ADVANCING
ORPHAN
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Ticker symbol: ACE
Nasdaq Stockholm
www.ascelia.com

Orviglance® Completes Clinical Development with Successful Phase 3 Study

Half Year Report 2024

Conference call presentation on 15 August 2024, 10:00 CET

ASCELIA PHARMA

FORWARD LOOKING STATEMENTS

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QUARTERLY REPORT Q2 2024
INVESTOR CONFERENCE CALL

Agenda

Ascelia Pharma highlights
Recent key events
Portfolio
Financials and priorities ahead

Presenters

CEO - Magnus Corfitzen
Deputy CEO - Julie Waras Brogren
CSO - Andreas Norlin

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ASCELIA PHARMA - HIGHLIGHTS

Pipeline

ORVIGLANCE® – Registration phase

- 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 study successful and clinical development completed

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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Q2 2024 PROGRESS

Key events in Q2 2024

- SPARKLE image reading completed with expected headline results first half of May 2024
- Ascelia Pharma draws down SEK 15 million second tranche under existing loan
- **Primary endpoint successfully met with strong headline results in Orviglance phase 3 study**
- Bulletin from the Annual General Meeting in Ascelia Pharma AB on 6 May 2024
- Ascelia Pharma hosts Investor Update: Bringing Orviglance to Patients

Key events after the period

- **Ascelia Pharma carries out a Rights Issue of units of approximately SEK 105 million to fully finance the NDA submission for Orviglance**
- Notice of Extraordinary General Meeting in Ascelia Pharma 14 August
- Bulletin from the Extraordinary General Meeting in Ascelia Pharma 14 August

RIGHTS ISSUE TO CAPITALIZE ON PHASE 3 RESULTS

Allowing all shareholders to take part of the value creation opportunities ahead

- Raising up to 105 MSEK
- Investment commitments and guarantees amounting to 70 MSEK

Use of proceeds

- NDA submission to FDA
- Partnering of Orviglance
- Amortize 7.5 MSEK of convertible to Fenja Capital

Key dates

EGM to approve the Rights Issue	14 Aug 2024
Last day of trading in shares including the right to receive unit rights	14 Aug 2024
First day of trading in shares excluding the right to receive unit rights	15 Aug 2024
Record date for participation in the Rights Issue	16 Aug 2024
Publication of the Prospectus	16 Aug 2024
Trading in unit rights on Nasdaq Stockholm	20 Aug – 29 Aug 2024
Subscription period	20 Aug – 3 Sept 2024
Announcement of the final outcome of the Rights Issue	5 Sept 2024
Trading in paid subscribed units ("BTU")	20 Aug – 20 Sept 2024

ATTRACTIVE ORVIGLANCE OPPORTUNITY

- A well-defined unmet need for liver imaging in cancer patients with impaired kidney function
- A global addressable market opportunity of USD 800 million
- Clinical development completed with 9 studies and strong phase 3 results
- Commercial scale manufacturing
- Orviglance advances to regulatory filing and approval phase

SUBSTANTIAL VALUE CREATION OPPORTUNITIES

	Advance Orviglance to approval	Progress Orviglance commercialization readiness	Develop pipeline potential
Objectives	**Timely submission and approval** by the US FDA as an orphan drug with an optimal label for the use in the target population	**Focused launch** for well-defined patient population **Global commercialization through partners**	**Demonstrate Oncoral efficacy** and safety in Phase 2 **Expand Orviglance franchise** with 2nd generation
Milestones	▪ Full Clinical Study Report early **Q4 2024** ▪ Conclusions from FDA pre-submission meeting by **Q1 2025** ▪ NDA submission **mid-2025**	▪ Advance **launch readiness** ▪ Commercialization **partnership**	▪ Initiate **Oncoral Phase 2** clinical study when financing allows

Mid-2025 refers to the three months from mid-May to mid-August

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ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

PORTFOLIO

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ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Patient Landscape

Liver metastases are 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 severe 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 (NSF)

ORVIGLANCE

Aims to be the imaging option without gadolinium-related safety risks in patients with severe kidney impairment

- 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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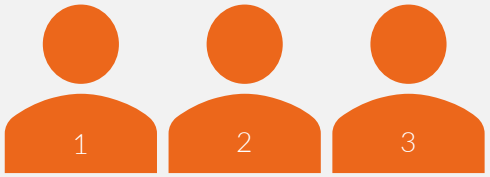
STRONG SUPERIORITY OF ORVIGLANCE IN PHASE 3

Primary Endpoint Met Successfully

- Phase 3 study demonstrated **strong superiority** in visualization of focal liver lesions with Orviglance (CMRI) compared to unenhanced MRI
- Visualization scored **significantly higher** with Orviglance than without for all three readers with
  - statistical significance ($p<0.001$)
  - strong and conclusive reliability of the data – including variability



- Common adverse events were consistent with previous studies, such as mild to moderate nausea; **no serious adverse drug reactions** were observed

PRESS RELEASE

02 May 2024 11:12:00 CEST

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Ascelia Pharma Successfully Meets Primary Endpoint with Strong Headline Results in Orviglance Phase 3 Study

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that liver imaging drug candidate, Orviglance®, significantly improved visualization of focal liver lesions, successfully meeting the primary endpoint in the pivotal Phase 3 study SPARKLE. Investors and analysts are invited to the virtual Investor Update: "Bringing Orviglance to Patients", on Tuesday, 7 May at 14:00 CEST

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CLINICAL DEVELOPMENT COMPLETED

