

A photograph of an older couple walking barefoot on a sandy beach. The woman is on the left, wearing a striped shirt and jeans, and the man is on the right, wearing a maroon sweater and khaki pants. They are both smiling and looking at each other. The background shows the ocean with waves and a blue sky with light clouds.

ADVANCING
ORPHAN
ONCOLOGY

Ticker symbol: ACE
Nasdaq Stockholm
www.ascelia.com

ASCELIA PHARMA

COMPANY PRESENTATION

May 2022

**ASCELIA
PHARMA**

FORWARD LOOKING STATEMENTS

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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

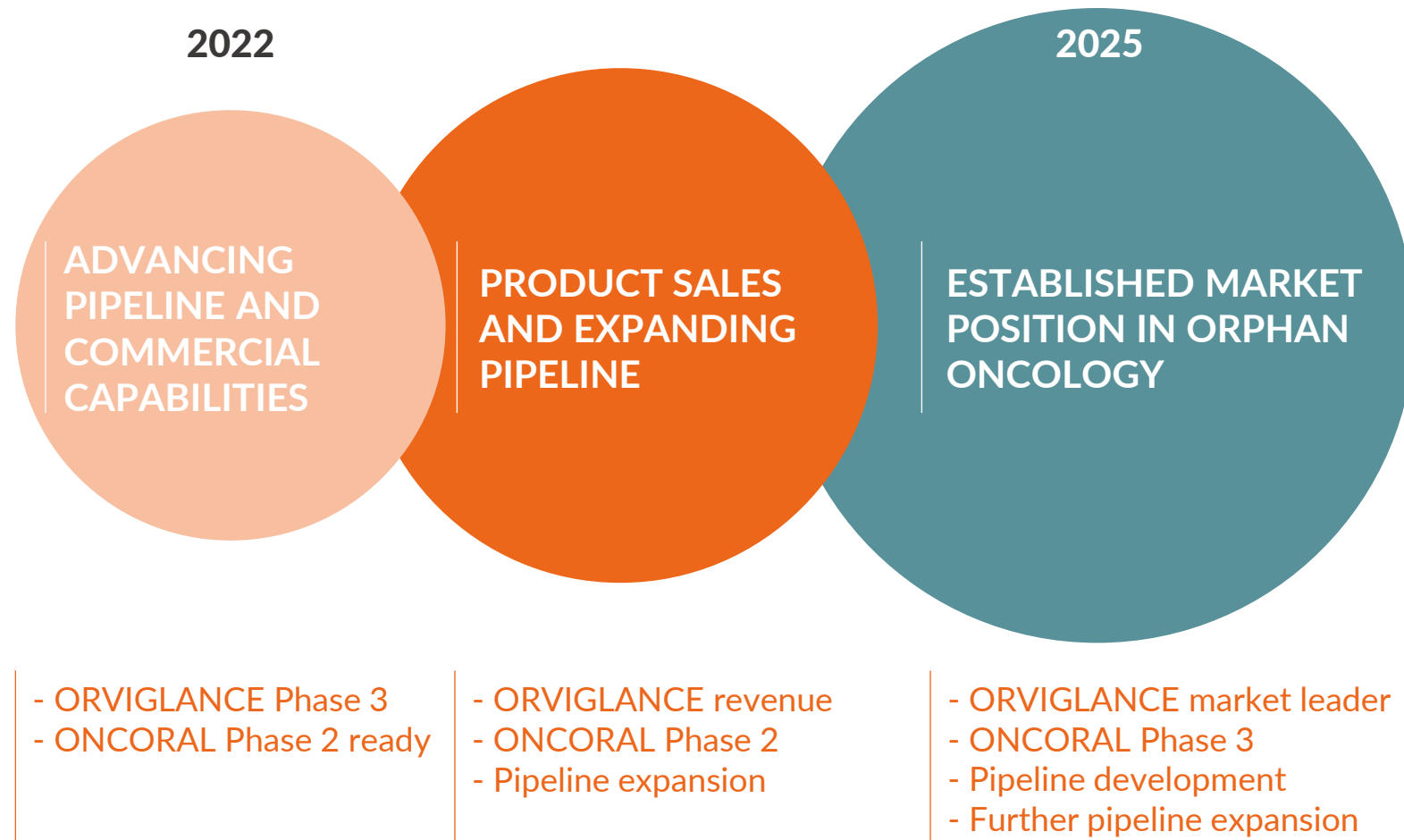
BUILDING GLOBAL CAPABILITIES

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

CURRENT CLINICAL STAGE PIPELINE

Drug candidate	Indication	Phase 1	Phase 2	Phase 3
ORVIGLANCE	Detection and visualization of focal liver lesions	Completed		Ongoing 2020 – 2022
ONCORAL	Gastric cancer	Completed	Ready for Phase 2	
	Other solid tumors			

BUILDING VALUE AND GROWTH TRAJECTORY





PORTFOLIO

ORVIGLANCE

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

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

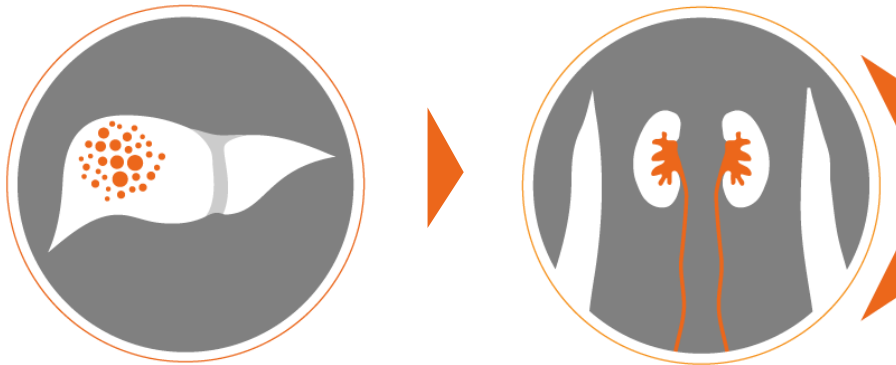
ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

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:

