ADVANCING ORPHAN ONCOLOGY

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www.ascelia.com

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Introduction
January 2024

ASCELIA PHARMA

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We identify, develop and commercialize novel drugs that address unmet needs of people with rare cancer conditions

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ASCELIA PHARMA - HIGHLIGHTS

Two drugs in advanced clinical development

ORVIGLANCE® – Nearing completion of Phase 3

- First-in-class contrast agent for use in liver MRI in patients with severely impaired kidney function
- FDA Orphan Drug Designation
- Global addressable market of USD 800 million
- Phase 3 patient recruitment completed; readout by May 2024

ONCORAL – Phase 2-ready

- Daily, oral irinotecan chemotherapy
- Clinical collaboration with Taiho Oncology
- Opportunity in gastric cancer and other solid tumors

Global outlook and Nordic roots

Based in Malmö (Sweden), US affiliate in New Jersey (US)

Listed on NASDAQ Stockholm (Ticker: ACE)

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ORVIGLANCE®

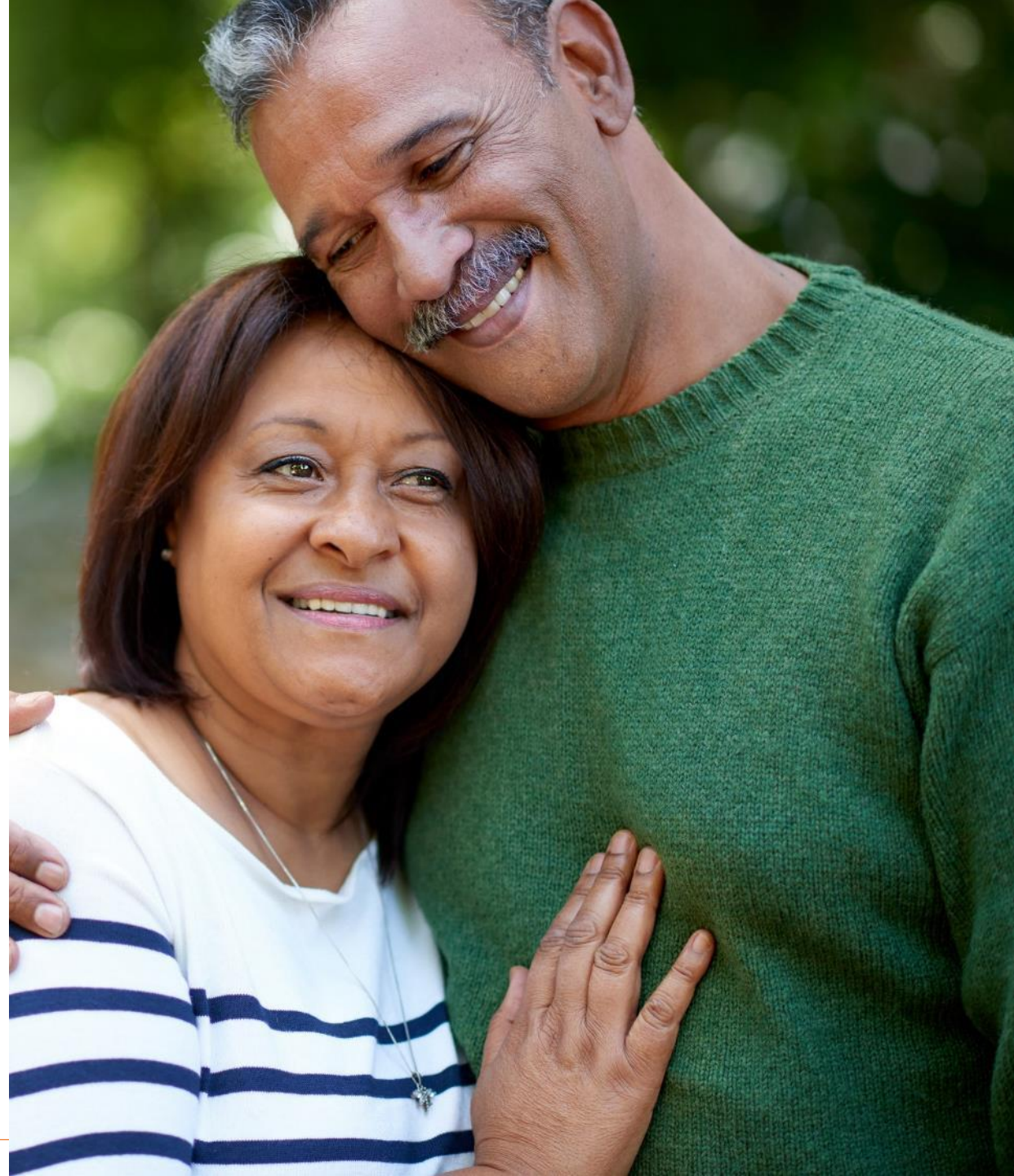
Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

CLEAR UNMET NEED AND CONSISTENT POSITIVE DATA

- A well-defined unmet need for liver imaging in cancer patients with poor kidney function
- A global addressable market opportunity of USD 800 million
- Consistent positive efficacy and safety in eight completed Phase 1 and 2 studies
- Patient recruitment and MR image collection for SPARKLE Phase 3 study completed
  - Common adverse events were in line with previous studies
  - Efficacy conclusions available by May 2024



ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Patient Landscape

Liver metastases critical in cancer care

Liver metastases are common in many cancer types and often the cause of mortality [1-3]

- Colorectal cancer, metastatic breast cancer, gastric cancer

Treatments

Contrast enhanced MRI is the gold standard

Contrast enhanced MRI

- Detection and visualization
- Surgery & drug treatment plan
- Post-treatment surveillance

Unmet Need

A role for ORVIGLANCE in patients with kidney impairment

Patients with healthy kidneys

- Receive MRI with gadolinium-based contrast agent (GBCA)

Patients with severe kidney impairment

- Black Box warning for gadolinium contrast agents
- Risk of severe side effects, incl. Nephrogenic Systemic Fibrosis

ORVIGLANCE

Aims to be the imaging option without gadolinium-related safety risks patients with poor kidney function

- Manganese based
- Liver specific

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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CLINICAL DATA PACKAGE FOR REGULATORY SUBMISSION

Consistent positive efficacy and safety in completed studies[1-7]