Nine studies with consistent positive efficacy and safety results[1-7]

286 patients and healthy volunteers

Phase 1 studies demonstrated safety, absorption and signal intensity

Total 4 studies with 126 healthy volunteers

Phase 2 studies demonstrated efficacy and safety in patients with known metastases

Total 4 studies with 75 patients

Orviglance efficacy confirmed vs. gadolinium & unenhanced in re-evaluation

Re-read of phase 2 study (20 patients) with liver metastases with same endpoint as in phase 3

Phase 3 study confirmed efficacy and safety in the target population

Pivotal study on visualization of focal liver lesions and safety in patients with severe kidney impairment (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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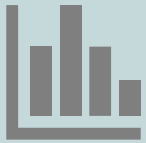
ADVANCING ORVIGLANCE TOWARDS APPROVAL

Clinical

Nonclinical



CMC

US FDA

Timely submission and approval by the US FDA as an **orphan drug** with an optimal label for use in the target population

- Full Clinical Study Report early **Q4 2024**
- Conclusions from FDA pre-submission meeting by **Q1 2025**
- NDA submission **mid-2025**

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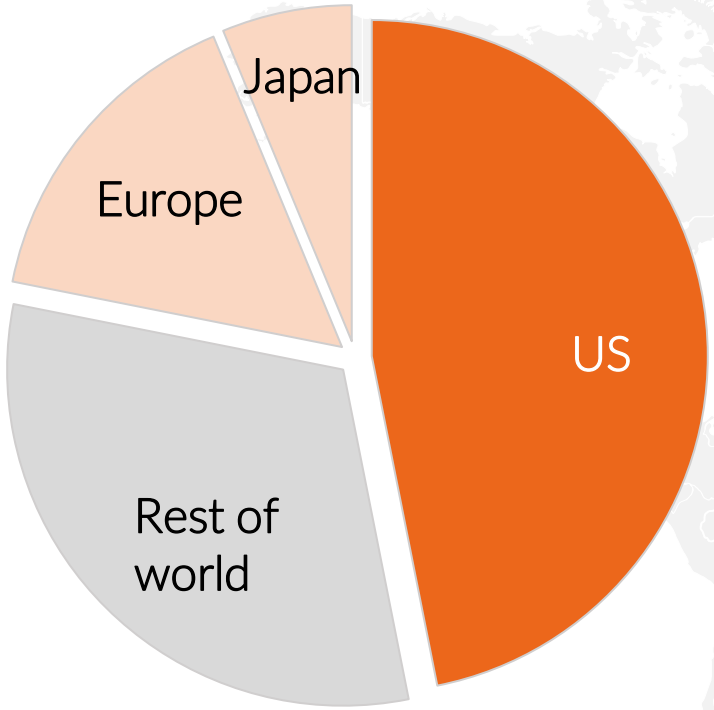
ADDRESSABLE MARKET OF USD 800 MILLION ANNUALLY



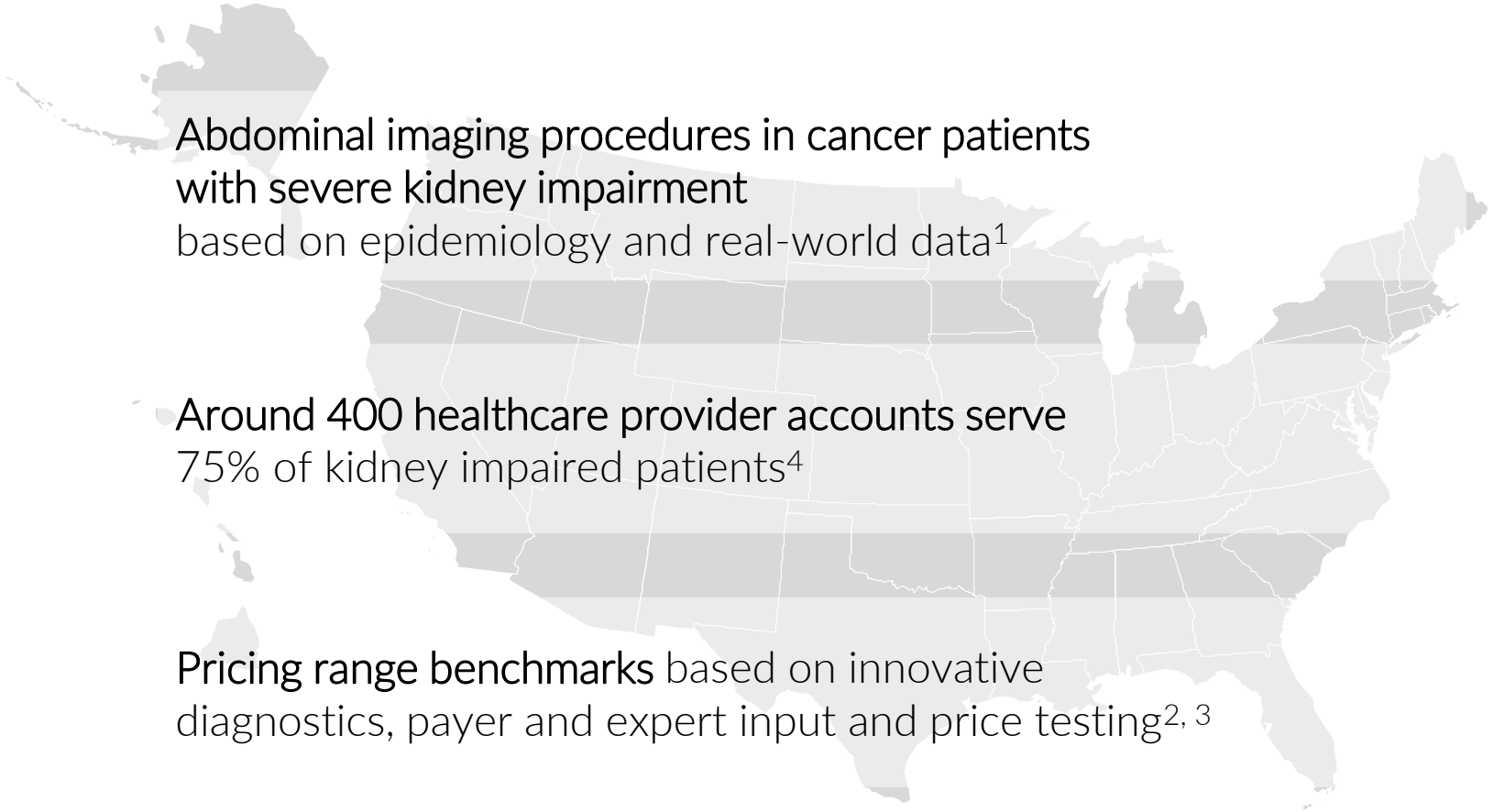
Global addressable market of USD 800 million, half of this in the US