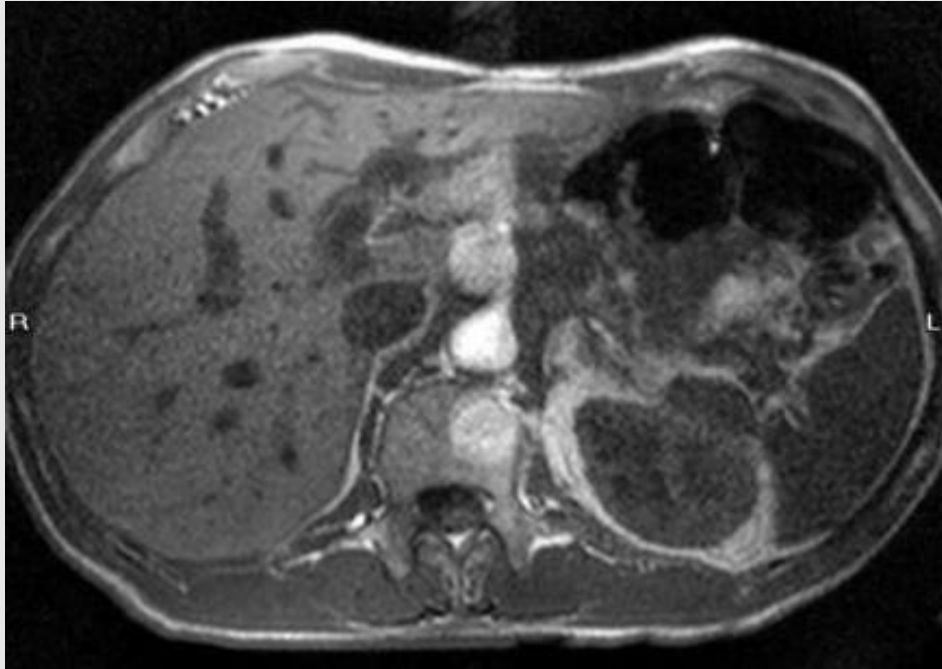
MRI with **ORVIGLANCE** (manganese based)



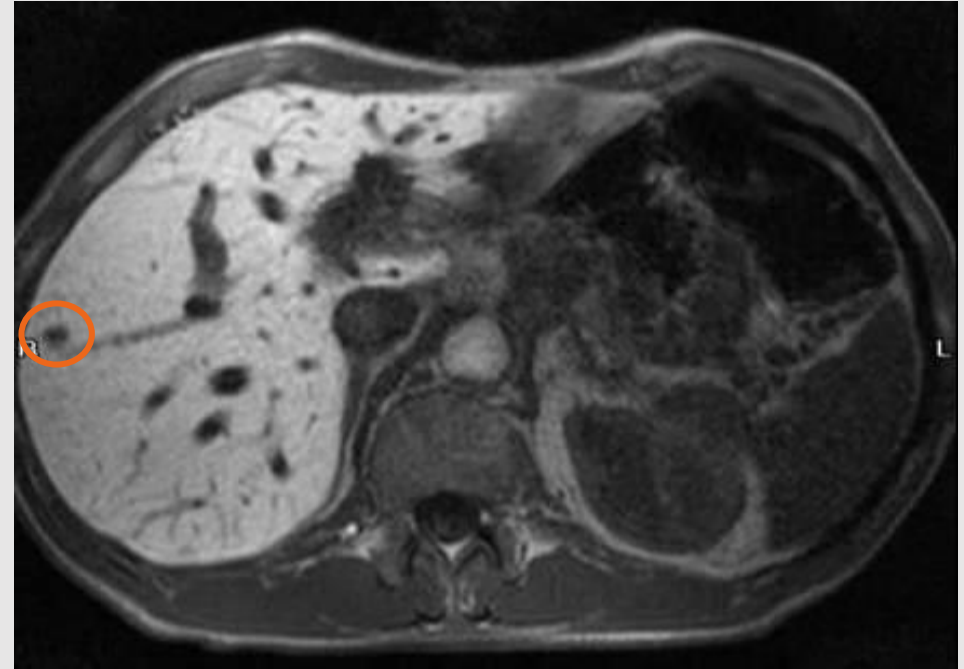
ORVIGLANCE aims to be the standard of care liver MRI contrast agent for target patients

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

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

Patients 	<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
Comparator 	Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI	No randomization – each patient as own control
Endpoint 	Lesion visualization <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
Follow-up 	Less than a week	Expected pivotal study patient enrollment: 2022

STUDY COMPARING ORVIGLANCE TO GADOLINIUM

ORVIGLANCE vs. GADOLINIUM CONTRAST AGENT

- Crossover study (n=20) where Orviglance was compared against a liver specific gadolinium contrast agent (Multihance)
- Compared visualization of lesions and number of detected lesions in the liver

EFFICACY PARAMETERS AND RESULTS

Efficacy parameter	Results from three independent blinded readers
1. Number of lesions detected	3 (out of 3) detected more lesions with Orviglance
2. Size of the detected lesions	3 (out of 3) saw smaller lesions with Orviglance
3. Lesion border delineation	2 (out of 3) reported higher scores for Orviglance
4. Lesion contrast compared to liver	2 (out of 3) reported higher scores for Orviglance

Note: Please observe that the results are not statistically sufficient to conclude that Orviglance is superior to gadolinium



CONCLUSIONS

- Robust evidence of the diagnostic value that Orviglance offers
- Important value message to healthcare payers and providers
- Strengthens the data package to regulatory authorities

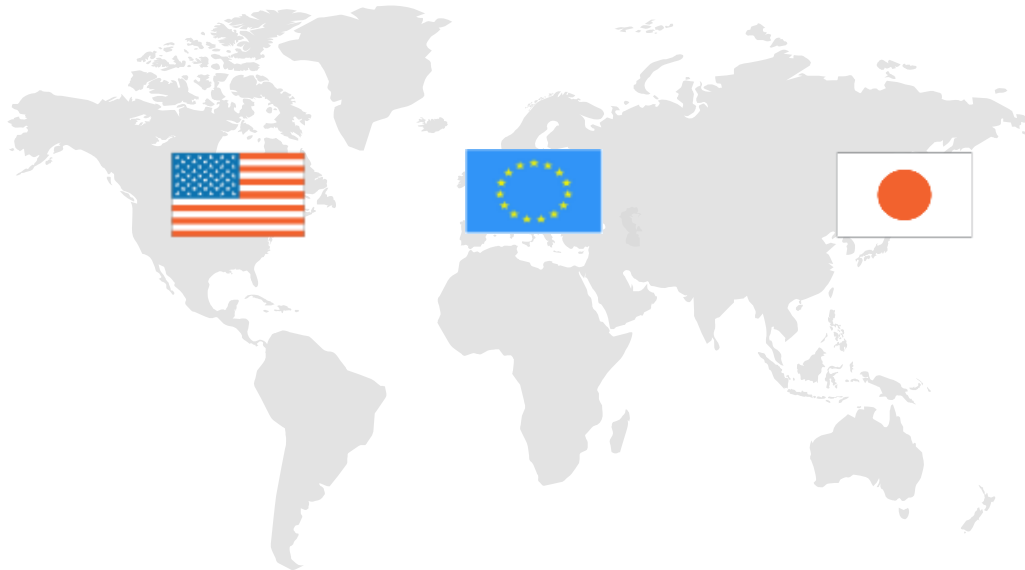
ORVIGLANCE PIVOTAL PROGRAM – SUPPORTING STUDIES