Completed program of 8 studies in 201 patients and healthy volunteers

Pivotal results pending

85 patients recruited

Eight Studies Completed [1-7]

Evaluating safety and efficacy

Totally 201 patients and healthy volunteers

Evaluation Before Phase 3

Re-read of efficacy across all studies

140 patients (72 study subjects and 68 compassionate use program)

Re-Evaluation Orviglance vs. Gadolinium & Unenhanced

Re-read by 3 blinded readers of 20 patients with liver metastases

Food Effect Study

Effect of food intake on absorption and signal intensity (39 subjects)

Hepatic Impairment Study

Effect of liver impairment on safety and pharmacokinetics (35 subjects)

Phase 3
Pivotal Study SPARKLE

Safety and efficacy
in target patient population
(85 patients)

1) Thomsen HS *et al*, Acad Radiol 2004: 11: 630-636
2) Thomsen HS et al. Eur Radiol 2007, 17: 273-278
3) Rief M *et al.* Invest Radiol. 2010; 45: 565-71
4) Brismar TB *et al*.. Eur Radiol 2012; 22:633-41
5) Albiin N *et al*. MAGMA. 2012; 25:361-368
6) Study CMC-P005, primary objective to study of Orviglance for imaging of bile ducts (not published)
7) Results from Phase 1 and 2 and Food Effect and Hepatic Impairment Studies presented at RSNA and ESGAR conferences between 2022 and 2023

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ASCELIA EXPERIENCE WITH EVALUATION METHODOLOGY

	Number of Patients	Liver Lesion Types*	Number of Radiologist Readers	Primary Endpoint	Orviglance Superior to Unenhanced	Statistical Significance
P004A Re-read	20	Metastases	3	Co-primary: Border delineation; Lesion contrast	Yes	(P=0.009)
Phase 3 Pivotal Study SPARKLE	85	Known or suspected lesion (metastases, primary tumors, benign lesions)	3	Co-primary: Border delineation; Lesion contrast	?	?

* Apart from the difference in population heterogeneity, other differences between P004A Re-read and SPARKLE includes dose and use of Diffusion Weighted Imaging in SPARKLE

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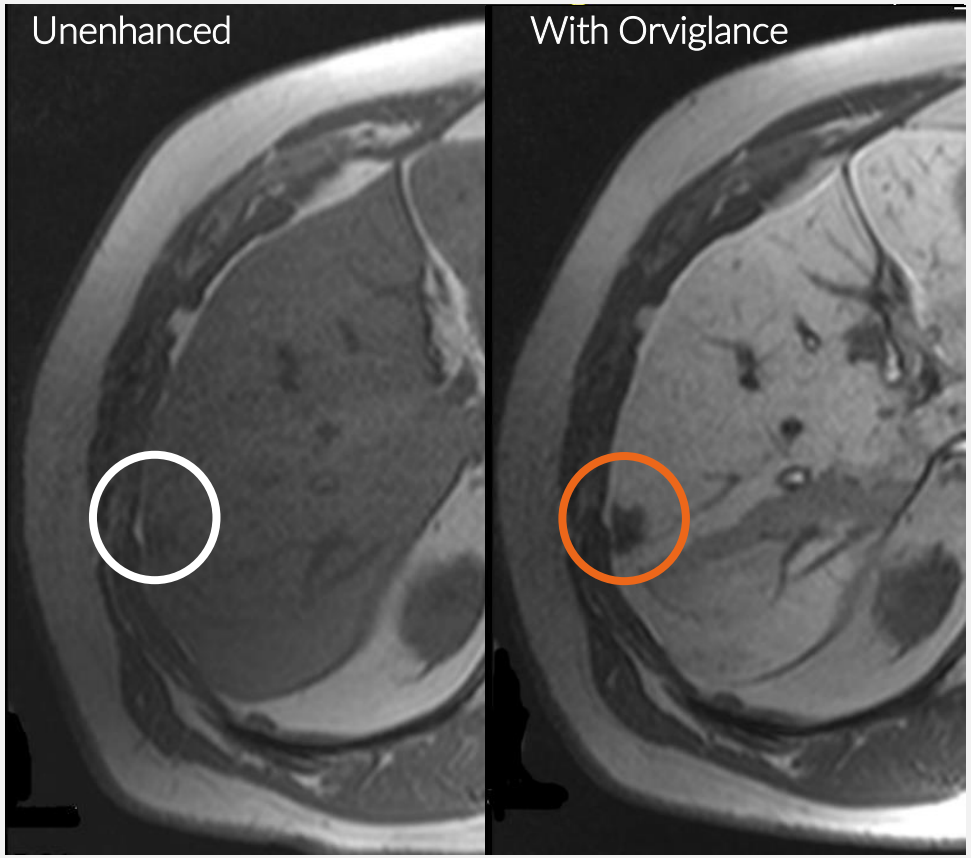
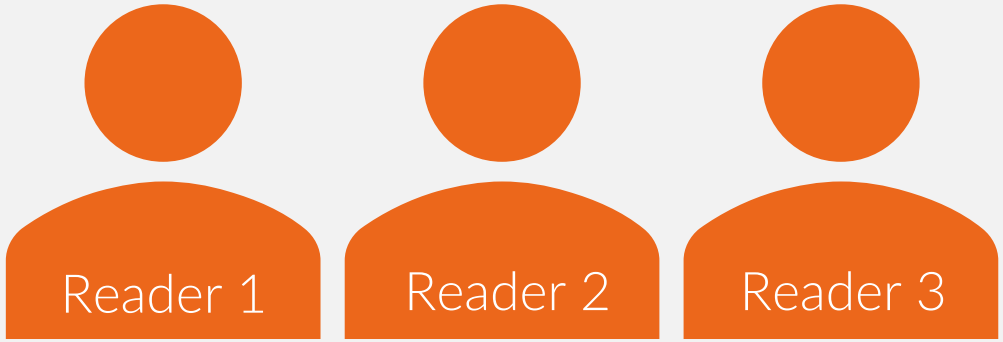
SPARKLE SUCCESS DETERMINED BY LESION VISUALIZATION



Images from Study CMC-P002, patient with colon cancer and liver metastasis.

