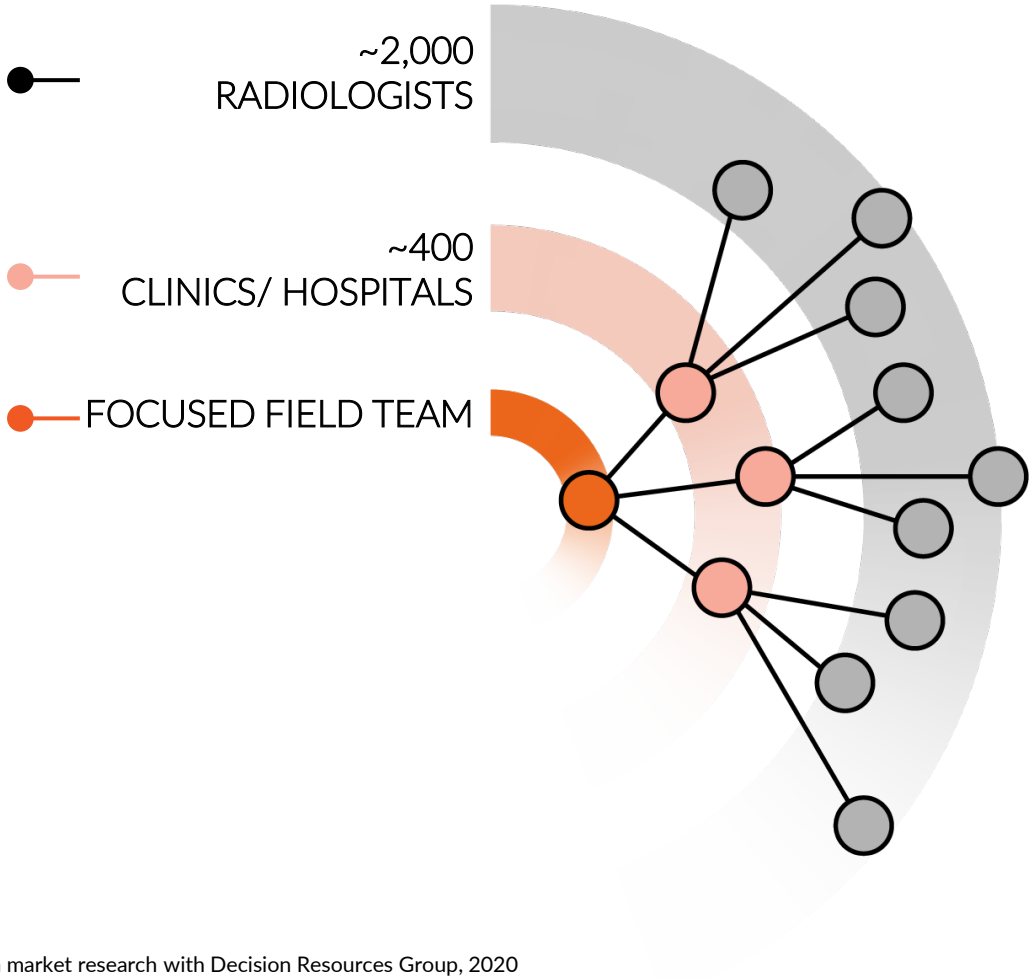
Market research for Ascelia Pharma conducted in Q4 2021/Q1 2022 by Two Labs Pharma Services
N =254 oncologist, nephrologist, and radiologist responses
Q: On a scale of 1 (not at all likely) to 7 (definitely), how likely are you to use or suggest using Orviglance for your patients?

CAPTURING US MARKET VALUE WITH ASCELIA'S TEAM

Perform regular liver MRIs in kidney impaired patients[1]

Serve ~75% of kidney impaired patients[1]

Reach priority decision makers



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 Mayo Clinic, Mass. General, Stanford