	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

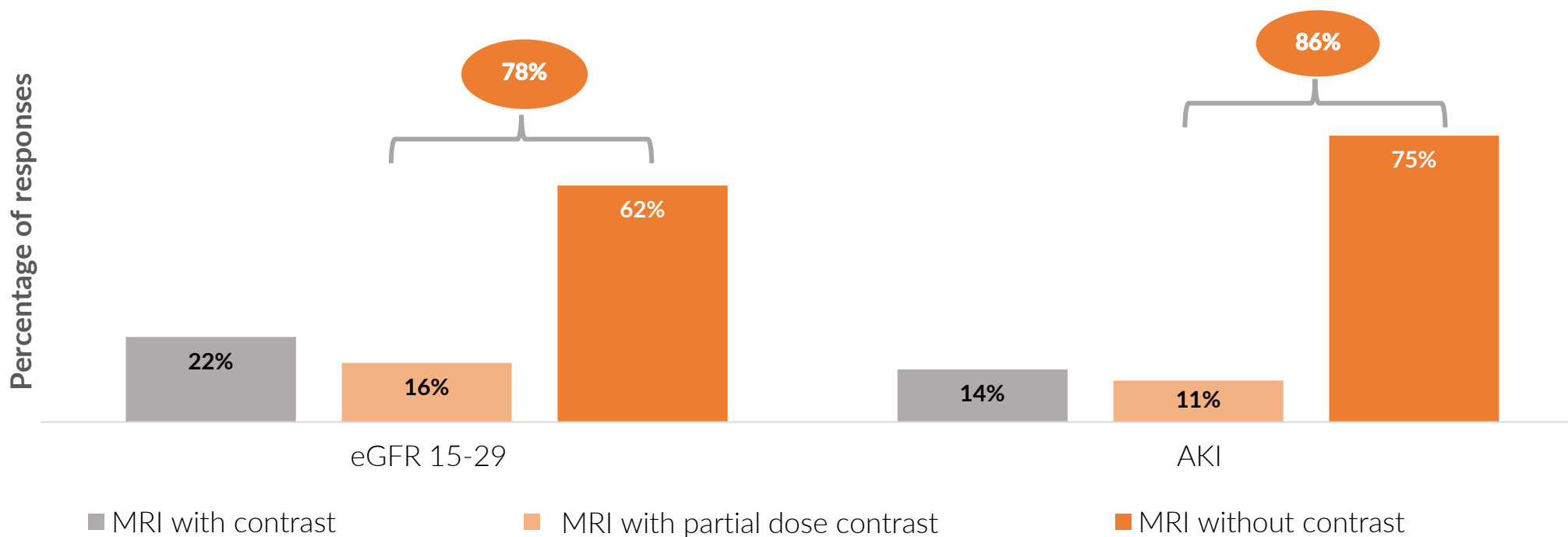
2) Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

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



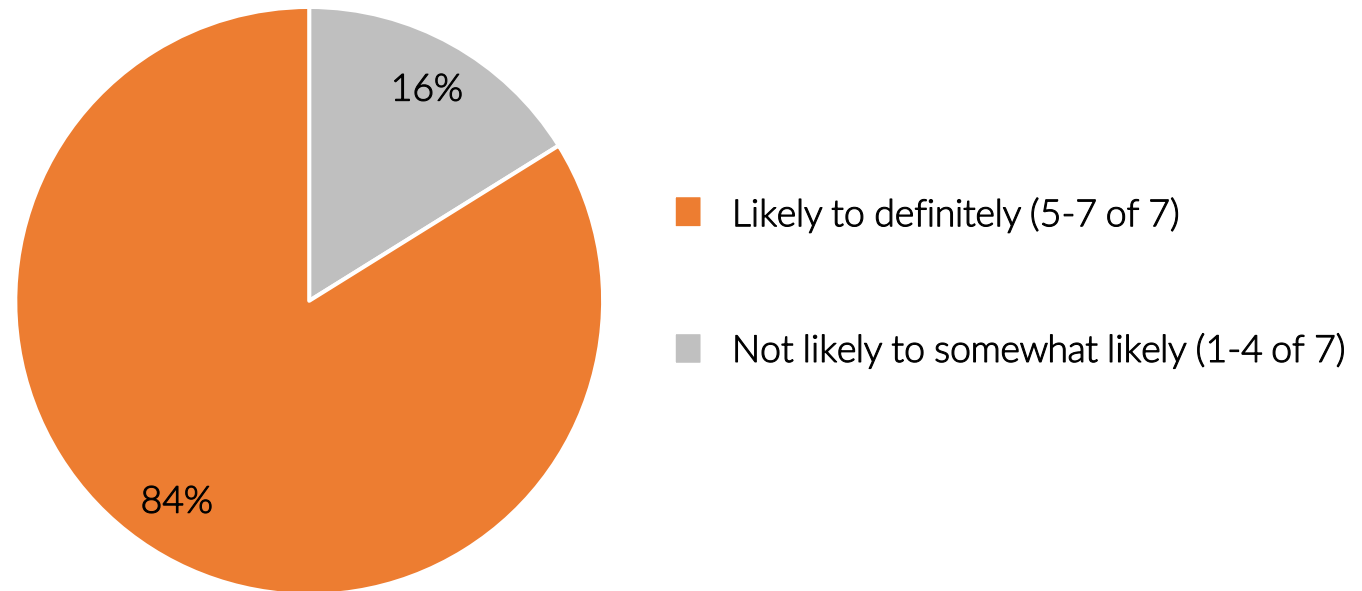
N=103 oncologist, nephrologist, and radiologist responses.