Focused launch for well-defined patient population in liver imaging in cancer patients with severe kidney impairment

Global commercialization through partners

Sources:
Ascelia Pharma market research on real-world volumes 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
based on epidemiology and real-world data[1]

Around 400 healthcare provider accounts serve
75% of kidney impaired patients[4]

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

~100,000
procedures annually

~400 accounts

$3,000-4,500

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

UNMET NEED RECOGNIZED IN CLINICAL PRACTICE

"Those of us who have seen NSF are frightened by it… you'll get **buy-in from a lot of nephrologists**…".
- Head of Renal section at US university hospital (from Ascelia Pharma Advisory Board meeting)

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

""The college [American Colleague of Radiology]…have a **growing sense of responsibility and accountability** about using these agents in high-risk patients…. our perception of which agents are "safe" has changed… this is another place where practice needed to evolve"
- SPARKLE Investigator and Head of Radiology at US university hospital

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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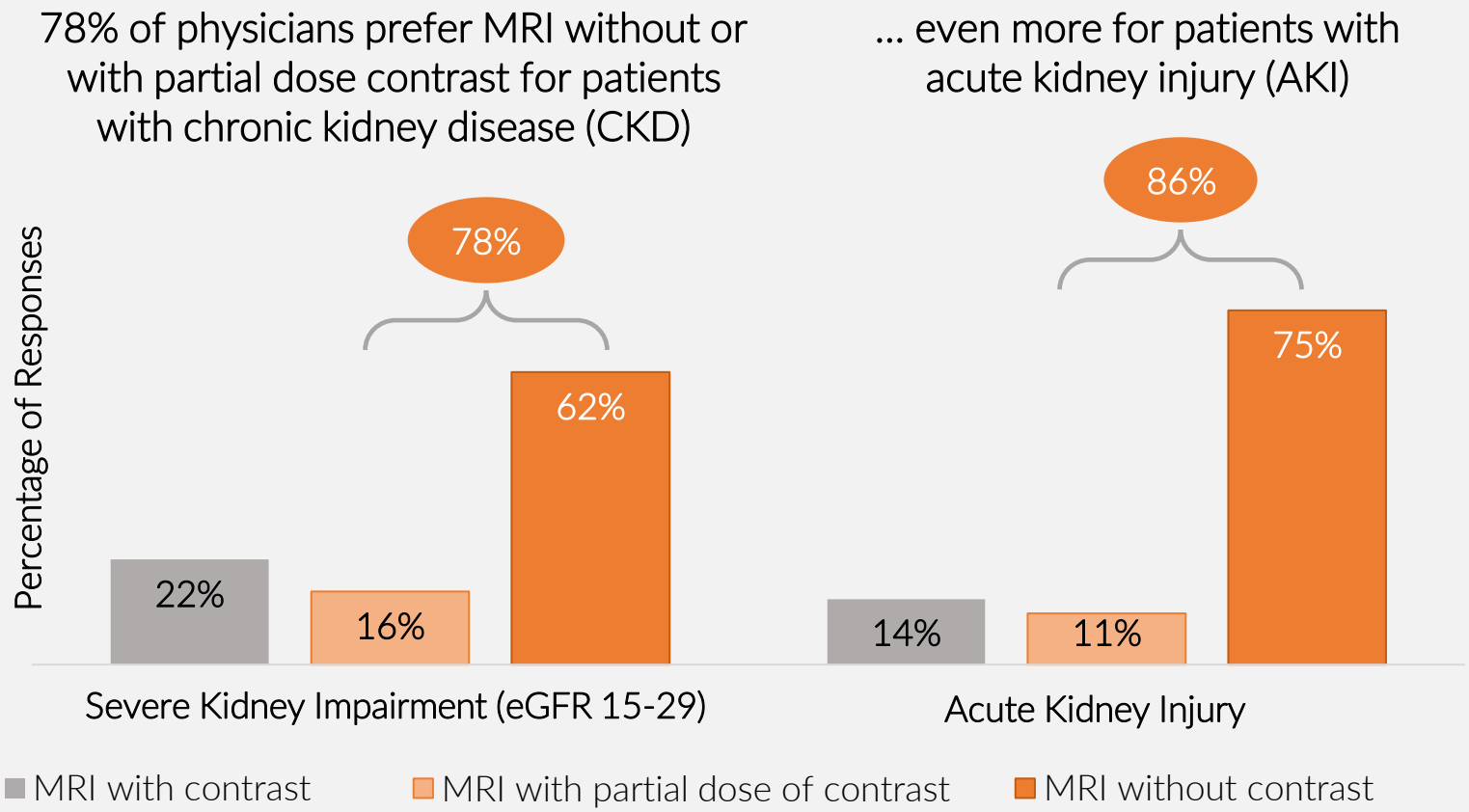
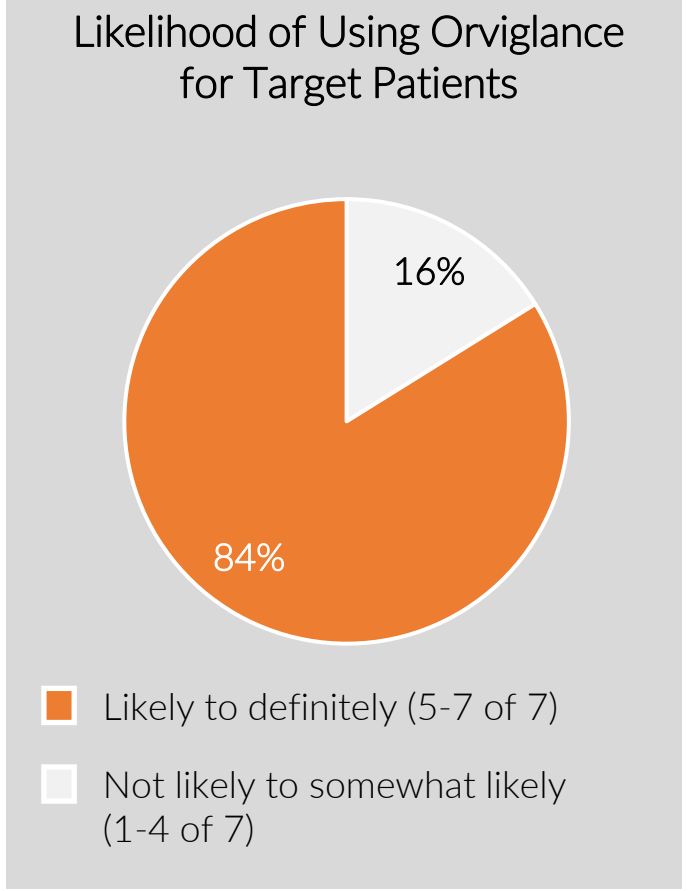
UNENHANCED MRI PREFERRED TODAY; 84% OF US PHYSICIANS LIKELY TO USE ORVIGLANCE