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

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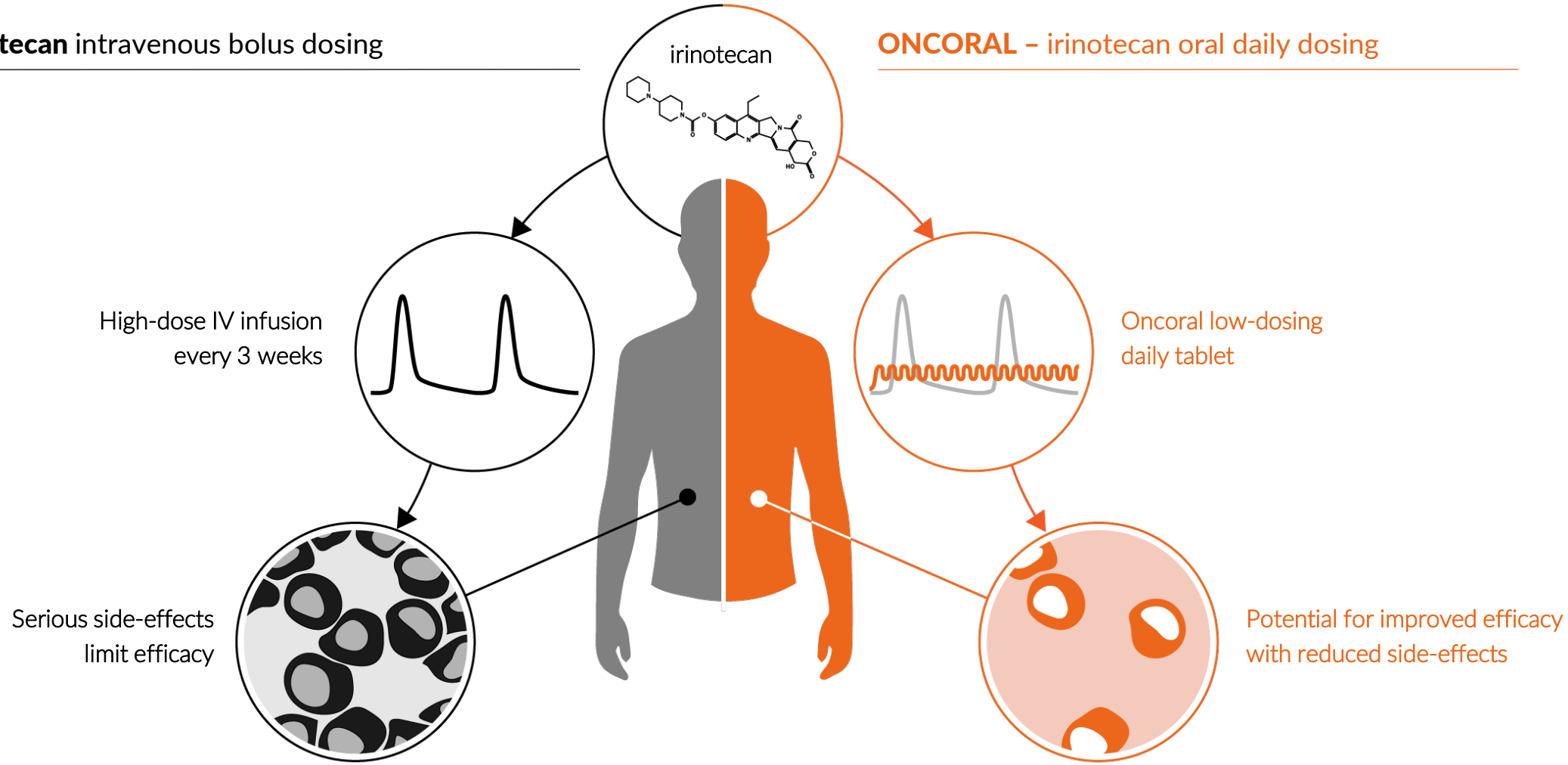
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