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)

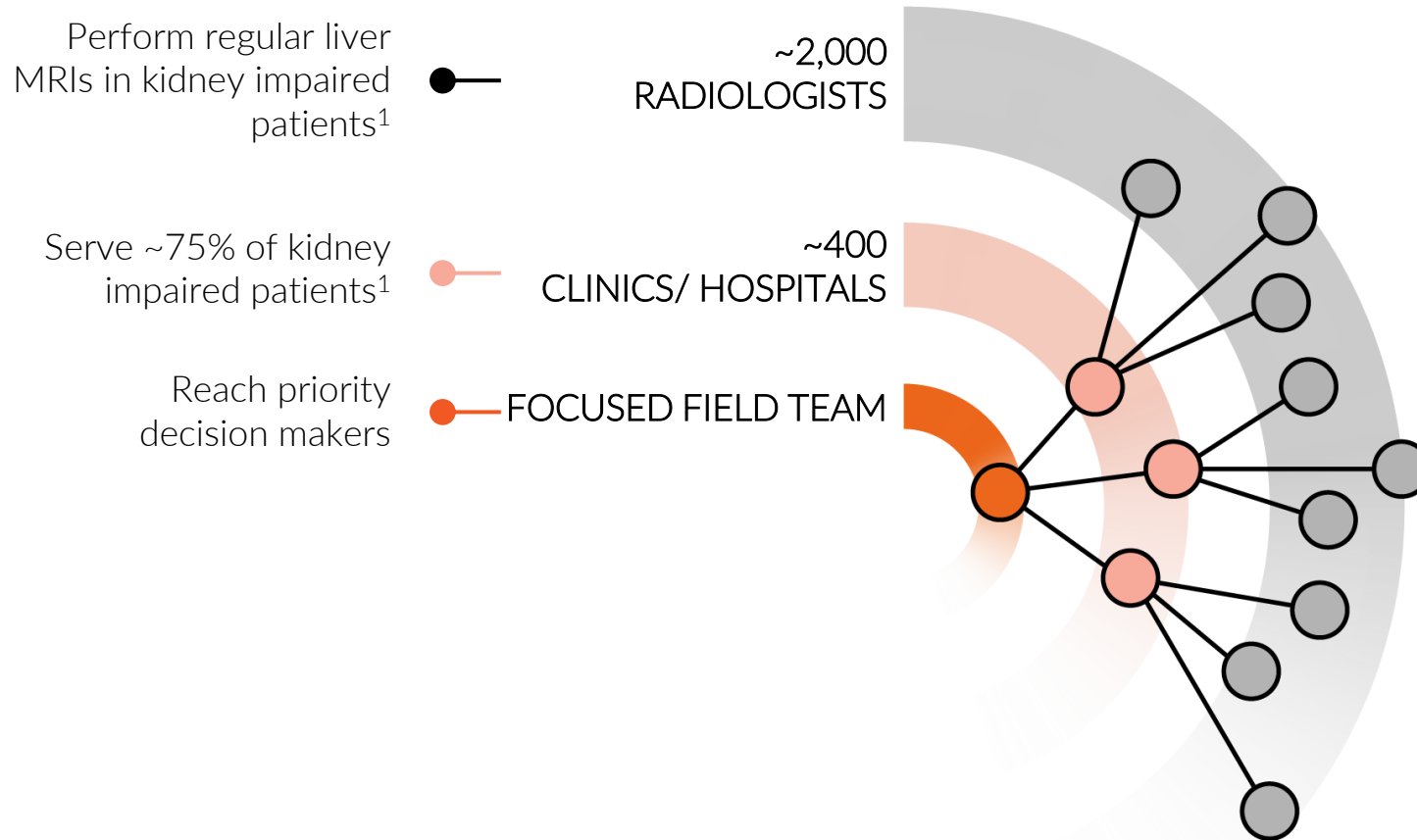
MARKET RESEARCH FROM MARCH 2022

– 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

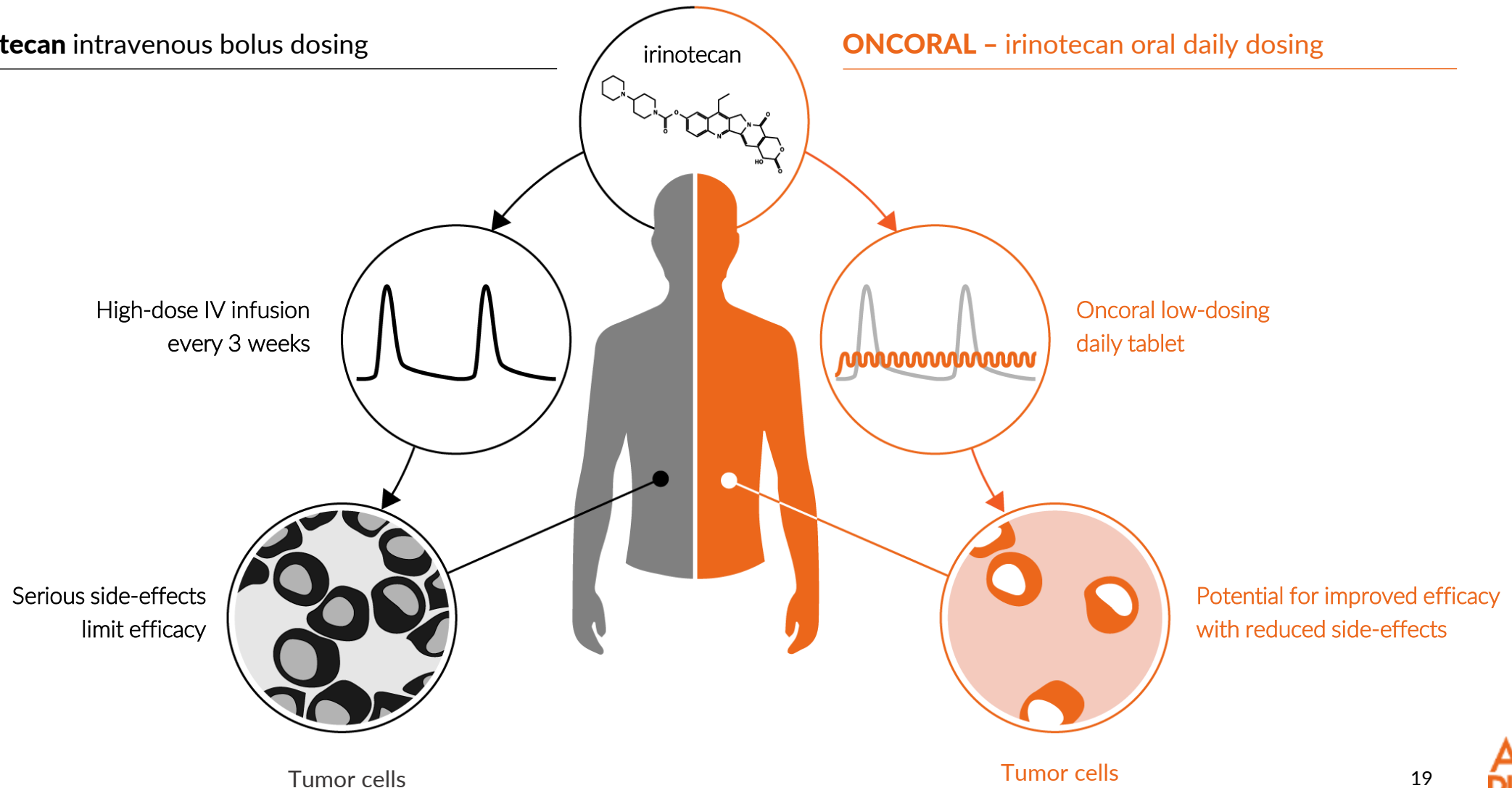
