



Share ticker: ACE
Nasdaq Stockholm

WEBCAST:
4 November 2022, 10:00AM CET

Link webcast:
<https://financialhearings.com/event/43395>

Dial-in teleconference:

DK: +4578150108
SE: +46850558375
UK: +443333009270
US: +16467224957

PRESENTATION OF Q3-2022 REPORT

Present from Ascelia Pharma:

CEO Magnus Corfitzen | Deputy CEO & CCO Julie Waras Brogren
CSO Andreas Norlin | CFO Déspina Georgiadou Hedin

www.ascelia.com

 Follow us on LinkedIn

FORWARD LOOKING STATEMENTS

This presentation, which includes all information and data on the following slides, any oral statements made when presenting these slides, and any other material distributed or statements made at, or in connection with, such presentation (the “Presentation”), relates to Ascelia Pharma AB (publ) (hereinafter, together with its subsidiaries, the “Company”) is furnished to you solely for your information and may not be reproduced or redistributed, in whole or in part, to any other person without the prior written consent of the Company. You should not rely upon it or use it to form the definitive basis for any decision, contract, commitment or action whatsoever, with respect to any transaction or otherwise.

The information included in this Presentation may contain certain forward-looking statements relating to the business, financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words “believes”, “expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. The forward-looking statements contained in this Presentation, including assumptions, opinions and views of the Company or cited from third party sources are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause actual events to differ materially from any anticipated development. Neither the Company nor any of its affiliates, directors, employees or advisors provides any assurance that the assumptions underlying such forward-looking statements are free from errors nor do any of them accept any responsibility for the future accuracy of the opinions expressed in this Presentation or the actual occurrence of the forecasted developments. This Presentation speaks as of the applicable reporting date, and there may have been changes in matters which affect the Company subsequent to the date of this Presentation. Neither the issue nor delivery of this Presentation shall under any circumstance create any implication that the information contained herein is correct as of any time subsequent to the date hereof or that the affairs of the Company have not since changed, and the Company does not intend, and does not assume any obligation, to update or correct any information included in this Presentation.

Each person should make their own independent assessment of the merits of the Company and should consult their own professional advisors. By receiving this Presentation, you acknowledge that you will be solely responsible for your own assessment of the market and the market position of the Company and that you will conduct your own analysis and be solely responsible for forming your own opinion of the potential future performance of the Company's business.

ASCELIA PHARMA – COMPANY HIGHLIGHTS



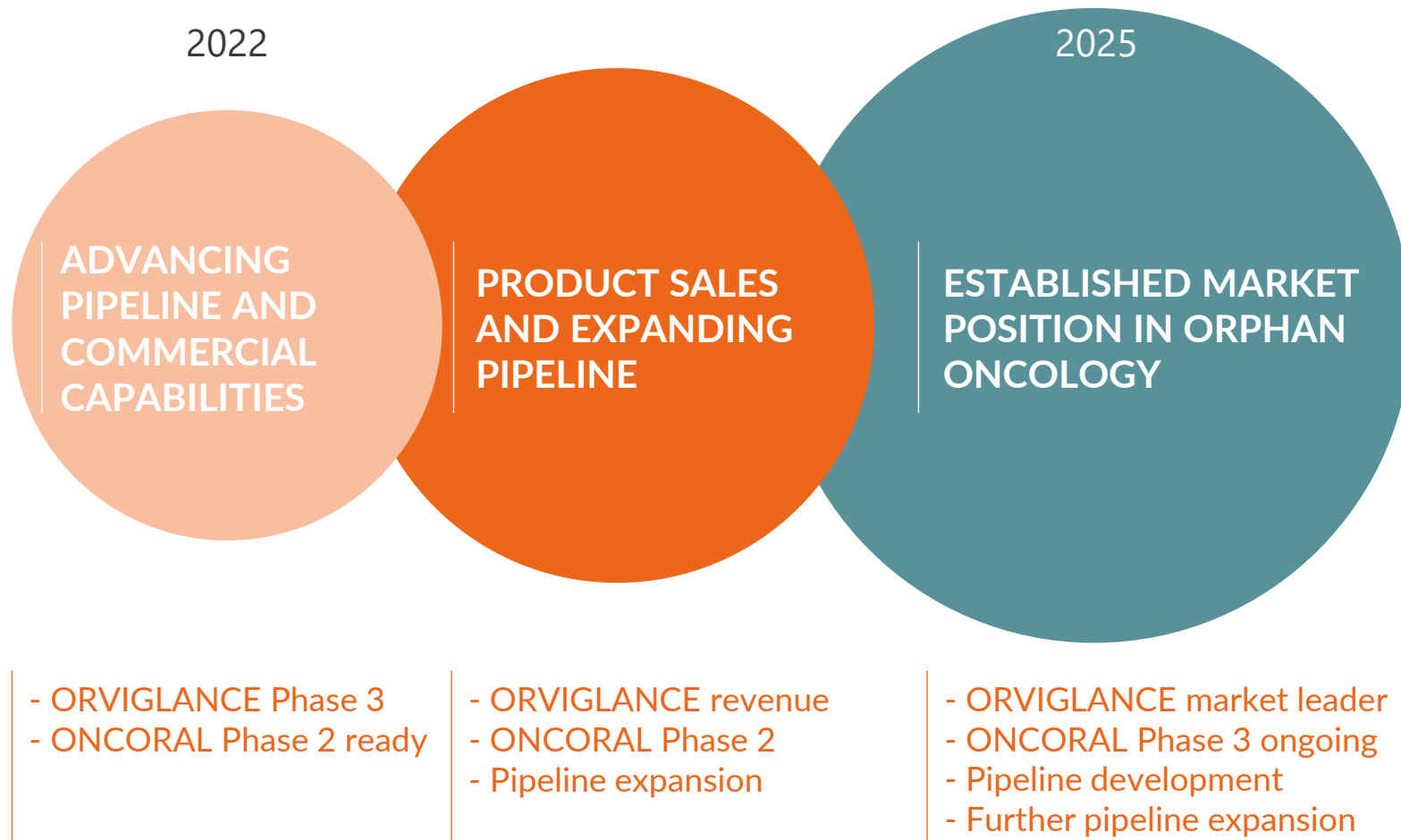
ADVANCING ORPHAN ONCOLOGY

- 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)

BUILDING VALUE AND GROWTH TRAJECTORY



RECENT KEY EVENTS

Key events in Q3-2022

- Aug** Results from the Orvigance Food Effect Study have been accepted as an oral presentation at the world's largest radiology conference, RSNA.
- Sep** Final results for the Hepatic Impairment Study marks the completion of the second study in the ongoing Phase 3 clinical program for registration of Orvigance.