Criteria for statistical test of primary endpoint



Primary endpoint is met if 2 out of 3 independent radiologists rate both Border Delineation and Lesion Contrast (Conspicuity) for Orviglance MRI higher than unenhanced MRI with statistical significance

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RE-EVALUATION OF PHASE 3 IMAGES ON TRACK

Data collected with results of image re-evaluation pending

- **Clinical data collected** from 85 patients; no further patient enrollment required
- **Common adverse events** in line with previous studies
- **Re-evaluation of all images required** due to unreliable scoring by two readers with high intra-reader variability

Intra-Reader Variability Assessment

1st evaluation ≠ *2nd evaluation*

Re-evaluation on track for headline results by May 2024

- **Re-evaluation designed** to secure reader consistency
- **Readers selected** and trained
- **Reading and monitoring initiated** in early December and progressing according to plan

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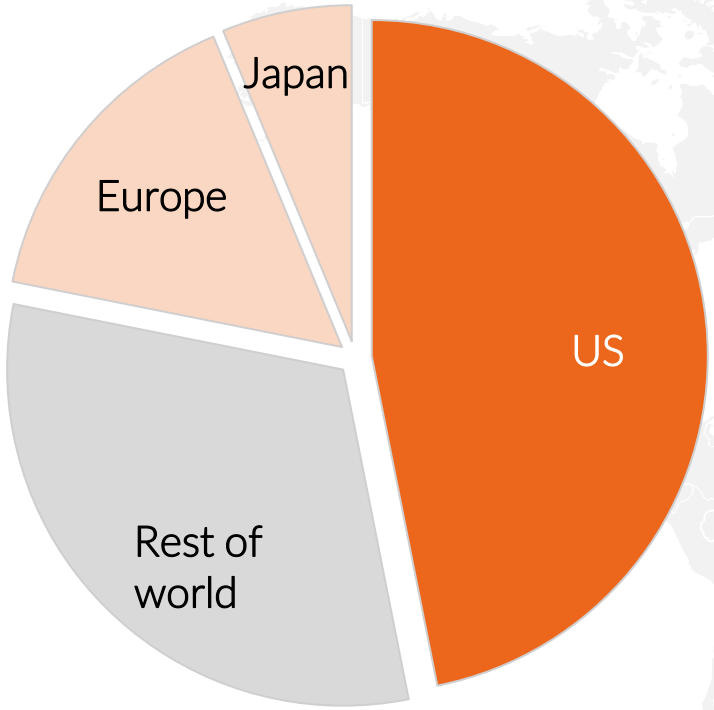
ATTRACTIVE ADDRESSABLE MARKET



Global addressable market of USD 800 million

Well-defined unmet need for liver imaging in cancer patients with severe kidney impairment

Attractive pricing and access opportunity based on recognized value proposition[1]

Global commercialization through partners with potential for Ascelia led launch in the US

Sources:
Ascelia Pharma market research with Decision Resources Group, 2020.
Ascelia Pharma market access research and analyses with Revenue Reimbursement Solutions and Charles River Associates (2020), Triangle (2022) and Trinity (2022), incl. 75 stakeholder and expoert interactions
1) Final pricing strategy is subject to Phase 3 data, payer evidence, negotiations, discounts and access strategy

ATTRACTIVE US OPPORTUNITY

Abdominal imaging procedures in cancer patients with severe kidney impairment (CKD 4/5/AKI) based on epidemiology and real-world data[1]

Pricing range benchmarks based on innovative diagnostics, payer and expert input and price testing[2, 3]

Volume growth driven by demographics as well as prevalence and long-term care in cancers and kidney disease

~100,000
procedures annually

$3,000-4,500

4-5%
vol. annually

Sources:
1) Ascelia Pharma market research with Decision Resources Group, 2020. Literature on prevalence and epidemiology of kidney disease, cancer and liver metastases.
2) Ascelia Pharma market access research and analyses with Revenue Reimbursement Solutions and Charles River Associates (2020), Triangle (2022) and Trinity (2022)
3) Final pricing strategy is subject to Phase 3 data, payer evidence, negotiations, discounts and access strategy

UNMET NEED RECOGNIZED

NSF* risk
with warnings for target population

+90%

of HCPs are concerned by issues relating to GBCAs (including NSF)

+16%

of providers have experienced GBCA-induced NSF

*nephrogenic systemic fibrosis

Source: Independent research by Two Labs Pharma Services for Ascelia Pharma in the USA conducted in Q4 2021/Q1 2022 included 16 in depth interviews and a survey of 254 healthcare professionals (HCPs), including 154 radiologists, 50 nephrologists and 50 oncologists. Participants in the study were asked about their choices of imaging and contrast agents in patients with cancer

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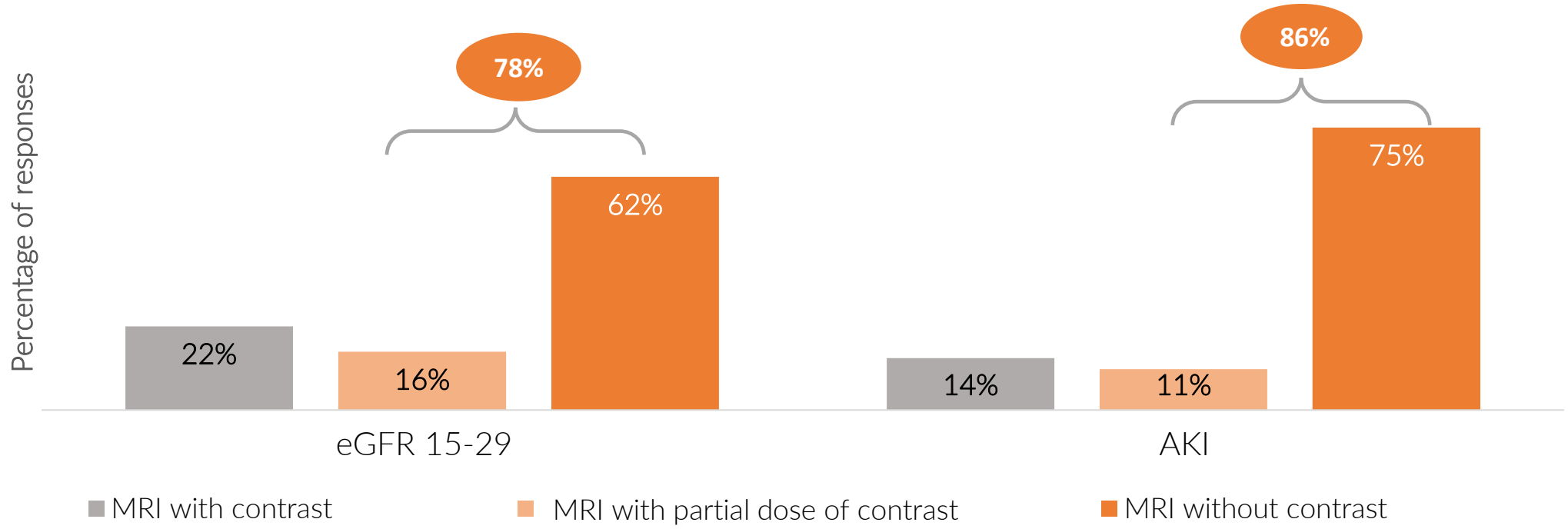
UNENHANCED MRI IS PREFERRED FOR TARGET PATIENTS