ONCORAL

Daily oral chemotherapy ready for Phase 2

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

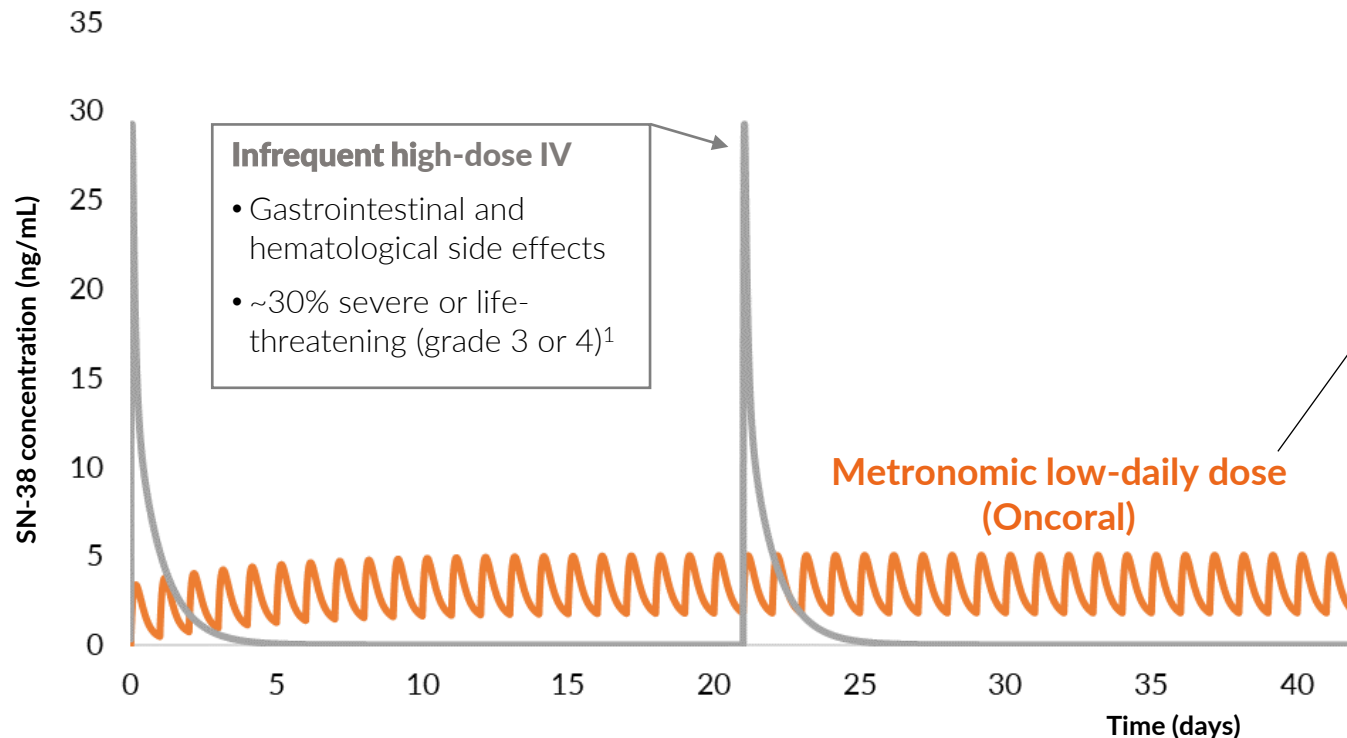
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