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
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?

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 excreted in urine is discharged into our environment and drinking water

Future with less/no gadolinium

focus of leading gadolinium manufacturers

Low dose full-body gadolinium contrast agents pursued by GBCA players with one approved by the FDA in priority review

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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ON TRACK FOR OPTIMAL COMMERCIALIZATION

Strategic objectives for commercialization

- Optimal balance between investment required and future revenues
- Leverage established commercialization capabilities
- Maximize value with global launch strategy

Global commercialization through partners

Secure launch readiness

Establish commercial partnerships

Progress dialogue with potential partners

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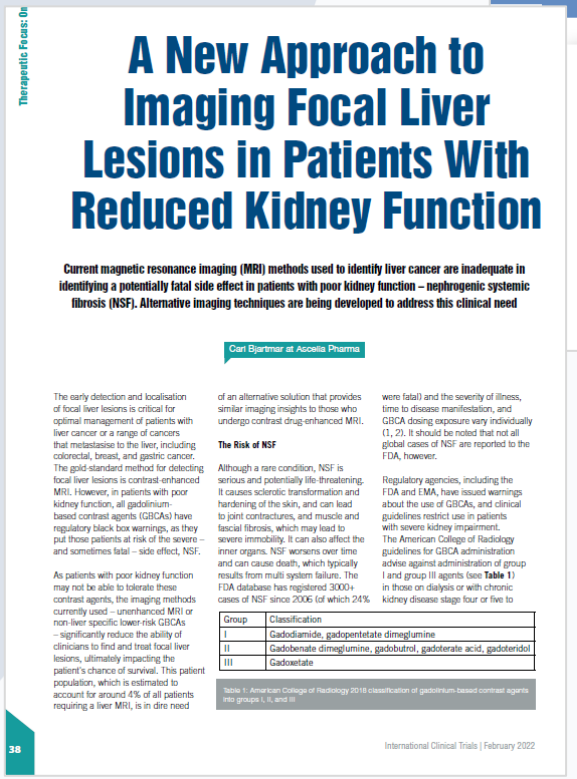
Reimagine imaging for people with poor kidney function.



Therapeutic Focus: On

A New Approach to Imaging Focal Liver Lesions in Patients With Reduced Kidney Function

Current magnetic resonance imaging (MRI) methods used to identify liver cancer are inadequate in identifying a potentially fatal side effect in patients with poor kidney function – nephrogenic systemic fibrosis (NSF). Alternative imaging techniques are being developed to address this clinical need

Cari Bjartmar at Ascelia Pharma

The early detection and localisation of focal liver lesions is critical for optimal management of patients with liver cancer or a range of cancers that metastasise to the liver, including colorectal, breast, and gastric cancer. The gold-standard method for detecting focal liver lesions is contrast-enhanced MRI. However, in patients with poor kidney function, all gadolinium-based contrast agents (GBCAs) have regulatory black box warnings, as they put those patients at risk of the severe – and sometimes fatal – side effect, NSF.