Key events after Q3-2022

- Oct** Leadership team expanded to seven members to prepare for expected growth.
-





PORTFOLIO

ORVIGLANCE

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

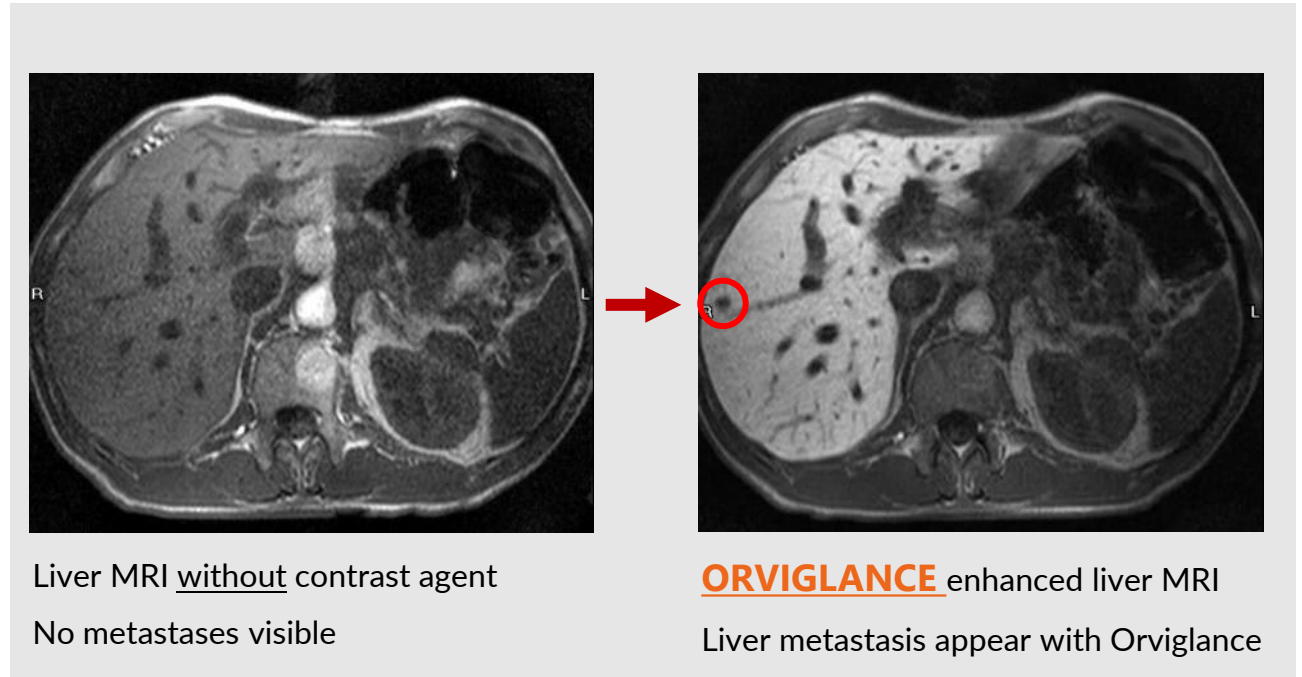
ORVIGLANCE – PHASE 3 LIVER MRI CONTRAST AGENT

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
- Strong results to pivotal program from supportive studies
- Orphan Drug Designation from FDA



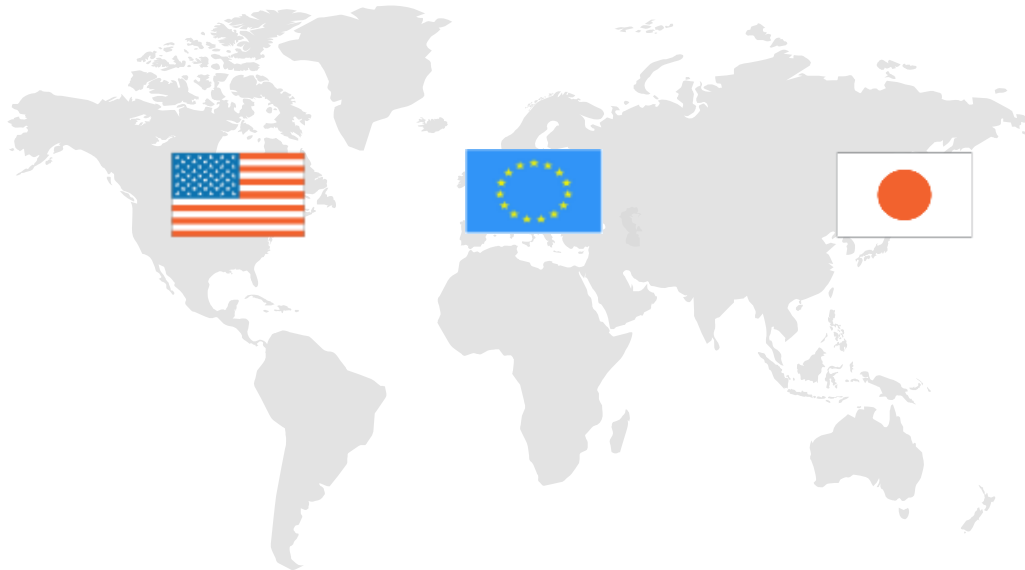
EIGHT COMPLETED CLINICAL STUDIES

Phase 1 and 2 program	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 <ul style="list-style-type: none"> • Significantly improved MRI parameters • 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 up to 200 target patients Unenhanced + ORVIGLANCE MRI vs. Unenhanced MRI Lesion visualization (lesion border delineation and conspicuity)	Pivotal study patient enrollment completion expected in 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:

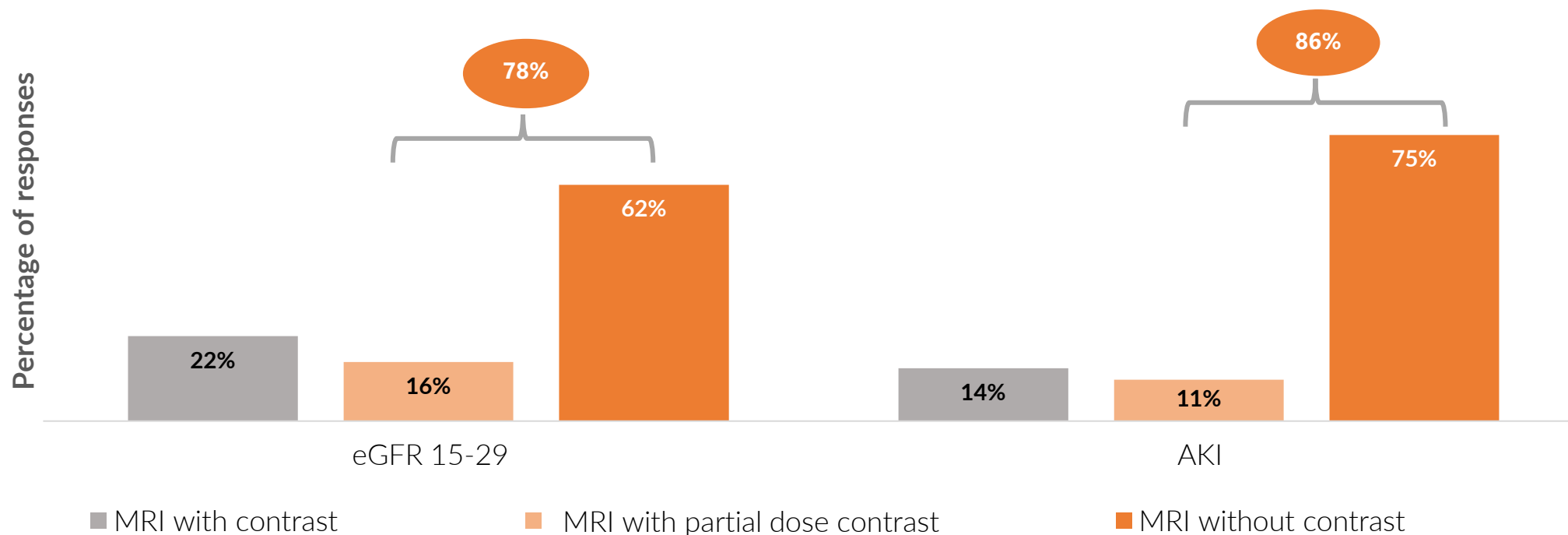
1) Ascelia Pharma market research with Decision Resources Group, 2020

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

US HCPs PREFER UNENHANCED MRI FOR TARGET PATIENTS

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

... EVEN MORE FOR AKI PATIENTS

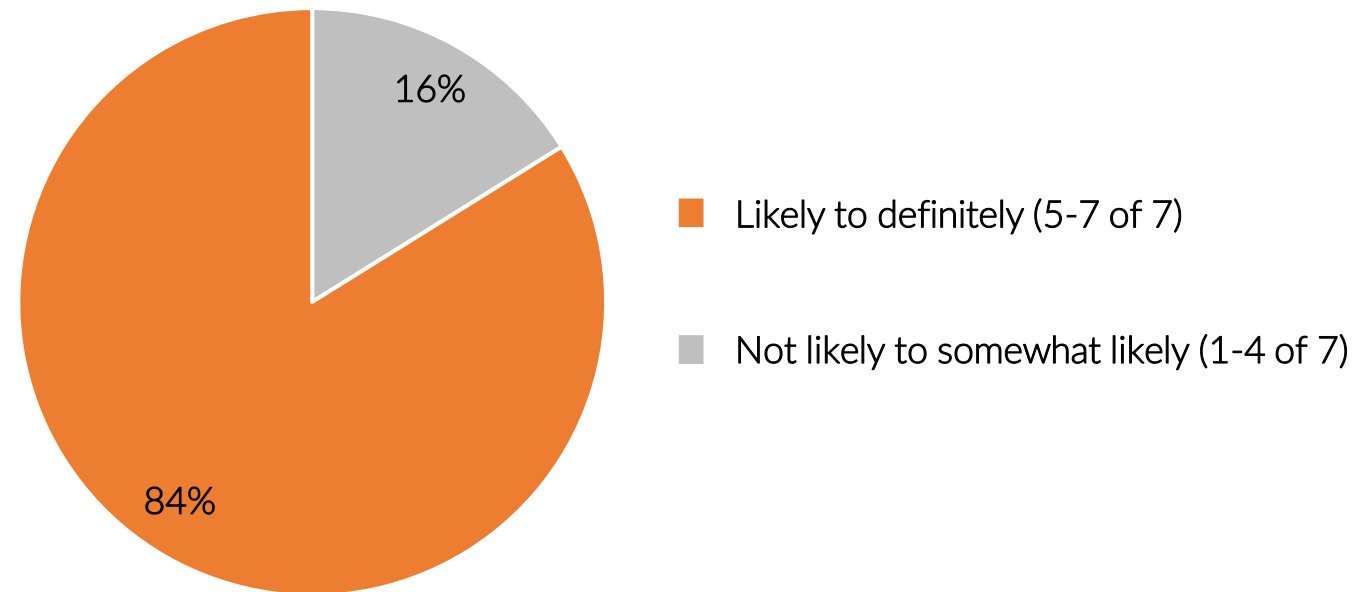


N=103 oncologist, nephrologist, and radiologist responses.