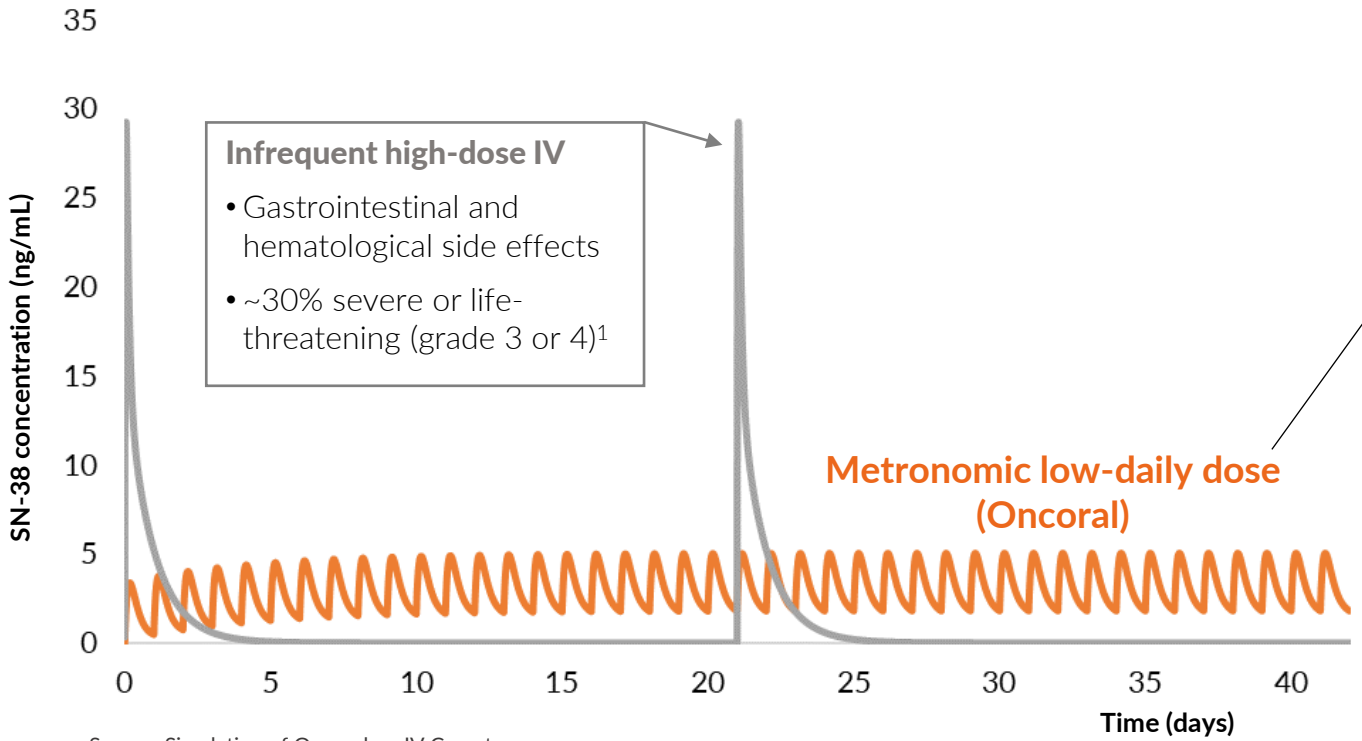
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar

Frequent (metronomic) low-dose irinotecan

- Several studies show improved tolerability[2,3]
- Daily dosing – adjust quickly if acute toxicity

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

1) Camptosar prescribing information 2) Furman et al 1999 3) Perez et al 2004 4) Kumler et al 2018