As patients with poor kidney function may not be able to tolerate these contrast agents, the imaging methods currently used – unenhanced MRI or non-liver specific lower-risk GBCAs – significantly reduce the ability of clinicians to find and treat focal liver lesions, ultimately impacting the patient's chance of survival. This patient population, which is estimated to account for around 4% of all patients requiring a liver MRI, is in dire need of an alternative solution that provides similar imaging insights to those who undergo contrast drug-enhanced MRI.

The Risk of NSF

Although a rare condition, NSF is serious and potentially life-threatening. It causes sclerotic transformation and hardening of the skin, and can lead to joint contractures, and muscle and fascial fibrosis, which may lead to severe immobility. It can also affect the inner organs. NSF worsens over time and can cause death, which typically results from multi system failure. The FDA database has registered 3000+ cases of NSF since 2006 (of which 24% were fatal) and the severity of illness, time to disease manifestation, and GBCA dosing exposure vary individually (1, 2). It should be noted that not all global cases of NSF are reported to the FDA, however.

Regulatory agencies, including the FDA and EMA, have issued warnings about the use of GBCAs, and clinical guidelines restrict use in patients with severe kidney impairment. The American College of Radiology guidelines for GBCA administration advise against administration of group I and group III agents (see **Table 1**) in those on dialysis or with chronic kidney disease stage four or five to

Group	Classification
I	Gadodiamide, gadopentetate dimeglumine
II	Gadobenate dimeglumine, gadobutrol, gadoterate acid, gadoteridol
III	Gadoxetate

Table 1: American College of Radiology 2018 classification of gadolinium-based contrast agents into groups I, II, and III

REVIEW ARTICLE

OPEN

Oral Manganese Chloride Tetrahydrate: A Novel Magnetic Resonance Liver Imaging Agent for Patients With Renal Impairment

Efficacy, Safety, and Clinical Implication

Torkel B. Brismar, MD, PhD, Dominik Geisel, MD, Nikolaos Kartalis, MD, PhD, Beatrice L. Madrazo, MD, Hanna Persson Hedman, PhD, and Andreas Norlin, PhD

itn IMAGING TECHNOLOGY NEWS

COVID-19 IMAGING INFORMATION TECHNOLOGY WOMEN'S HEALTH RADIATION ONCOLOGY

NEWS | RSNA | DECEMBER 03, 2022

Study compares effect of food intake on manganese-based MRI contrast agent absorption

A study presented at RSNA 2022 evaluated the effect of food intake on the absorption and signal intensity of Orviglance, a manganese-based MRI contrast agent, and successfully concluded that image enhancement is not impacted by a light meal.