78% physicians prefer MRI without or with partial dose contrast for patients with poor kidney function (low eGFR)

... even more for patients with acute kidney injury (AKI)



Source: Independent research by Two Labs Pharma Services for Ascelia Pharma in the USA conducted in Q4 2021/Q1 2022 included 16 in depth interviews and a survey of 254 healthcare professionals (HCPs), including 154 radiologists 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

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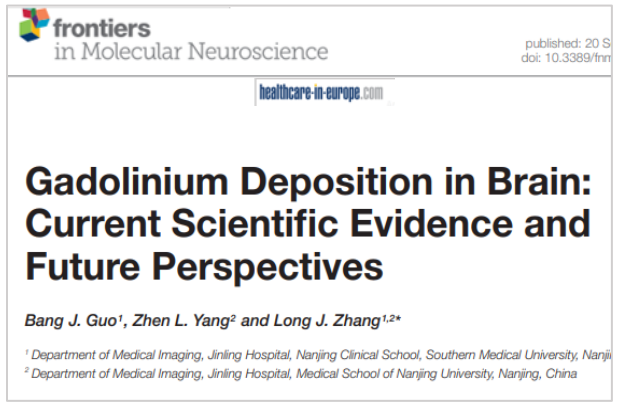
MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

Deposition in brain & organs

concerns around safety for all patients

New safety category recommended for Symptoms Associated with Gadolinium exposure (SAGE), by Am. College of Rad. (2022)

Multiple-GBCA effect on body movement and mental skills study requested by the FDA (ODYSSEY, 2020)


frontiers in Molecular Neuroscience

published: 20 S
doi: 10.3389/fnm

healthcare-in-europe.com

Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives

Bang J. Guo[1], Zhen L. Yang[2] and Long J. Zhang[1,2]*

[1] Department of Medical Imaging, Jinling Hospital, Nanjing Clinical School, Southern Medical University, Nanji
[2] Department of Medical Imaging, Jinling Hospital, Medical School of Nanjing University, Nanjing, China

Water contamination

scrutiny of environmental impact

Gadolinium is excreted in urine. Hard to remove in our sewage systems, it is discharged into our environment and drinking water

"The increasing use of gadolinium-based contrast agents (GBCAs) for MRI is leading to widespread contamination of freshwater and drinking water systems"[1]

Future with less/no gadolinium

focus of leading gadolinium manufactures

Low dose full-body gadolinium contrast agents

- FDA approved in priority review (2022) and EMA (2023) approved (gadopiclenol, Guerbet/Bracco
- Initiation of Phase 3 (gadoquatrane, Bayer 2023)

Completion of Phase 1 patient enrollment in full-body IV manganese-based contrast agent (GE HealthCare 2023)

1) Brünjes R. et al. Anthropogenic gadolinium in freshwater and drinking water systems, Water Research, Volume 182, 2020..
Other sources include:
Macke et al. Fast and automated monitoring of gadolinium-based contrast agents in surface waters, Water Research, Volume 207, 2021.
Oluwasola et al, Gadolinium based contrast agents (GBCAs): Uniqueness, aquatic toxicity concerns, and prospective remediation. Journal of Contaminant Hydrology, Volume 250, 2022.
M. Nicholl. Seeking alternatives to gadolinium-based contrast agents. Healthcareineurope.com. July 22022
Bang G. Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives. Mol. Neurosci., 20 September 2018.

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ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