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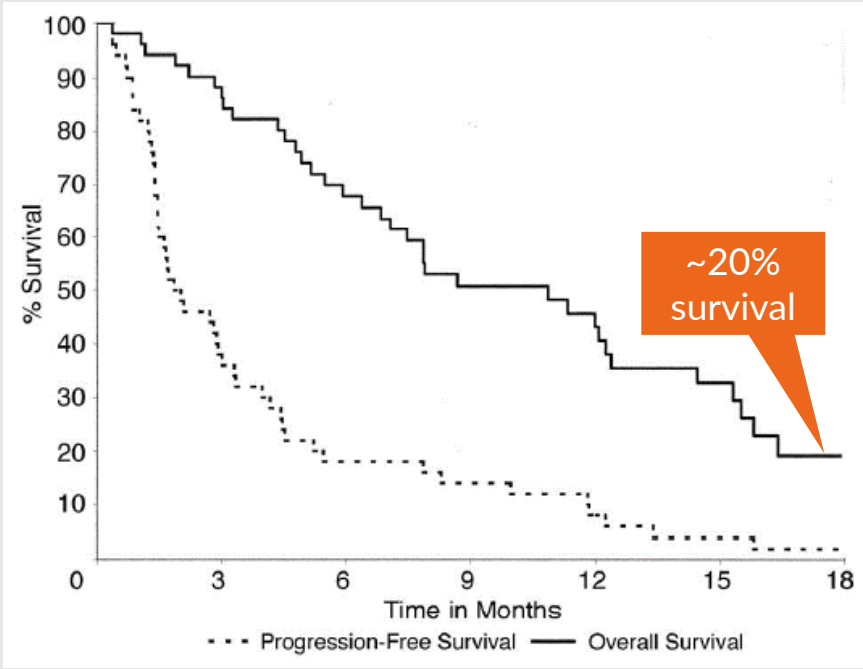
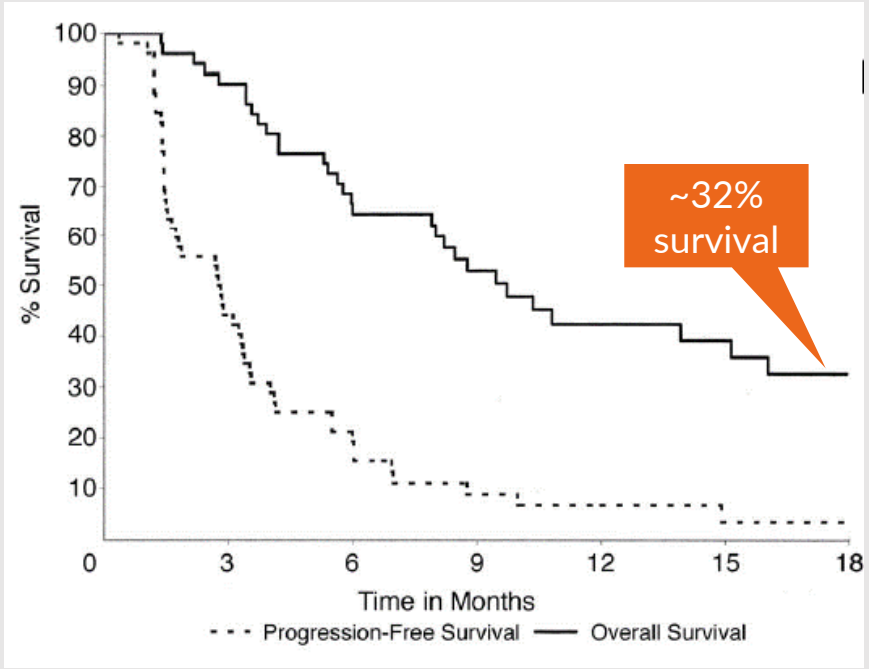
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

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

Irinotecan every 3 weeks (IV)



Irinotecan weekly (IV)



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

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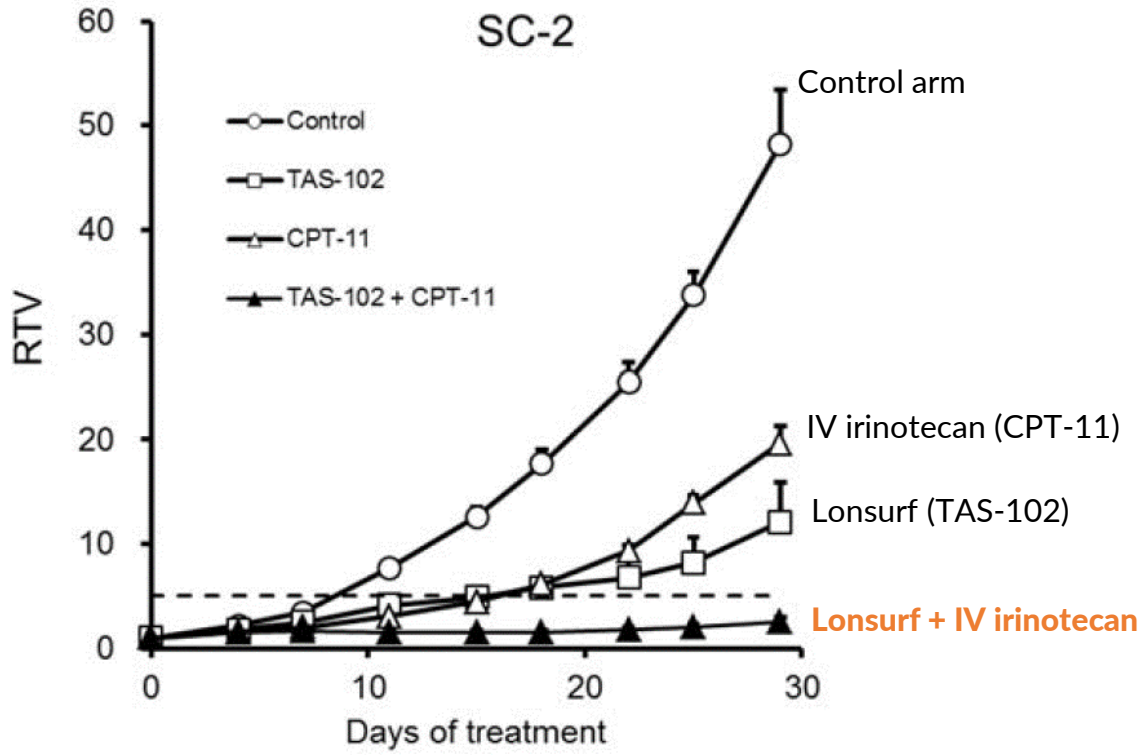
ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