orviglance®

800 mg powder for oral solution

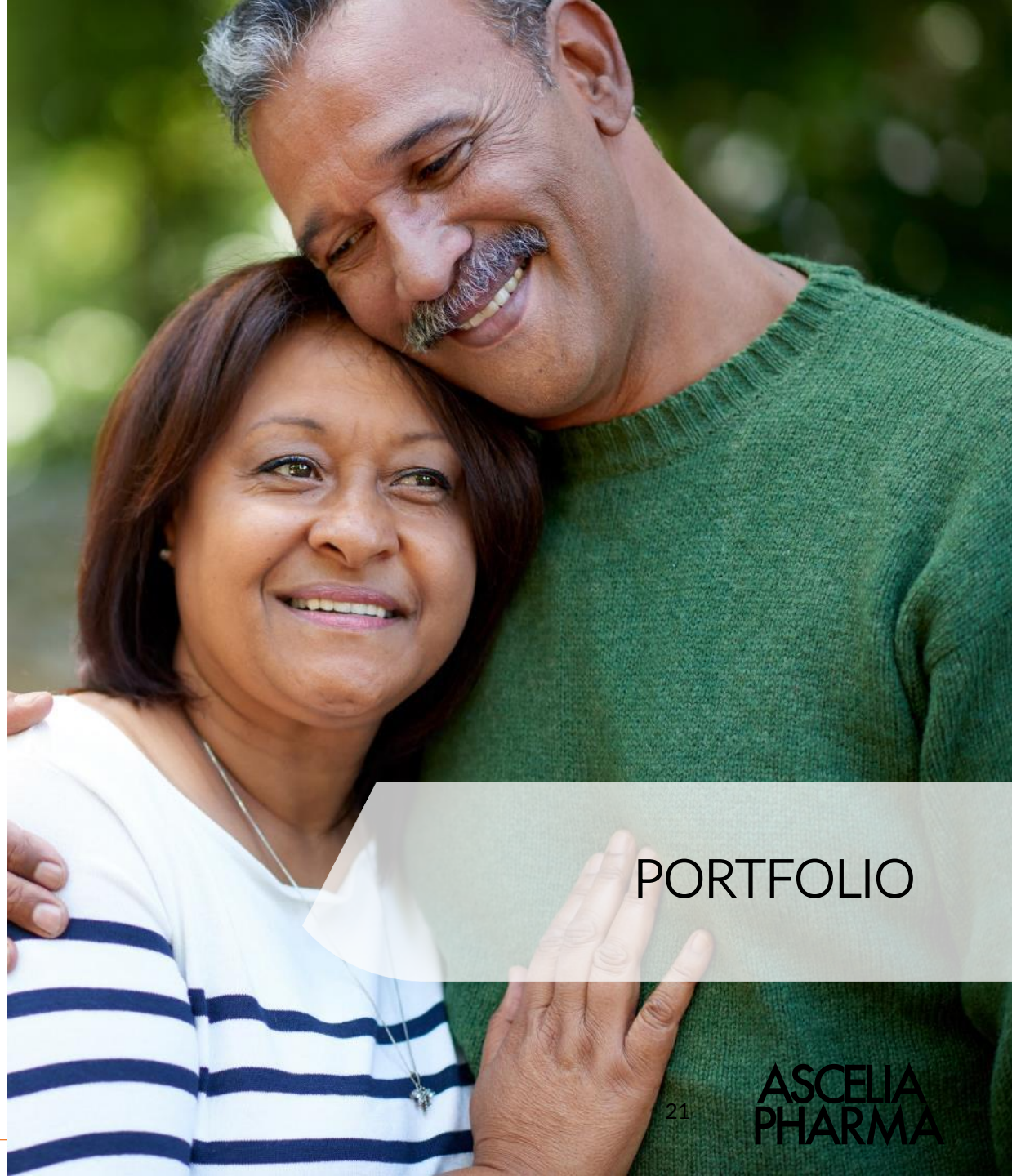
manganese chloride tetrahydrate

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



PORTFOLIO

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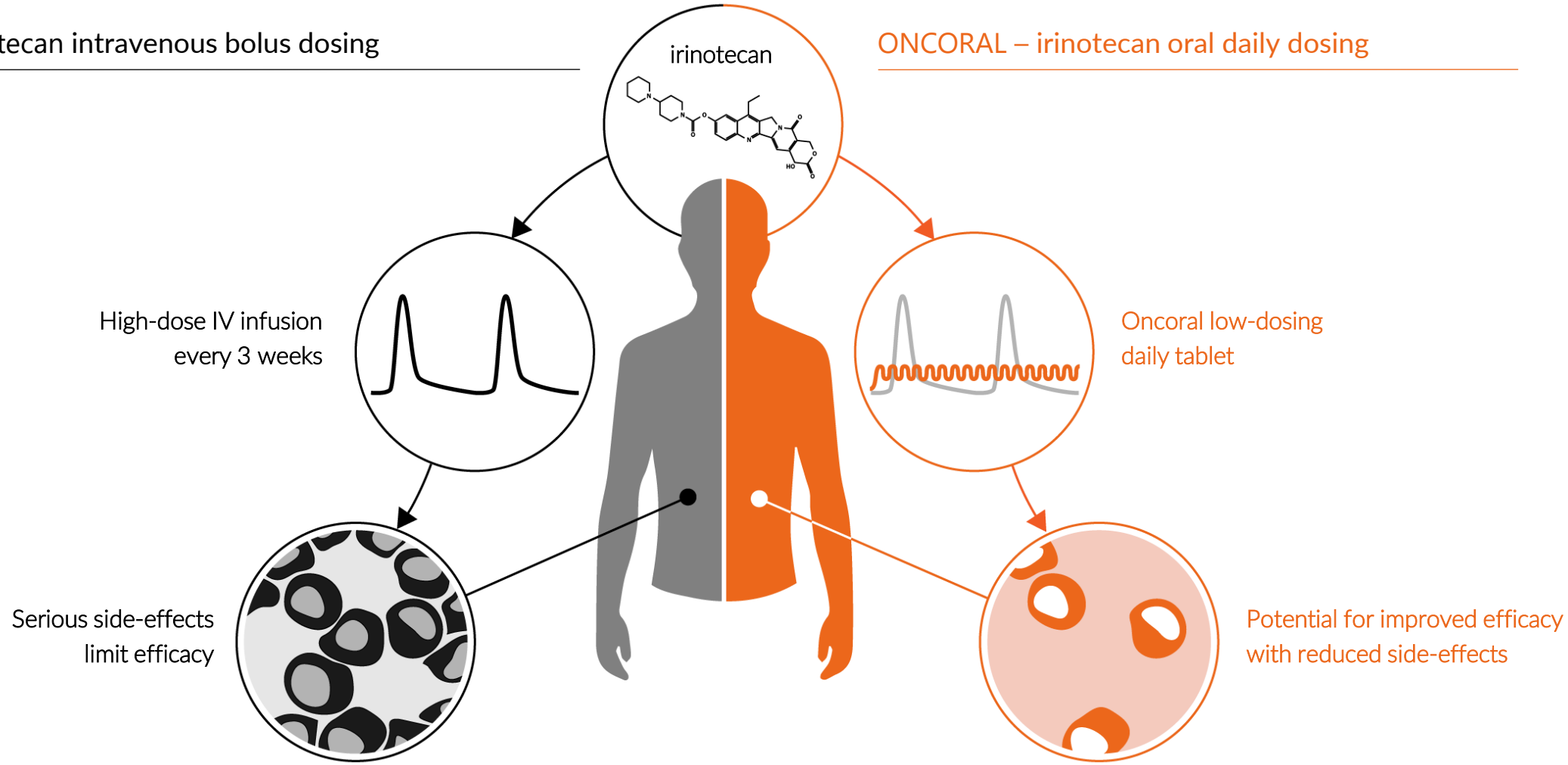
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