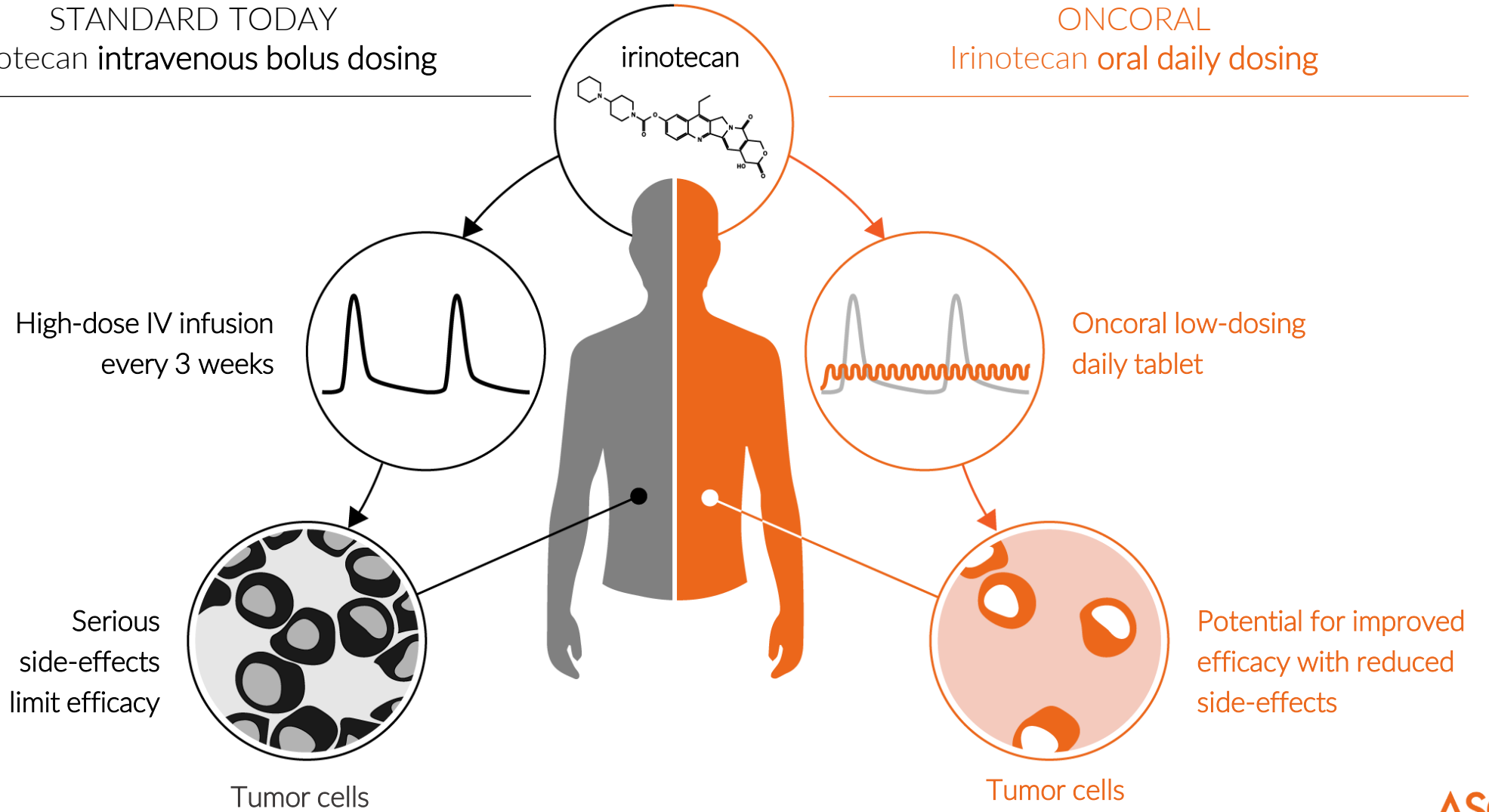
Daily, oral chemotherapy

OUR PORTFOLIO

IMPROVING **EFFICACY** AND **TOLERABILITY** IN SOLID TUMORS

STANDARD TODAY
Irinotecan **intravenous bolus dosing**

ONCORAL
Irinotecan **oral daily dosing**



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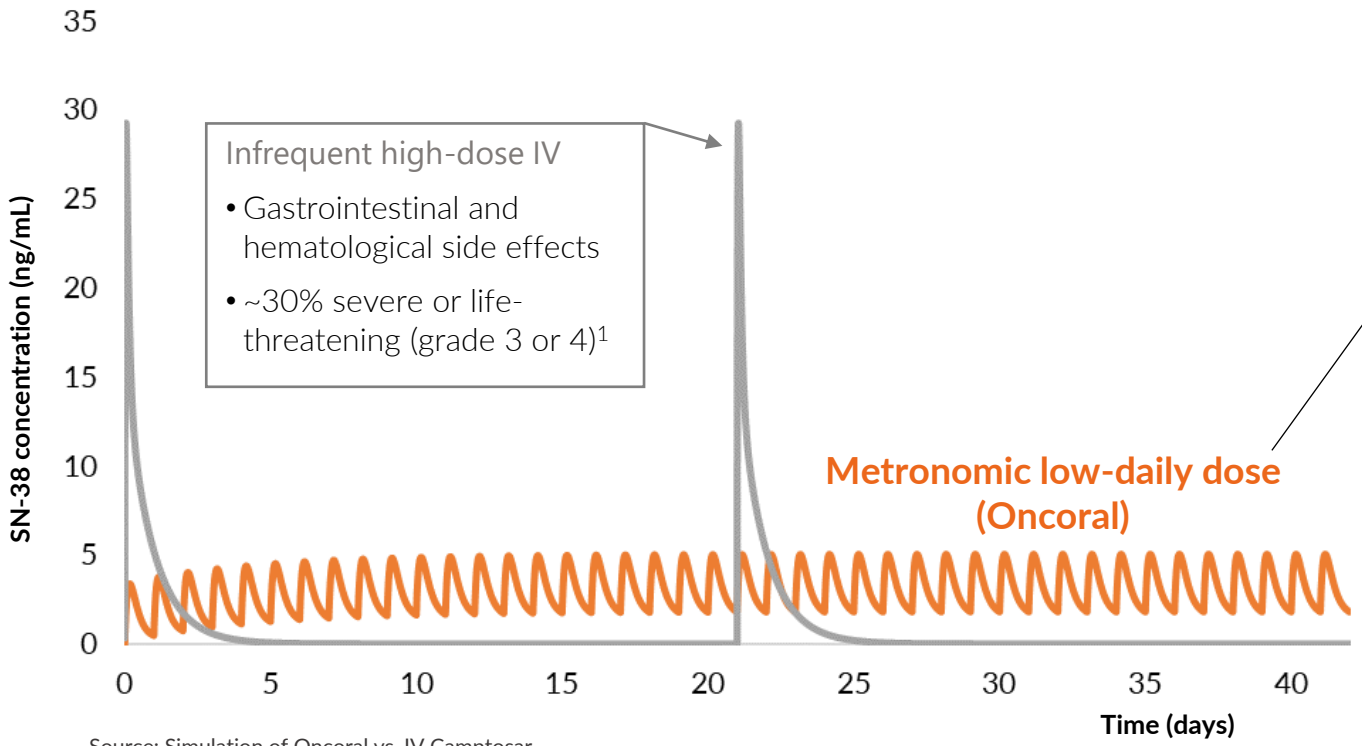
ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

