Ascelia Pharma

September 2025

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At Ascelia Pharma,

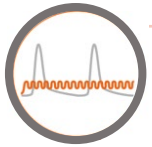
we identify, develop and commercialize novel drugs that address unmet needs

of people with rare cancer conditions

Global outlook and Nordic roots

Based in Malmö (Sweden), US entity in New Jersey (US)
Listed on NASDAQ Stockholm (Ticker: ACE)

ADVANCED ORPHAN ONCOLOGY PIPELINE

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Registration	Market
 ORVIGLANCE	Improved detection and visualization of focal liver lesions ▪ 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	Completed			Ongoing NDA submitted 3 Sept	
 ONCORAL	Improved efficacy and safety ▪ Daily, oral irinotecan chemotherapy ▪ Clinical collaboration with Taiho Oncology ▪ Opportunity in gastric cancer and other solid tumors	Completed	Ready			

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SUBSTANTIAL ORVIGLANCE VALUE CREATION OPPORTUNITIES

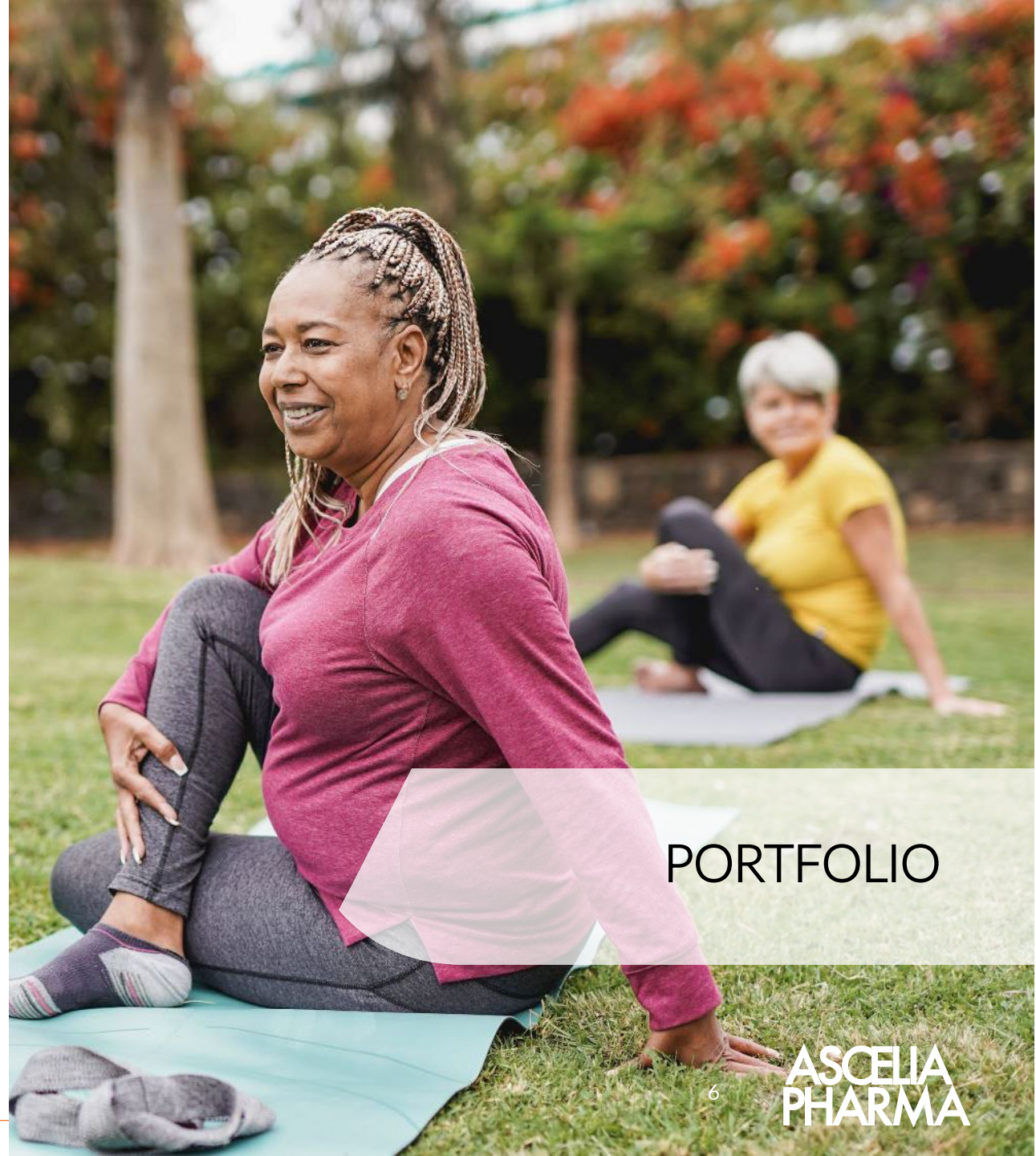
	Advance Orviglance to approval	Secure partnering and commercialization readiness
Objectives	**Timely approval** by the US FDA as an orphan drug for the use in liver MRI for patients with severe renal impairment or when gadolinium may otherwise be medically inadvisable	**Focused launch** for well-defined patient population with 800 MUSD annual addressable market **Partner** driven global commercialization
Looking ahead	✓ **NDA submission** September 2025 ▪ **FDA communication of PDUFA date** November 2025 ▪ **FDA approval following 10 months review** July 2026	▪ Advance **launch readiness** ▪ Establish commercialization **partnership(s)**