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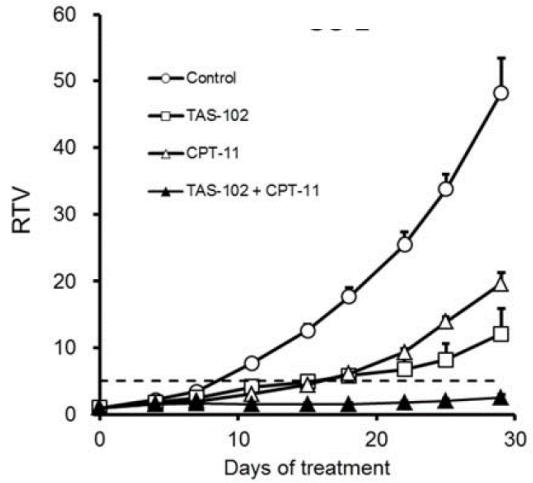
ONCORAL PHASE 2 IN GASTRIC CANCER

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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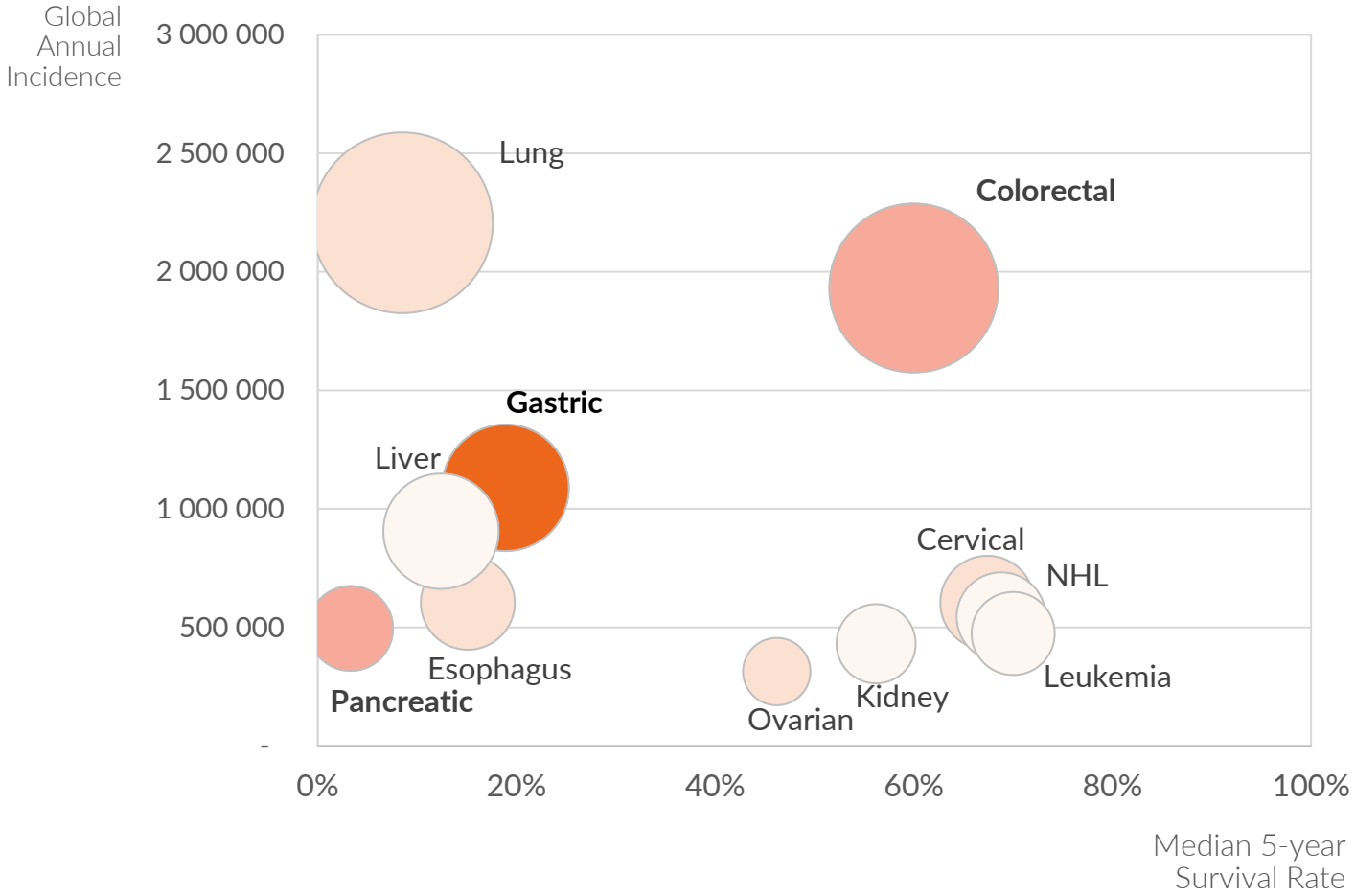
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

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

RIGHTS ISSUE TO CAPITALIZE ON STRONG PHASE 3 RESULTS

Rights Issue overview

- Raising up to 105 MSEK
- Investment commitments and guarantees amounting to 70 MSEK
- Unit price of 5.07 SEK consisting of 3 shares and 1 warrant
- Guarantor fee of 11% in cash or 13.5% in units

Use of proceeds

- NDA submission to FDA
  - Phase 3 full Clinical Study Report, Q4 2024
  - Conclusions from FDA pre-submission meeting, Q1 2025
  - NDA submission, mid-2025
- Partnering of Orviglance
- Amortize 7.5 MSEK of convertible to Fenja Capital (Formue Nord)