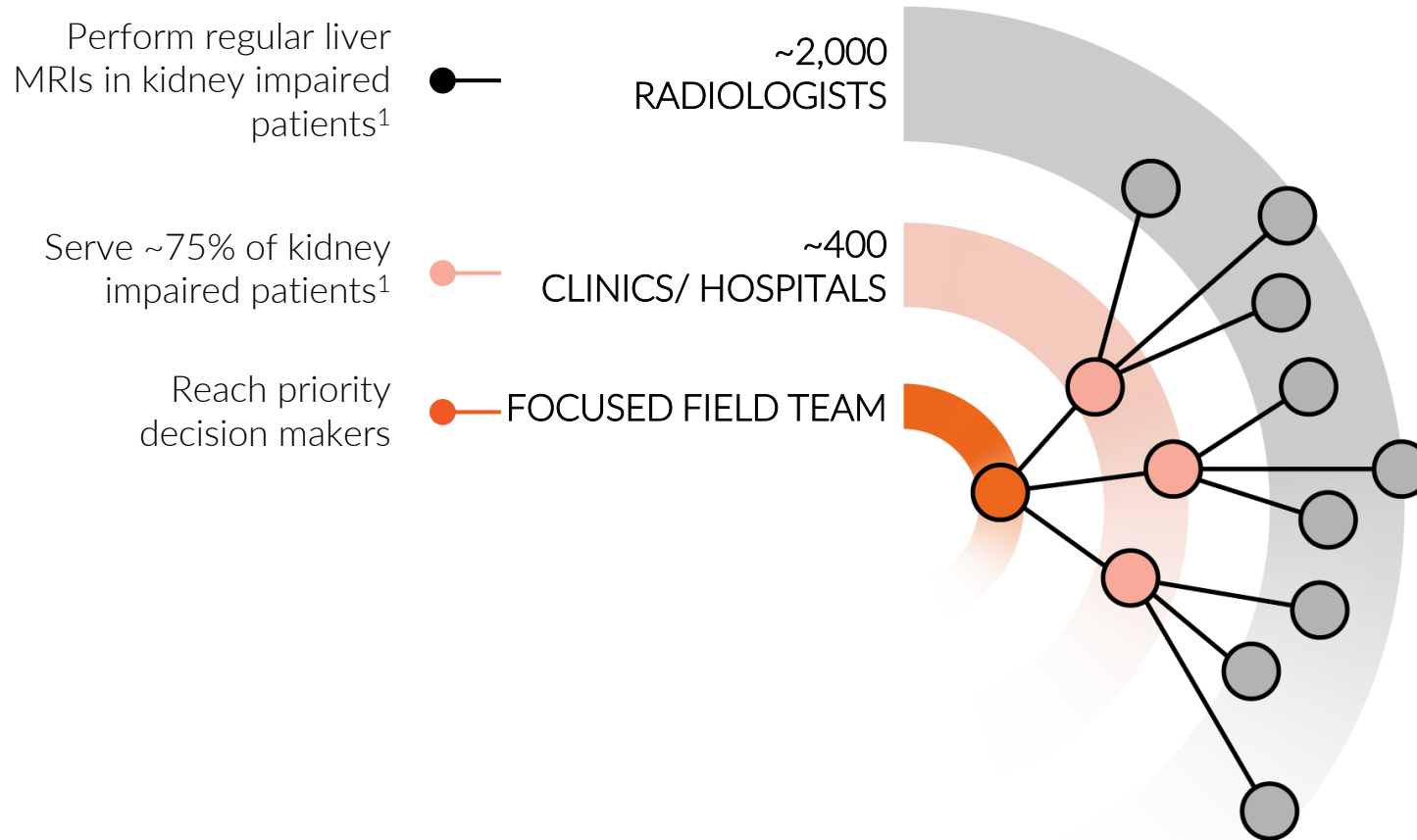
Q: Please assign priority to the imaging tests in the sequence or order in which you would recommend or perform them (shown as % split of first priority of MRI options)