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



PORTFOLIO

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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**
- Commercial scale **manufacturing**
- **Clinical development completed** with 9 studies and strong phase 3 results
- **NDA submitted** to the FDA
- Commercialization with **partner**

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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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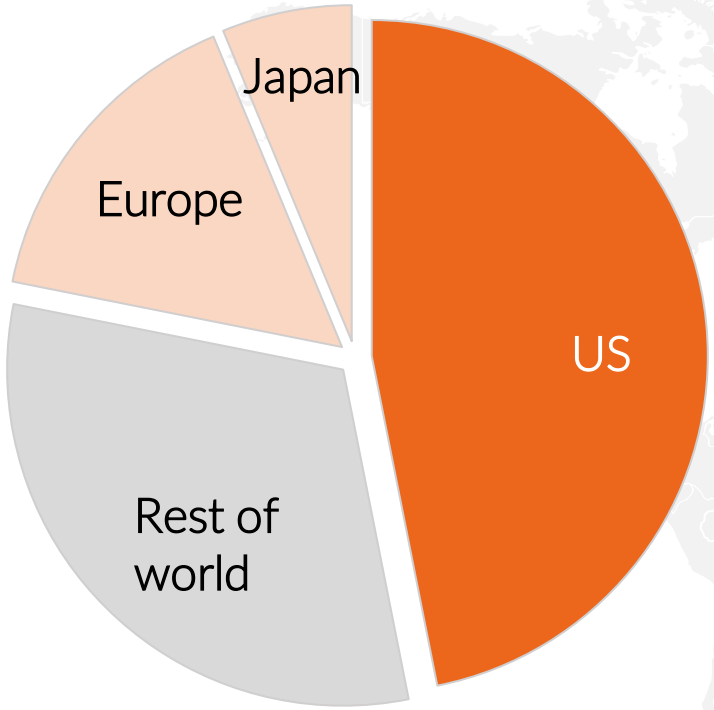
ADDRESSABLE MARKET OF USD 800 MILLION ANNUALLY