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

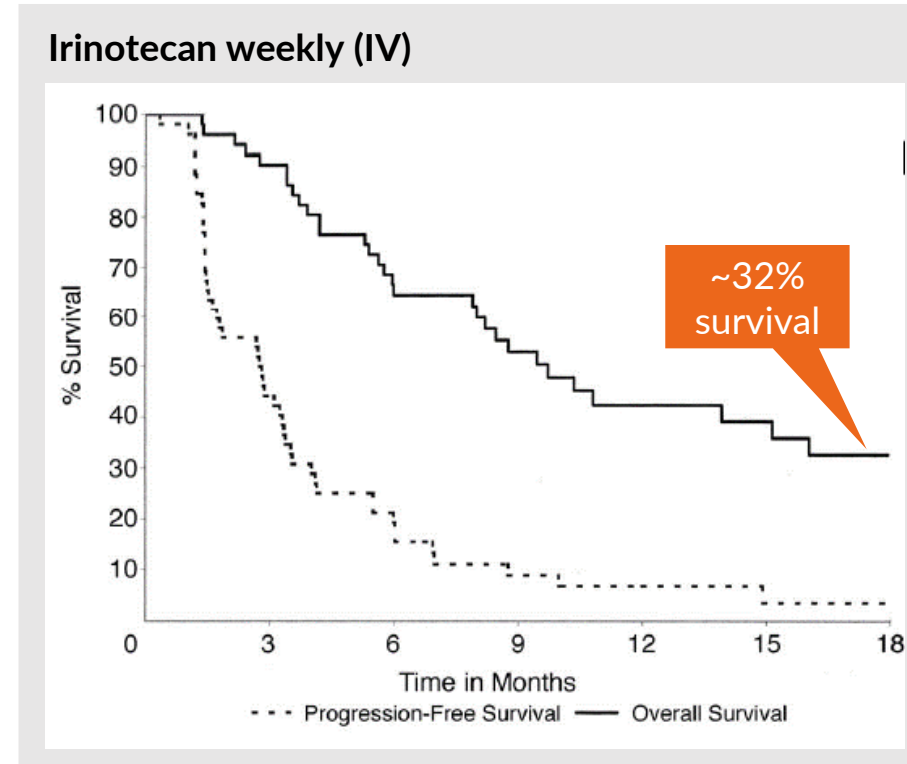
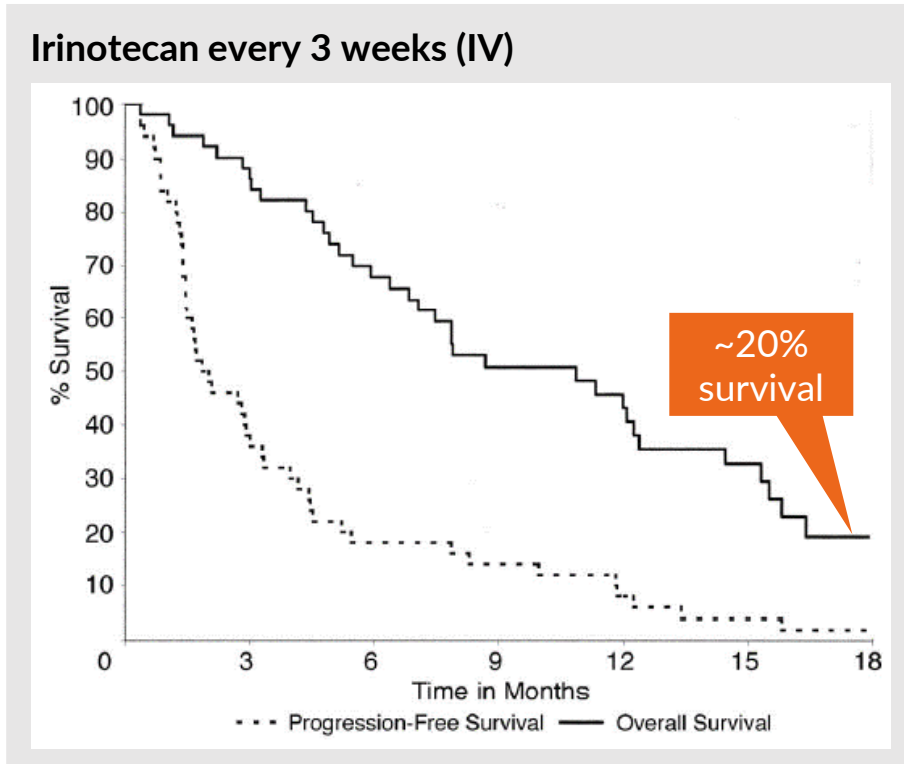
Oncoral Phase 1 results

- 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

IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

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



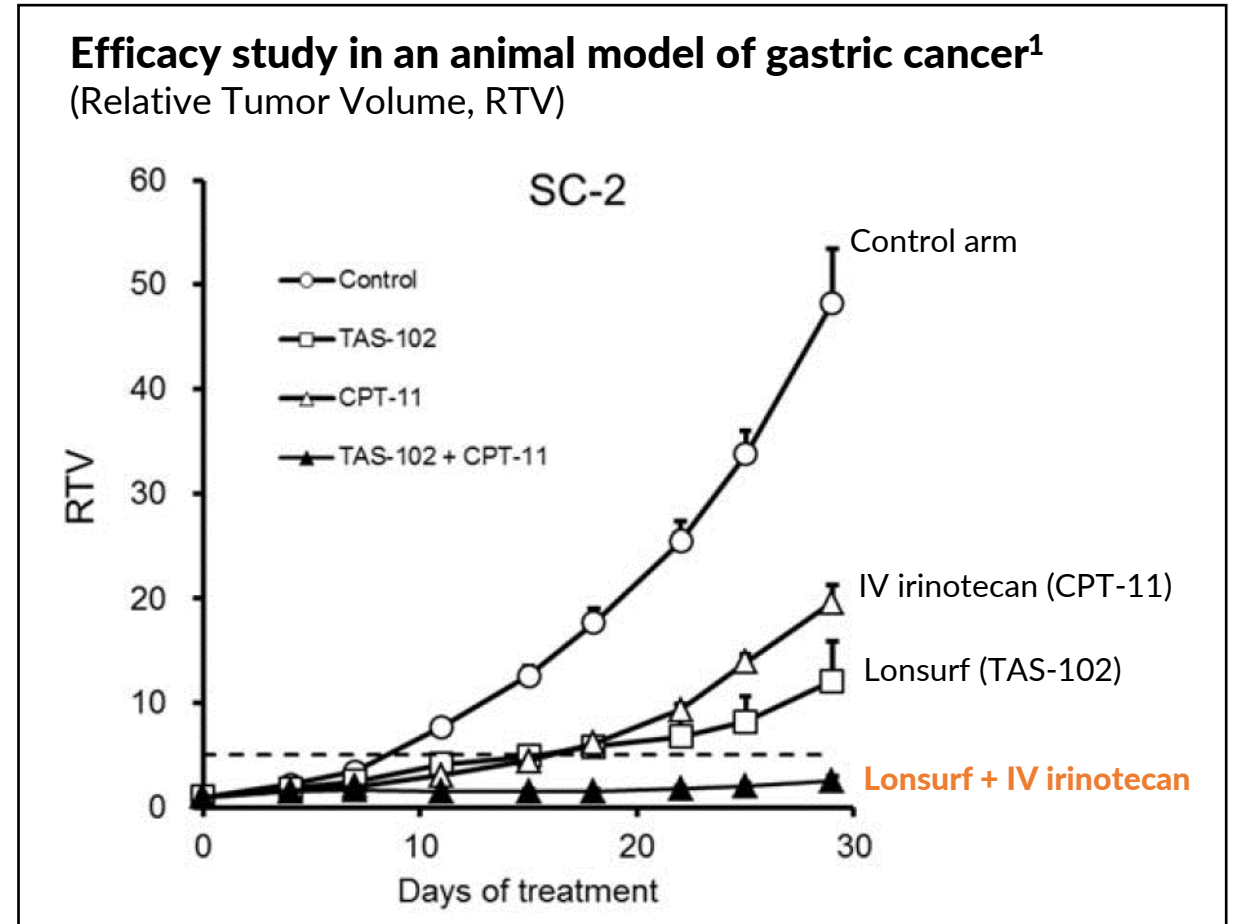
Study in patients with metastatic refractory breast cancer, N=103