84% US HCPs 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

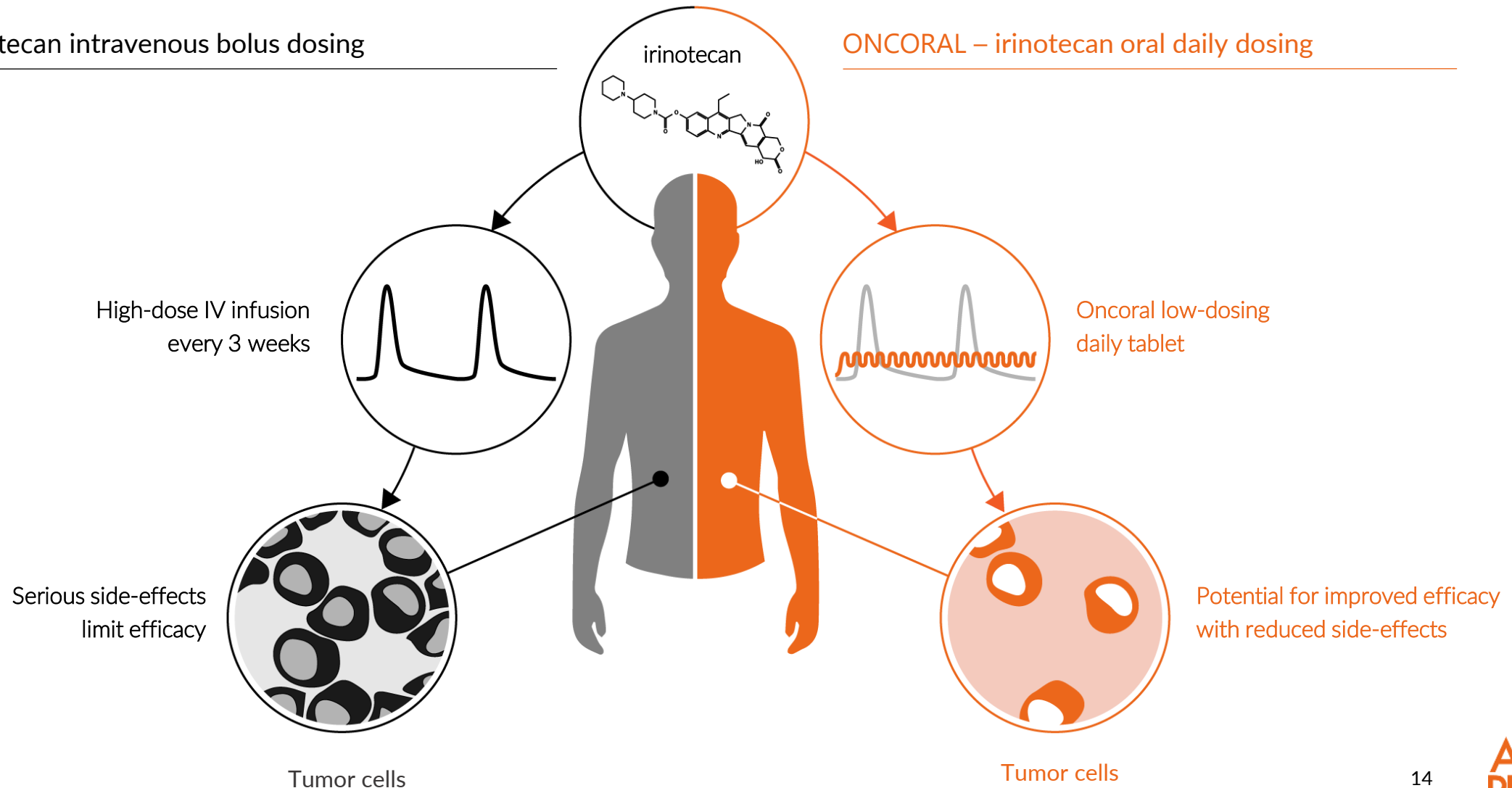
ONCORAL

Daily oral chemotherapy ready for Phase 2

IMPROVING IRINOTECAN EFFICACY and TOLERABILITY

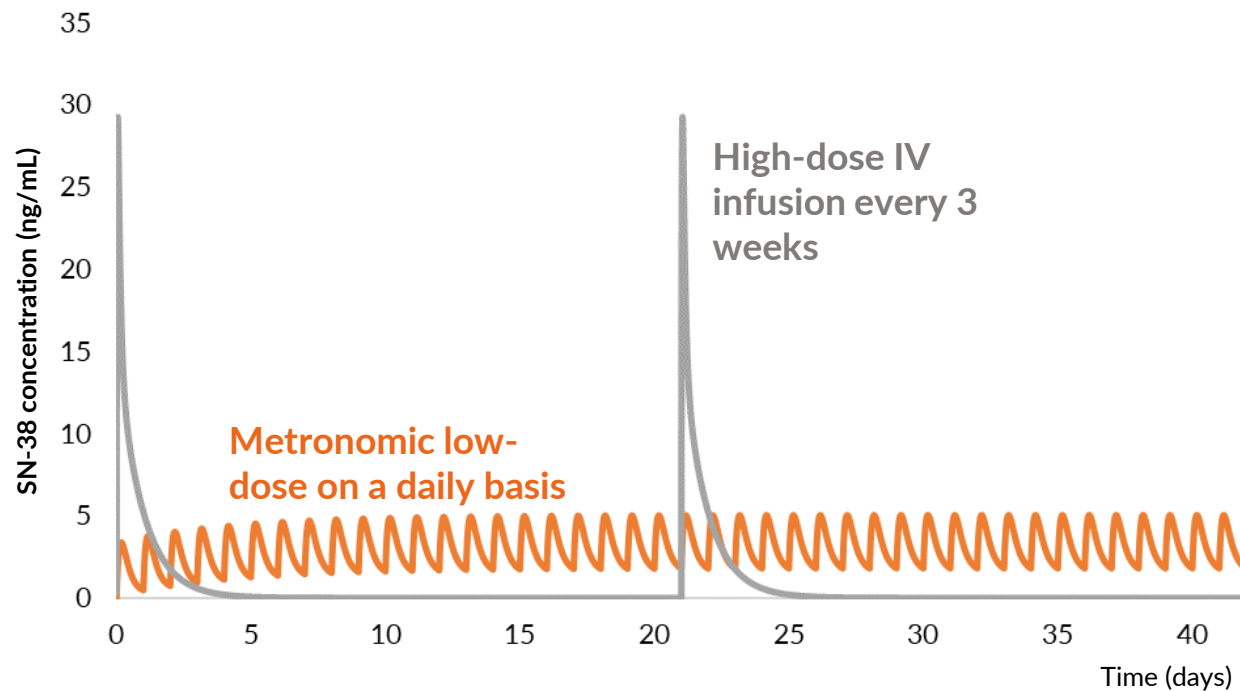
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar

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

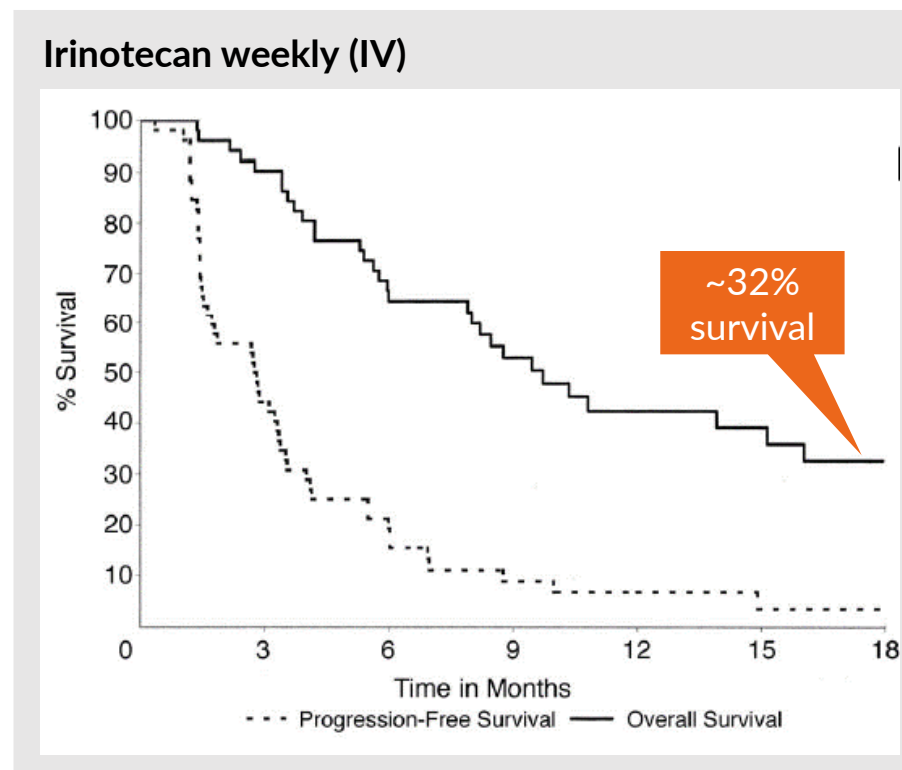
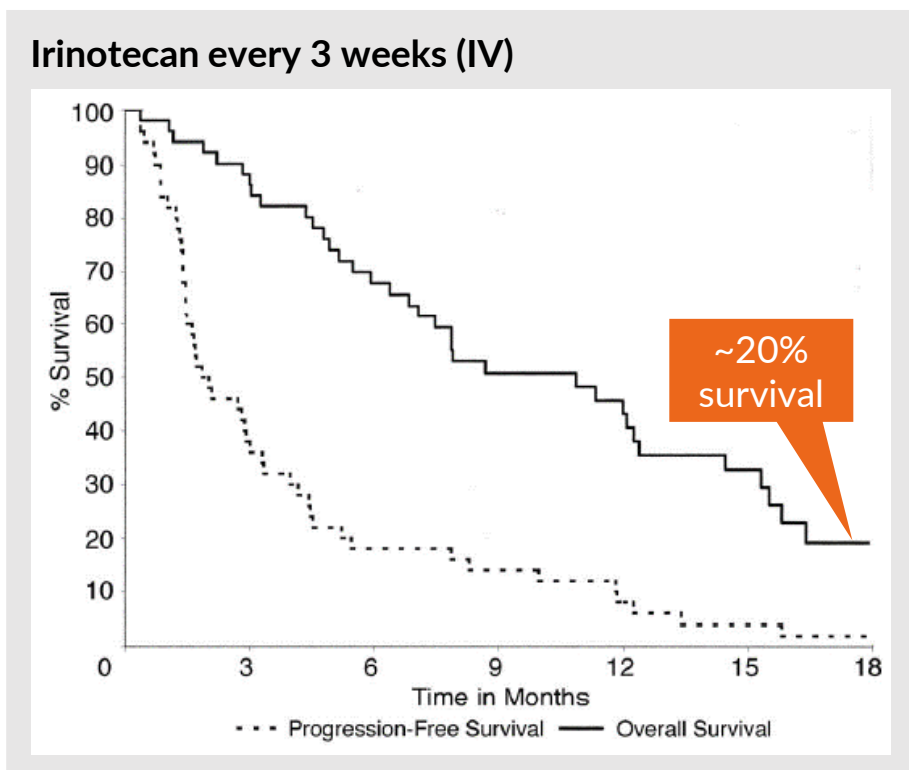
Gastrointestinal and hematological side effects, ~30% severe or life-threatening (grade 3 or 4)¹

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



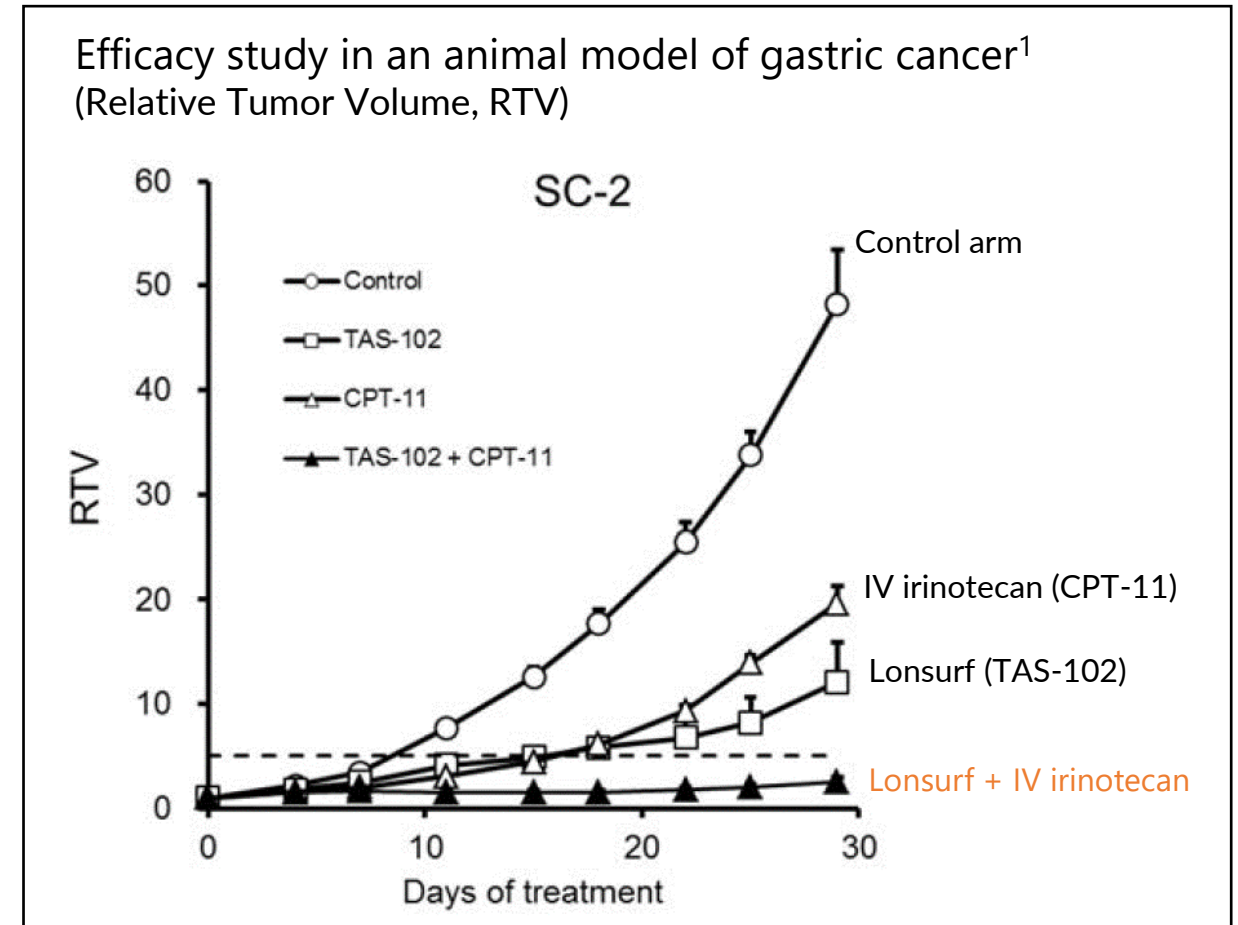
Study in patients with metastatic refractory breast cancer, N=103