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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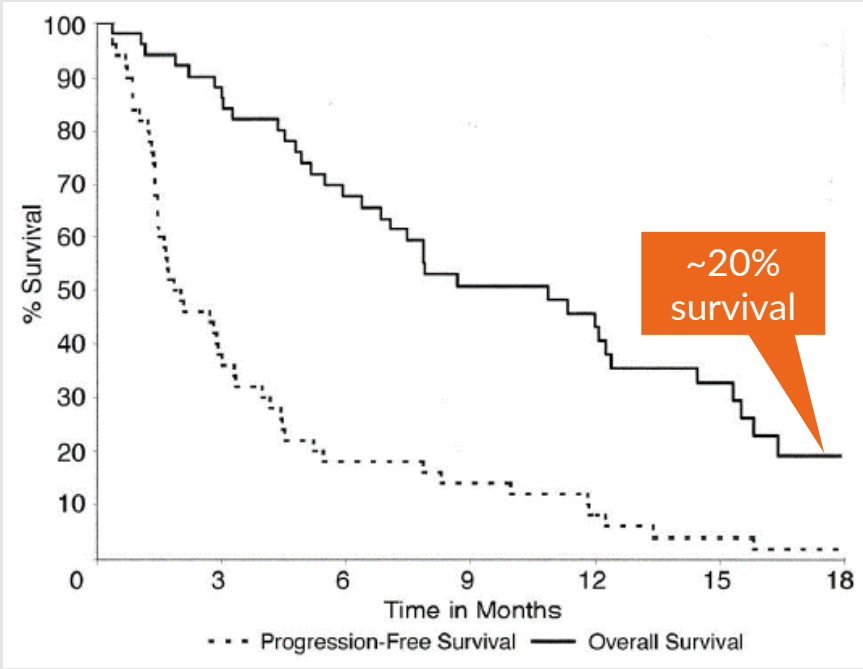
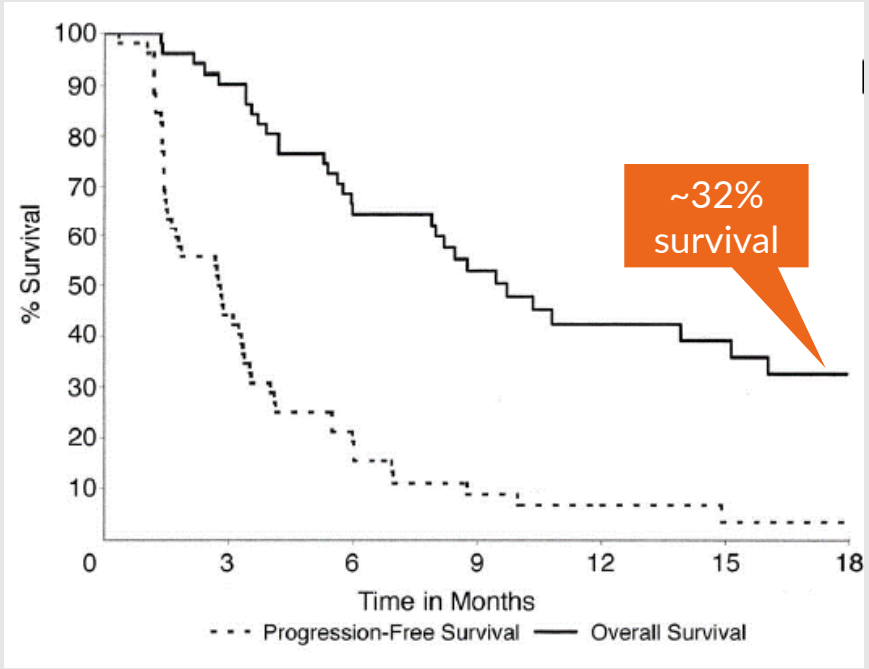
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

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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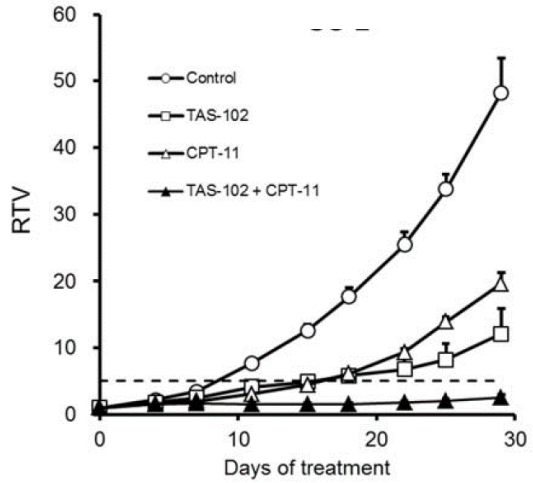
ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

- High unmet need and clinically demonstrated
- Potential for synergistic effect between Lonsurf and irinotecan

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



Control arm

IV irinotecan (CPT-11)
Lonsurf (TAS-102)

Lonsurf + IV irinotecan

LONSURF AND IRINOTECAN COMBINATION

RANDOMIZED CONTROLLED PHASE 2 STUDY

- ~100 patients with metastatic gastric cancer
- Study arms: Oncoral + Lonsurf vs. Lonsurf
- Endpoints: Progression Free Survival (Primary), Response Rate, PK, Safety (Secondary) and Overall Survival (follow-up)
- IND approved in the US
- To focus all resources on Orviglance, patient enrollment is not initiated until it can be done effectively