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

Efficacy study in an animal model of gastric cancer[1]
(Relative Tumor Volume, RTV)



1) Nukatsuka et al: Combination Chemotherapy Using TAS-102 and Irinotecan Hydrochloride, ANTICANCER RESEARCH 35: 1437-1446 (2015)

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PHASE 2 STUDY DESIGN

STUDY DESIGN (ALL-ORAL COMBINATION STUDY)

Patients	• 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)

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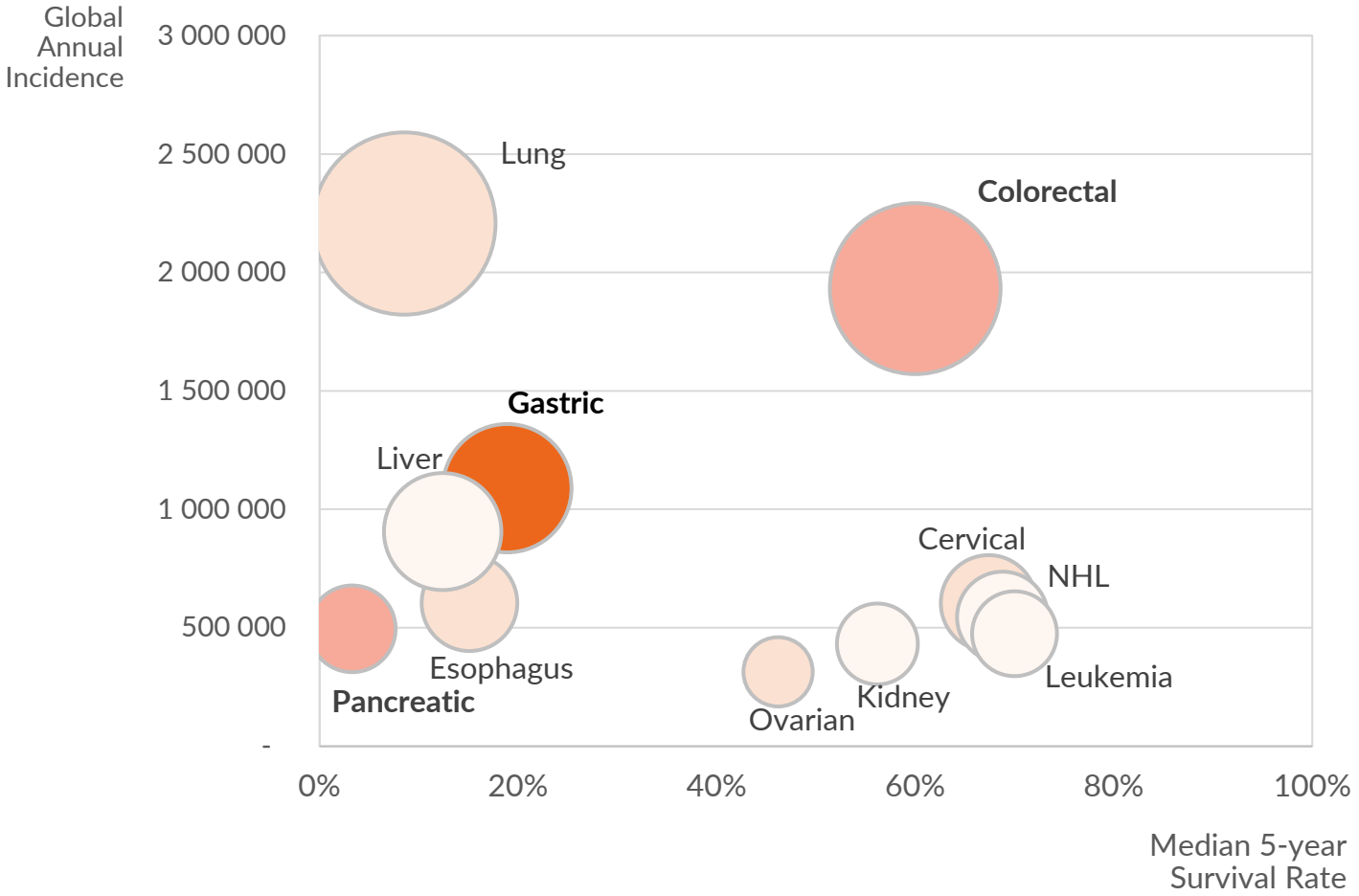
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN[3]