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

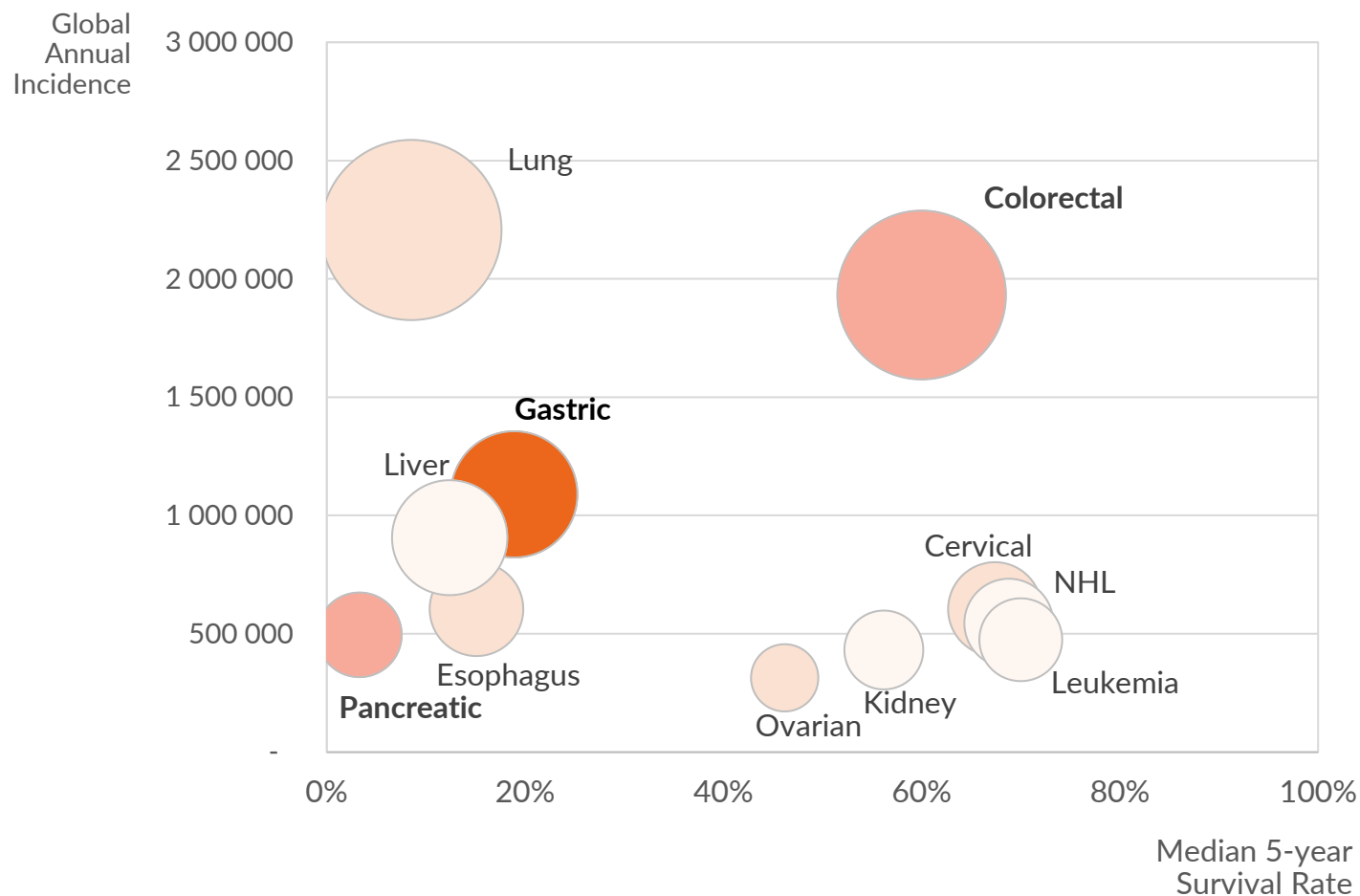
LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

PHASE 2 READY – AWAITING START 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
- In May 2022, US Patent and Trademark Office issued a notice of allowance for a second Oncoral patent application for the method of use of Oncoral
- To focus all resources on Orviglance, patient enrollment is not initiated until it can be done effectively