Clinical collaboration with

TAIHO ONCOLOGY

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

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

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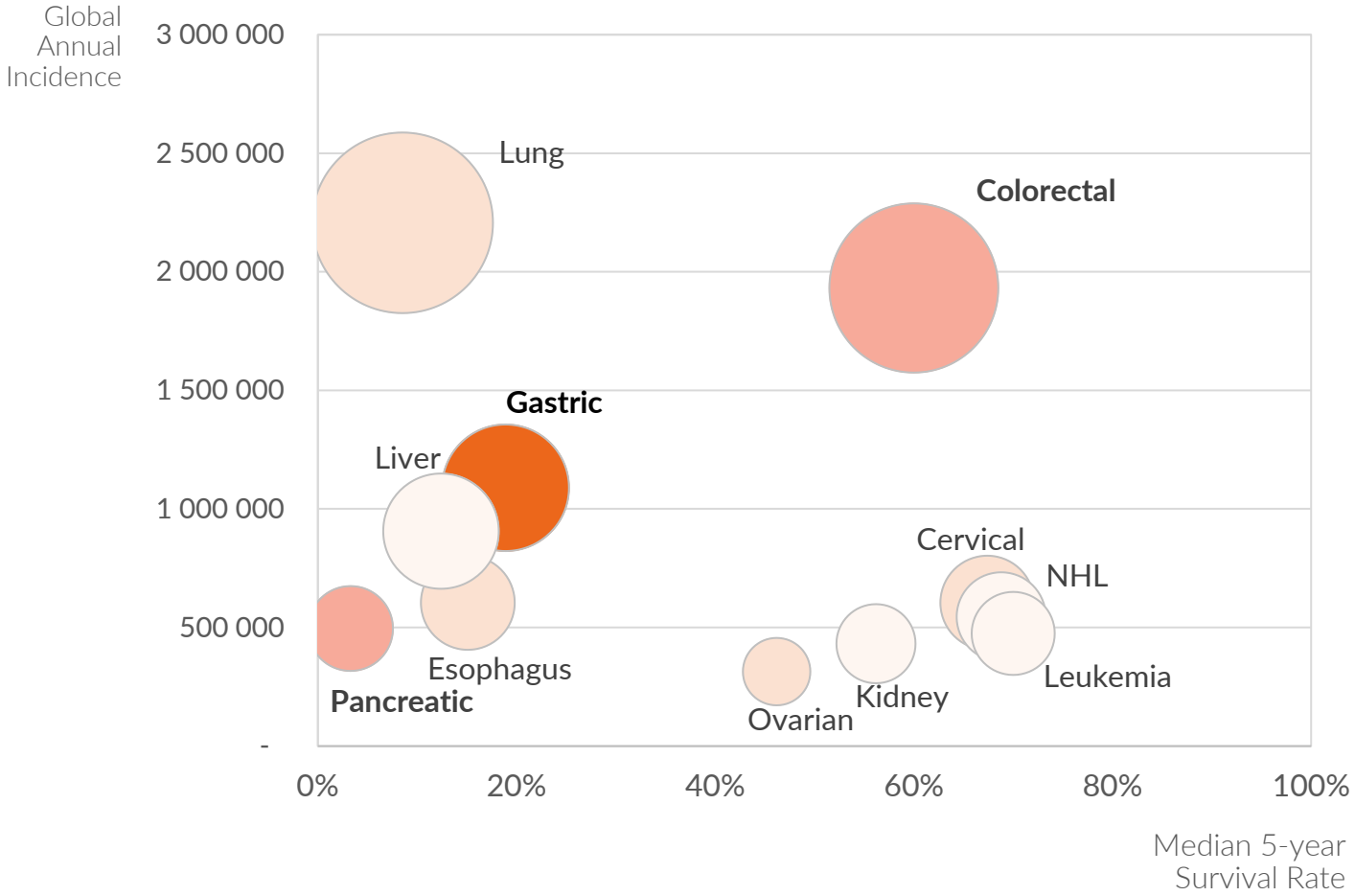
HIGH VALUE GASTRIC CANCER OPPORTUNITIES WITH EXPANSIONS

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN[3]



A WELL-ESTABLISHED CHEMOTHERAPY
with recognized anti-tumor effect in solid tumors

- Current focus: **Gastric cancer**
  - Clinically demonstrated
  - Guidelines recognized
  - 3rd highest cancer deaths[1]
  - Orphan disease (US and EU)
  - $3-4bn market[2]
- **Approved indications** for IV irinotecan
- Indications where IV irinotecan are clinically demonstrated & guidelines recognized
- Indications where IV irinotecan 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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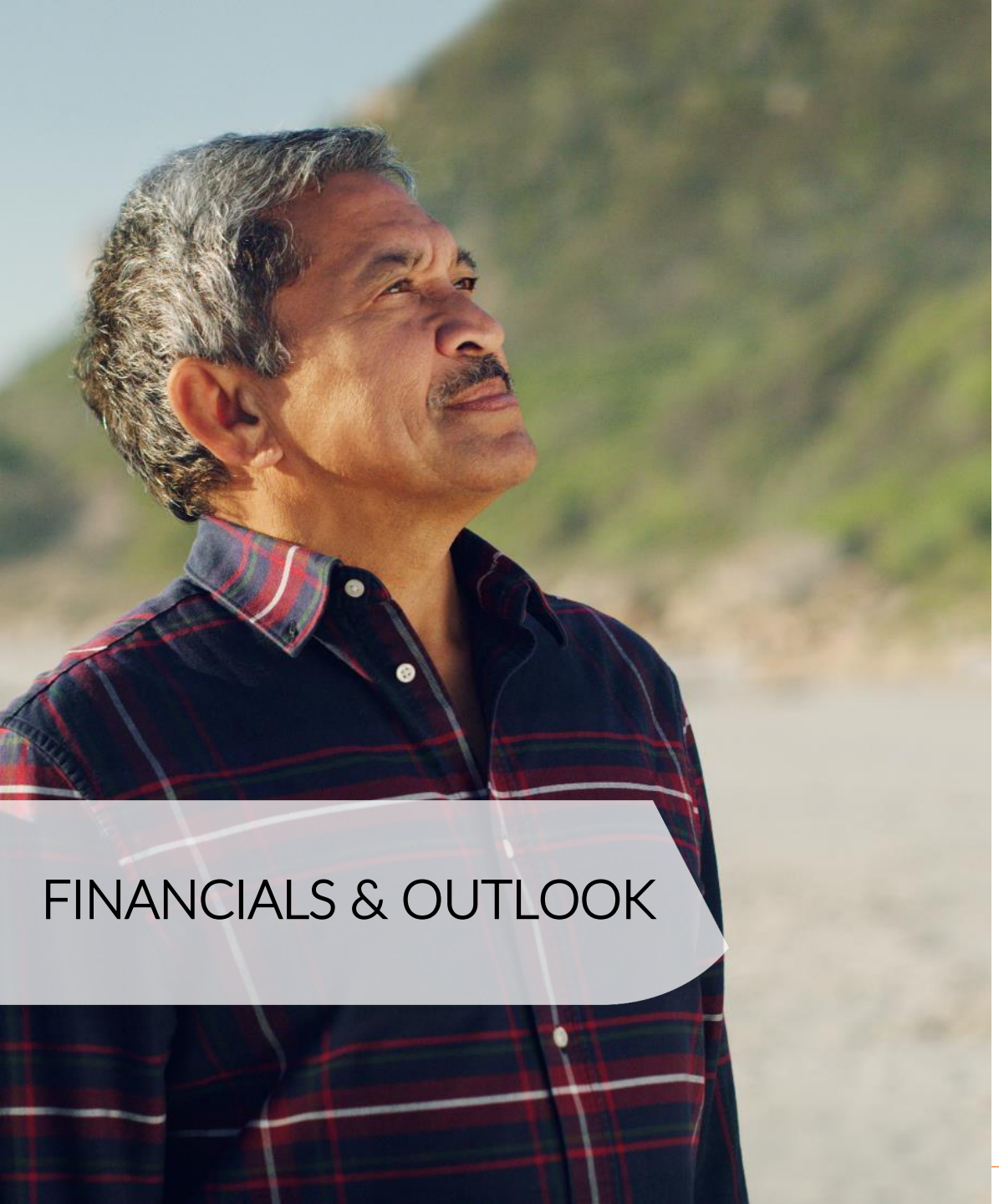