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



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

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



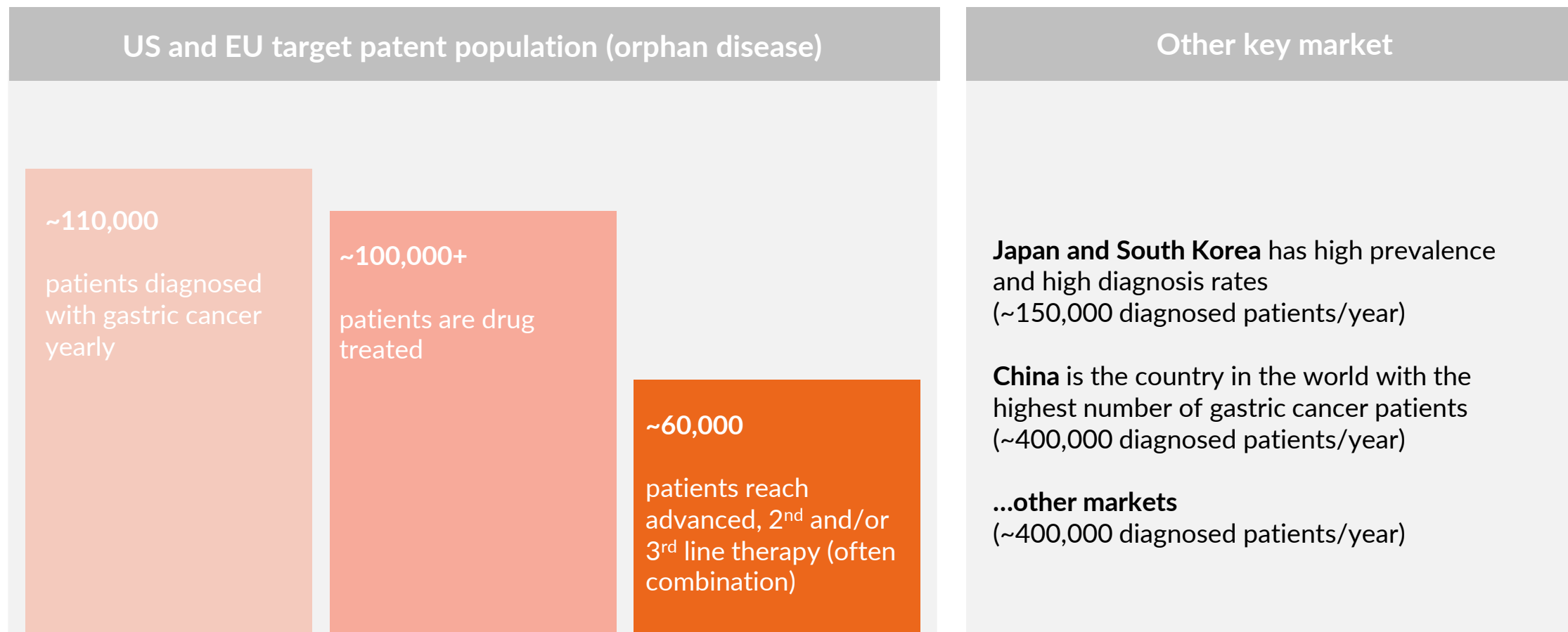
TAIHO ONCOLOGY

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)

GASTRIC CANCER – A \$3BN+ MARKET OPPORTUNITY

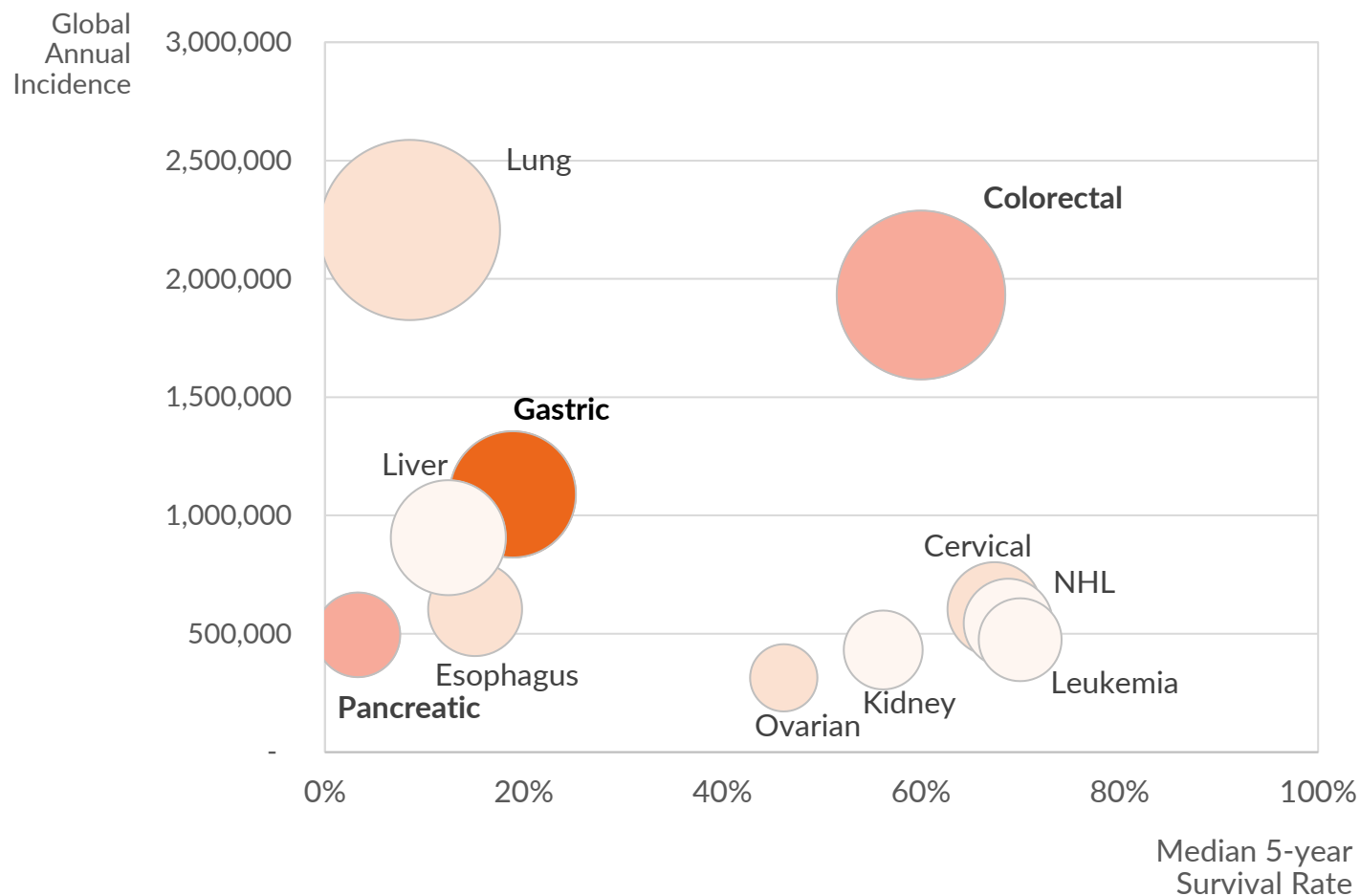


Sources:

International Agency for Research on Cancer (IARC, 2021, input from key opinion leaders and Ascelia analysis
GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024

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

PRIORITIES, FINANCIALS AND SUMMARY





PRIORITIES 2022

 Complete Orvigance Phase 3 patient enrollment

 Prepare Orvigance launch

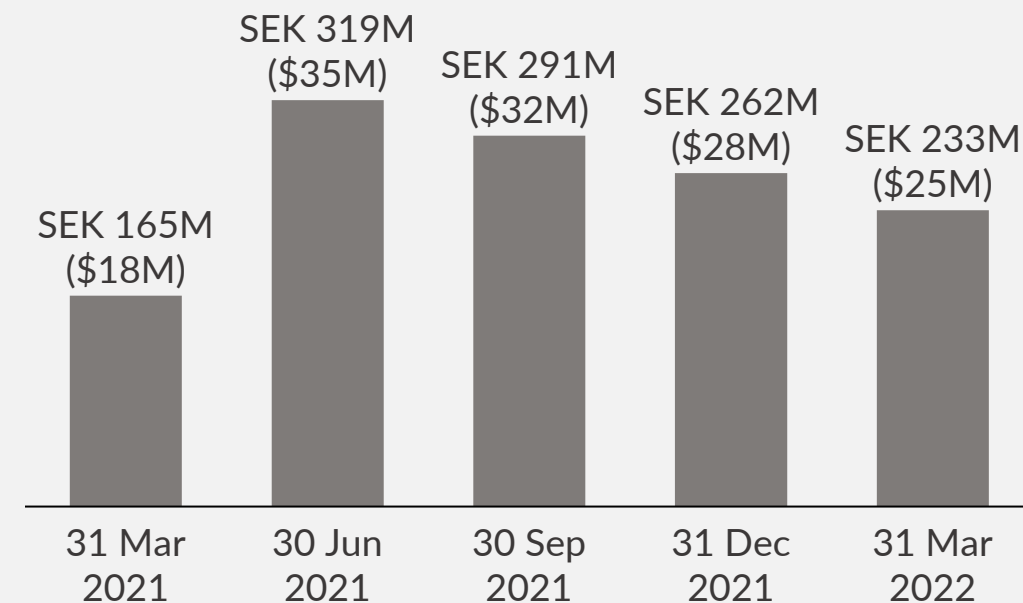
FINANCIAL HIGHLIGHTS Q1 2022 – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets of SEK 233 million (\$25 million) by 31 Mar 2022
- Quarterly burn rate in recent quarters of SEK 30-35 million (\$3.0-3.5 million)
- Current cash position provides financing into H2 2023

Liquidity

(million SEK and USD)



Note: Converted to USD at exchange rate USD/SEK per 31 Mar 2022 of 9.4

ASCELIA PHARMA – COMPANY HIGHLIGHTS



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- 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)

APPENDIX



EXECUTIVE MANAGEMENT



Magnus Corfitzen
Chief Executive Officer

- 20+ years experience investing, building and growing Life Science companies
- Board experience 10+ life science companies

Sunstone

Mekinessy&Company

Danske

Capital

VÆKSTFONDEN



Julie Waras Brogren
Chief Commercial Officer

- 20+ years experience life science. Leadership positions at Novo Nordisk, COO of Bresotec, Canada
- Excellent track record in global product launches and launch preparations. e.g. multi-blockbuster Victoza®



Bresotec

accenture



Carl Bjartmar
Chief Medical Officer, MD, Ph.D.

- 20+ years experience senior positions in big pharma; CMO for Wilson Therapeutics
- Outstanding track record in orphan drug development



genzyme

WILSON
THERAPEUTICS

Lundbeck



Kristian Borbos
Chief Financial Officer

- 20 years experience finance and IR in large caps and banking (sell-side, advisory)
- Completed and lead multiple capital market transactions



BOARD OF DIRECTORS



Peter Benson
Chairman

- Led the formation of Sunstone Life Science Ventures and Managing Partner 2007-2019
- Extensive experience from the Life Science sector from executive positions in Big Pharma and board member in listed companies as well as an investor
- Previous positions include: EVP and President Hospital Care at Pharmacia, VP Marketing & Sales at Kabi Pharmacia Parenterals and Head of Life Science Ventures at the Danish Growth Fund



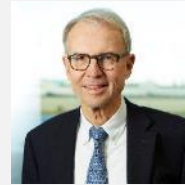
Prof. Hans Maier
Director

- Co-Founder and Managing Partner of BGM Associates GmbH
- Extensive big pharma experience from executive positions within Schering AG and Bayer AG
- Previous positions include: President of the Global Business Unit Diagnostic Imaging at both Schering AG and Bayer AG and part of the Executive Committee of Bayer-Schering AG



Lauren Barnes
Director

- SVP Market Access at Blueprint Medicines (listed on Nasdaq US)
- Extensive expertise and experience in pricing, market access, pre-commercialization and managed markets in particular for the US market. Involved in launch planning of more than 50 drugs
- Previous positions include: VP at Vertex Pharmaceuticals, SVP Avalere Health and led their Reimbursement & Commercialization practice. Various roles at Amgen and the agency that runs the United States Medicare Program, the Centers for Medicare and Medicaid Services



Niels Mengel
Director

- Founding Partner and CEO at Øresund-Healthcare Capital
- Extensive experience from the healthcare industry as an investor and Board member of Danish Shareholders Association
- Previous positions include: EVP at ISS World Services A/S and Director at PA Consulting Group



Helena Wennerström
Director

- Chief Financial Officer ViaCon Group
- Extensive finance executive experience from listed companies
- Previous position include: EVP and CFO of NASDAQ-listed Bulten AB



René Spogård
Director

- Chairman and investor in a number of companies including JEKA Fish A/S (fish) and Bollerup Jensen A/S (chemicals) and Flexfunding
- Extensive experience from investing in the healthcare sector and board positions in a public environment
- Previous positions include: Managing Director at TNS Gallup and Director at TNS plc (London Stock Exchange)