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



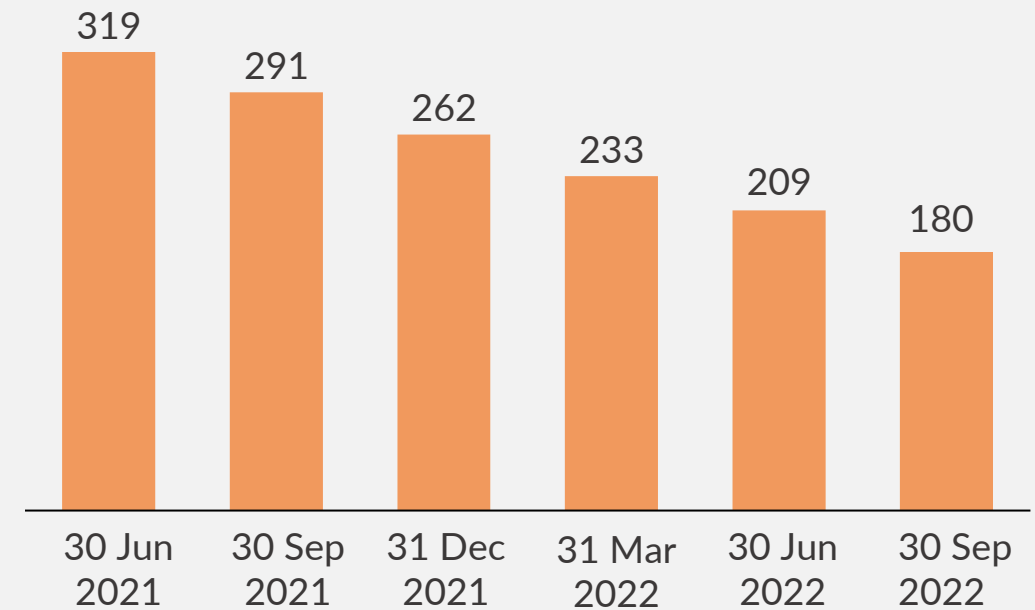
FINANCIALS AND PRIORITIES

FINANCIAL HIGHLIGHTS Q3 2022 – LIQUIDITY POSITION

Solid liquidity position:

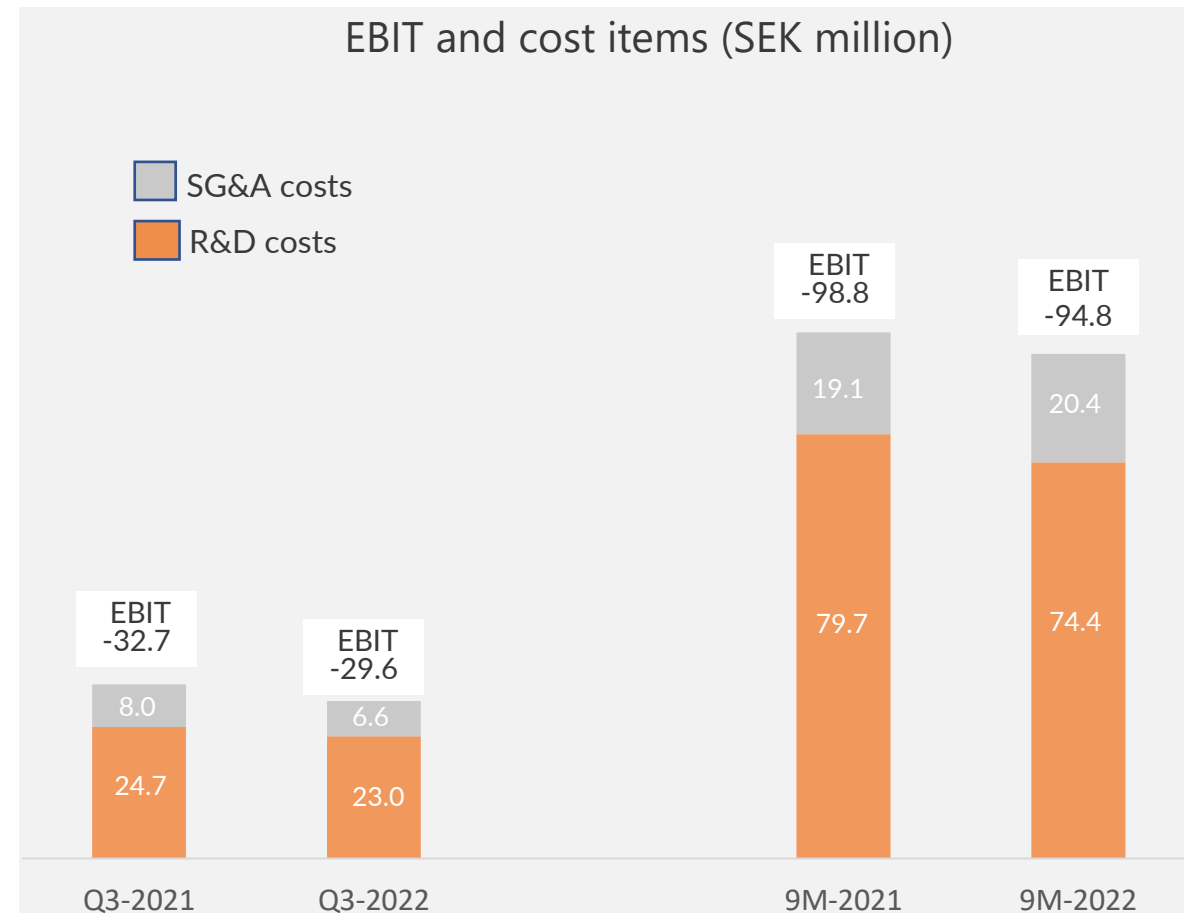
- Liquid assets of 180 MSEK (\$16.2 million) by 30 sept 2022
- Current cash position provides financing into Q4 2023

Liquid assets including marketable securities
(SEK million)



FINANCIAL HIGHLIGHTS Q3 2022 – OPERATING RESULTS

- Operating loss in Q3 2022 compared to loss in Q3 2021 primarily reflects the reduced costs of incentive programs for employees
- The development y/y in operating loss for Q3-2022 vs. Q3-2021 reflects the reduced costs of incentive programs for employees and the timing effect with lower R&D costs in Q1-2022, which was partly counterbalanced by higher commercial preparation costs.




Notes:

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



PRIORITIES 2022

 Complete Orvigance Phase 3 patient enrollment

 Prepare Orvigance launch

ASCELIA PHARMA

ascelia.com



[Follow us on LinkedIn](#)