FINANCIALS & OUTLOOK

RUNWAY PAST HEADLINE RESULTS AND INTO Q3

Liquid assets of 39 MSEK ($3.6M) by 30 Sept 2023

- Last directed share issue raised 200 MSEK in March 2021

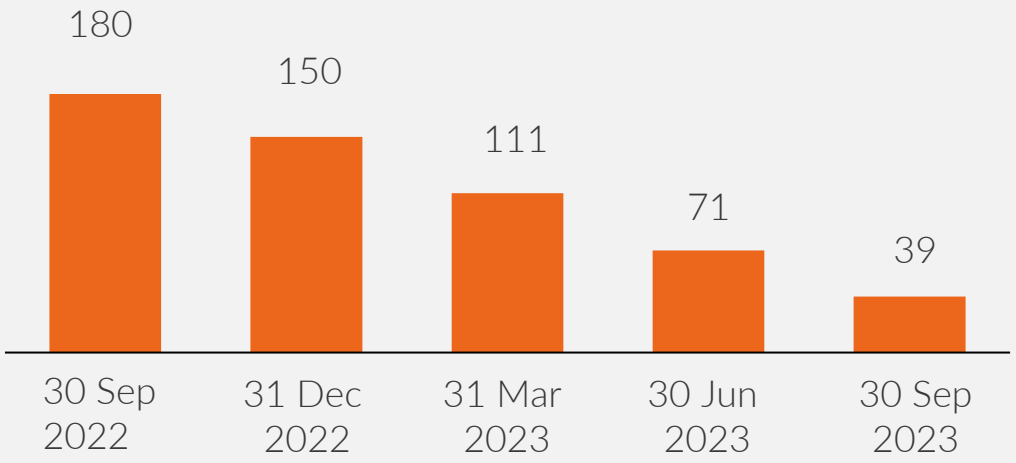
Decreasing operating loss driven by

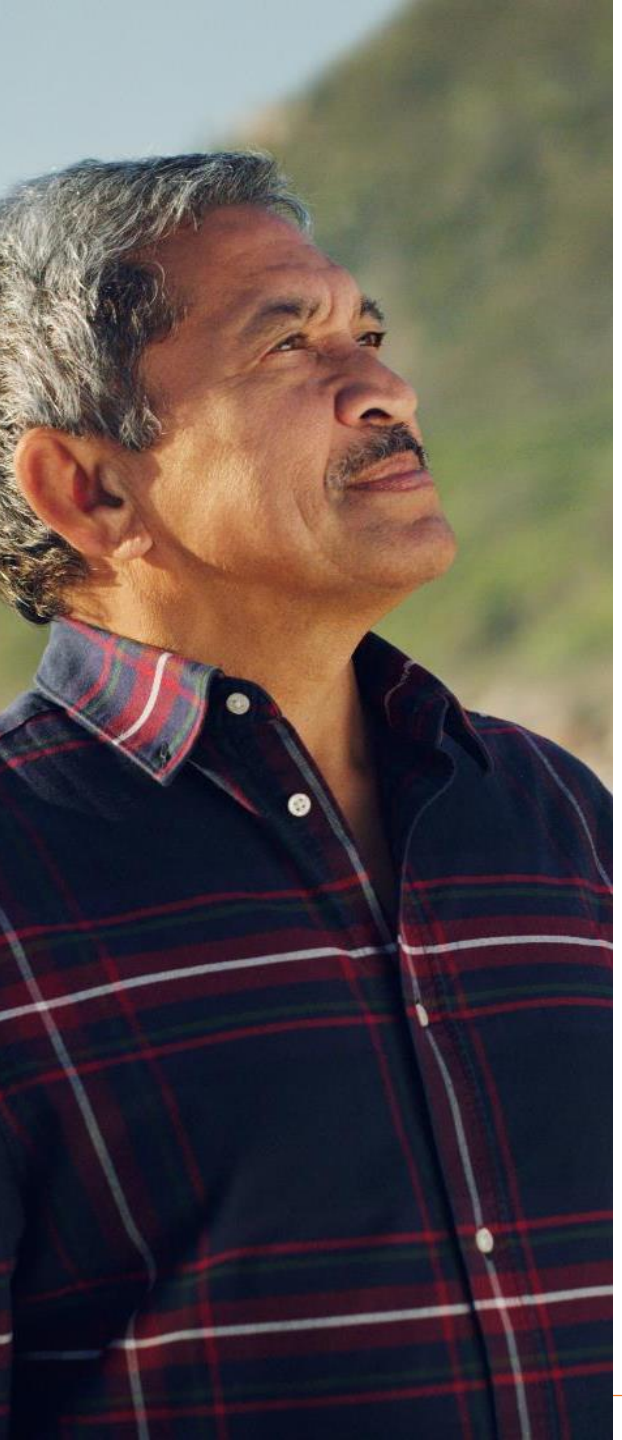
- Completion of SPARKLE patient recruitment activities
- Cost saving initiatives, including organizational reduction
- Focus on image re-evaluation with other activities on hold

Completing SPARKLE image re-evaluation by May 2024 with currently available funding

Runway into Q3 2024; suitable funding options to grow Ascelia beyond headline results explored in due time

Liquid assets including marketable securities
(SEK million)





SUBSTANTIAL VALUE CREATION OPPORTUNITIES

ORPHAN ONCOLOGY FOCUSED WITH TWO DRUGS IN ADVANCED CLINICAL DEVELOPMENT

ORVIGLANCE

- First-in-class orphan diagnostic drug targeting $800m market
- Consistent positive efficacy and safety data; incl. significantly improved visualization (Phase 3 endpoint) in a 20-patient phase 2 study (p=0.009)
- Phase 3 patient recruitment completed

2024 focus

- Phase 3 headline results on track for read-out by May 2024
- Progress US FDA NDA file
- Progress launch readiness including options for partnering

ONCORAL

- Phase 2 ready oral daily irinotecan with potential in gastric cancer and other solid tumors

2024 focus

- Prepare for initiating Phase 2 study when financing allows

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