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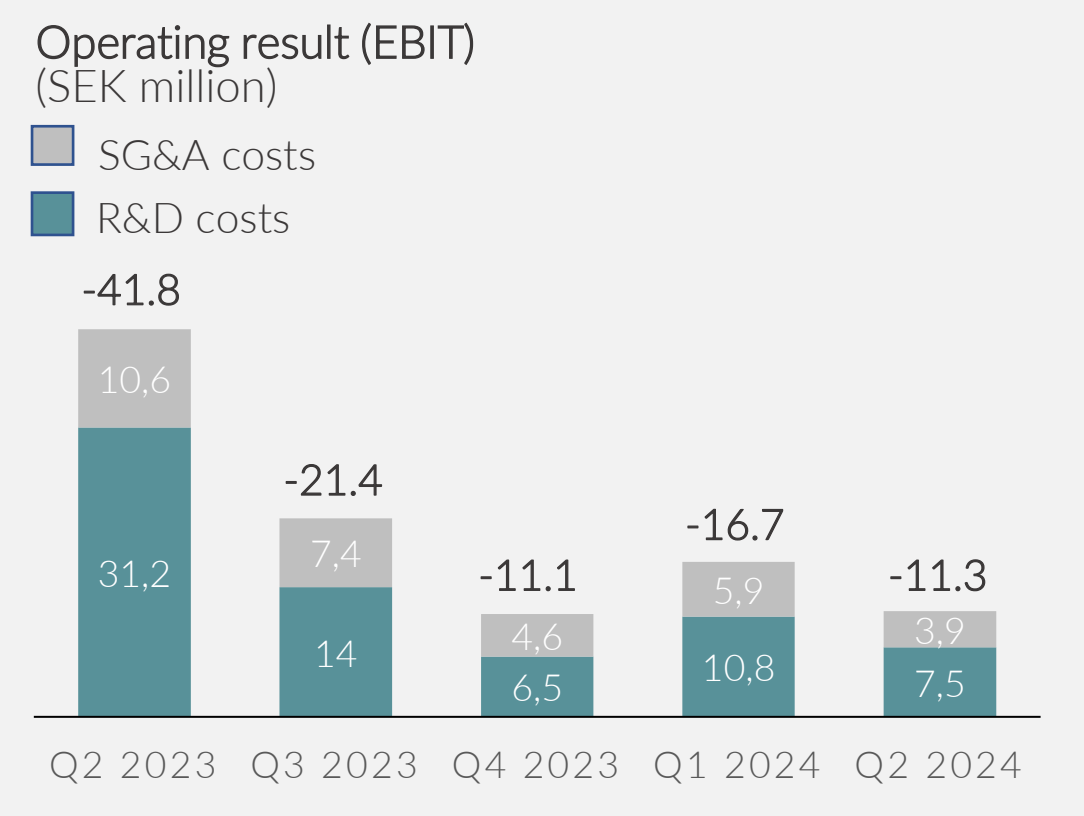
OPERATING RESULT– MAINTAINED LOW OPERATING EXPENSES

Operating loss of SEK 11.3 million in Q2 2024

Slightly decreased loss (costs) compared to Q1 2024 driven by completion of SPARKLE re-evaluation



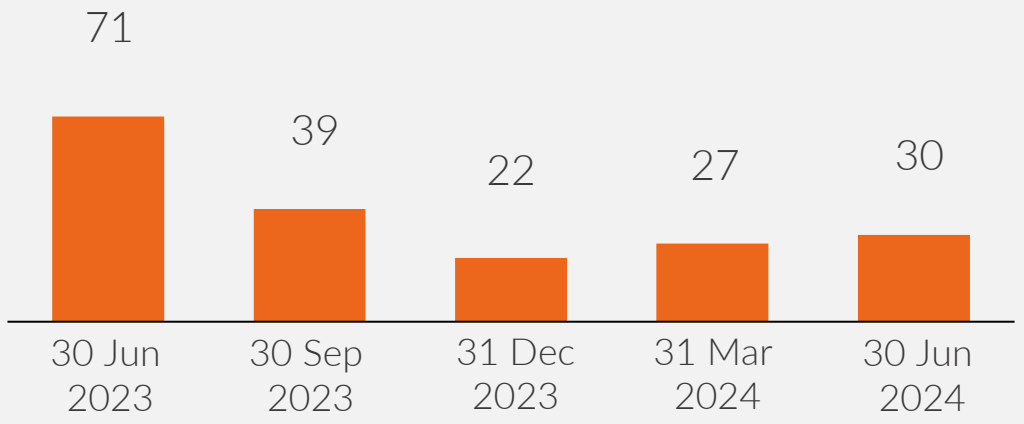
Notes:
1) Other operating income and other operating costs added to SG&A

LIQUIDITY - CASH RUNWAY BEYOND NDA SUBMISSION MID-2025

Liquid assets of 30 MSEK (30 Jun 2024), including 35 MSEK fully drawn Fenja Capital financing of loan and convertibles

Runway with minimum 70 MSEK Rights Issue financing beyond NDA submission 2025

Liquid assets including marketable securities
(SEK million)



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Objectives	**Timely submission and approval** by the US FDA as an orphan drug with an optimal label for the use in the target population	**Focused launch** for well-defined patient population **Global commercialization through partners**	**Demonstrate Oncoral efficacy** and safety in Phase 2 **Expand Orviglance franchise** with 2nd generation
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