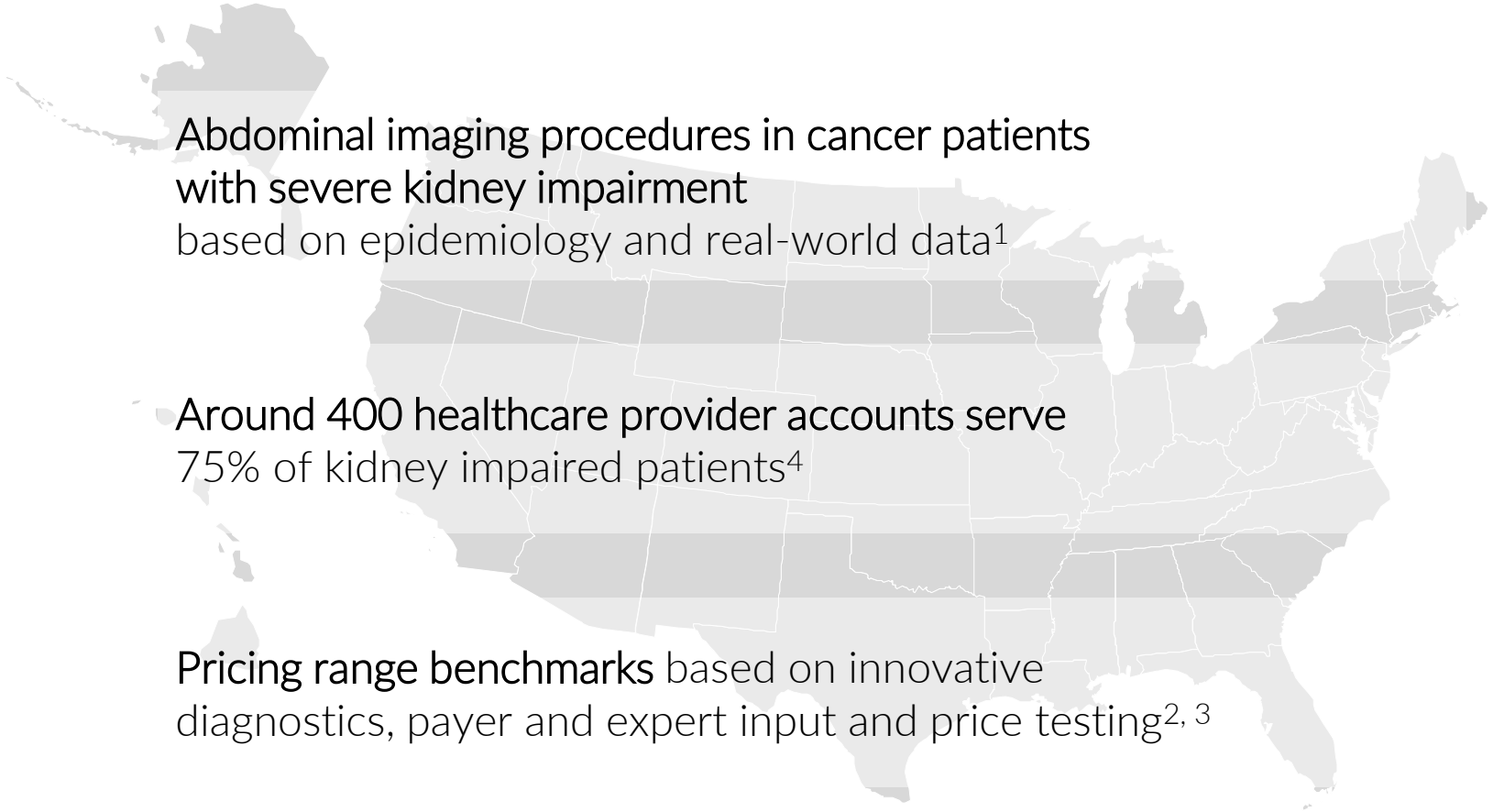
Global addressable market of USD 800 million, half of this in the US