- **Current focus:** Gastric cancer
  - 3rd highest cancer deaths[1]
  - Orphan opportunity (U.S. and EU)
  - $3-4bn market[2]
- **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

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PRIORITIES, FINANCIALS AND SUMMARY

PRIORITIES AHEAD

- Patient enrollment completion by Feb/Mar 2023

- Topline results by mid 2023

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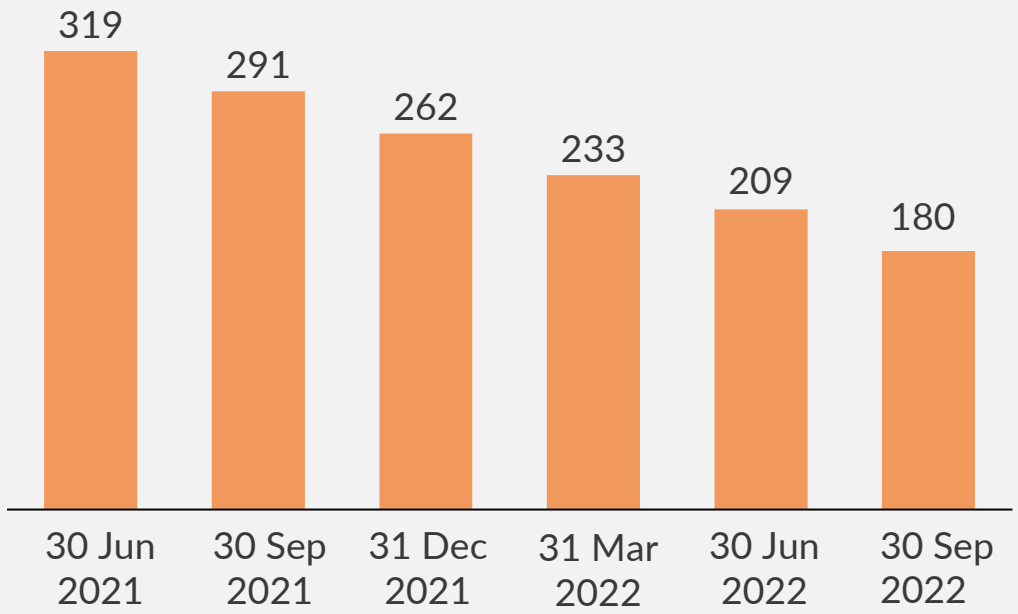
FINANCIAL HIGHLIGHTS Q3 2022 – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets of 180 MSEK ($16.2 million) by 30 sept 2022
- Current cash position provides financing into Q4 2023

Liquid assets including marketable securities
(SEK million)



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