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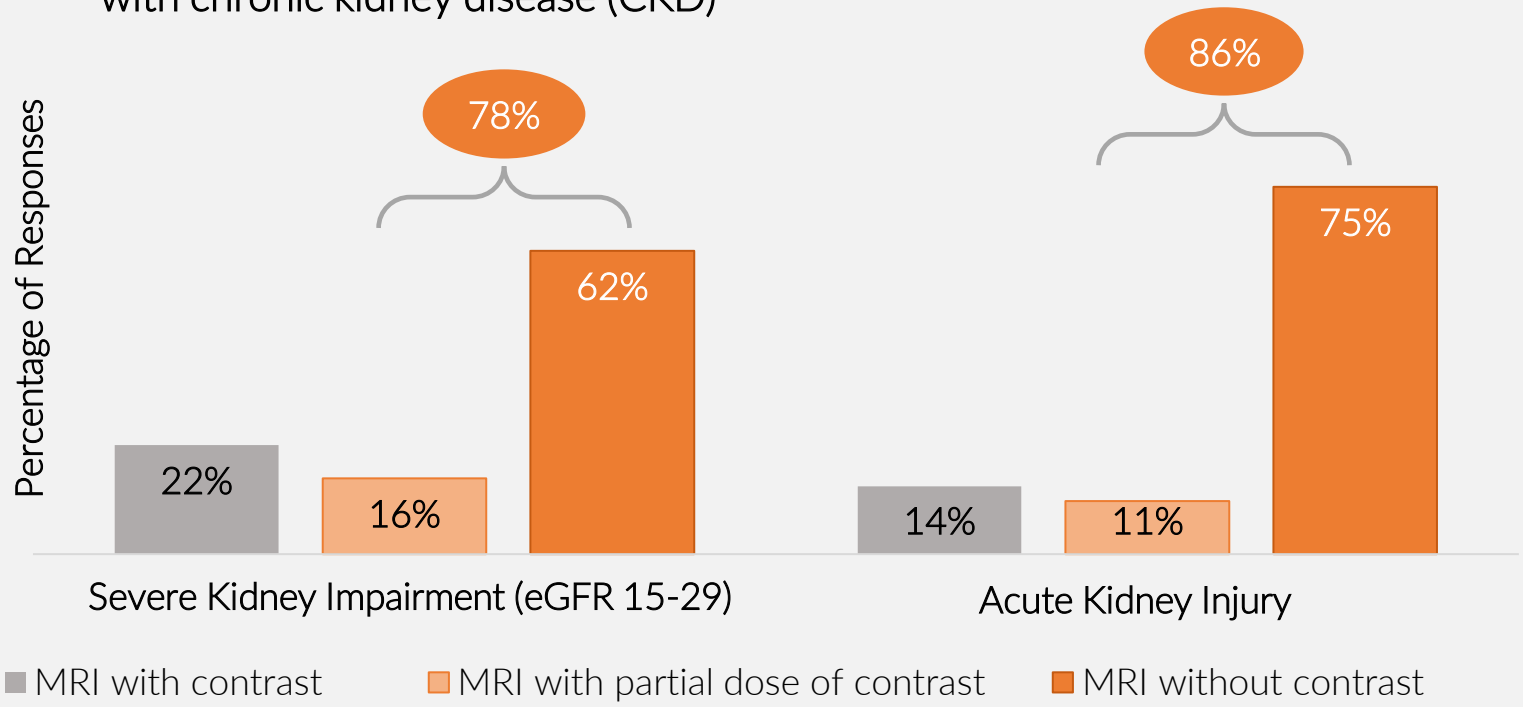
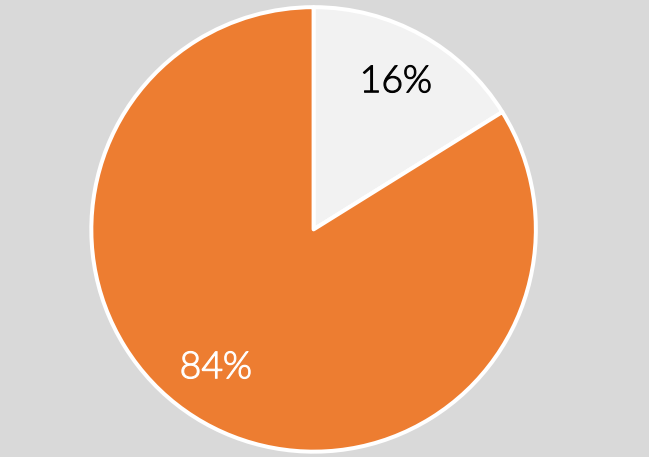
UNENHANCED MRI PREFERRED TODAY; 84% OF US PHYSICIANS LIKELY TO USE ORVIGLANCE

78% of physicians prefer MRI without or with partial dose contrast for patients with chronic kidney disease (CKD)



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

Likelihood of using Orviglance for target patients



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

MOMENTUM FOR CHANGE ALSO BEYOND RENAL IMPAIRMENT

Black-box warning
for use in renally impaired patients

Risk of potentially fatal side effects of gadolinium, incl. nephrogenic systemic fibrosis, in patients with severe renal impairment

Deposition in brain & organs
concerns around safety for all patients

New category for Symptoms Associated with Gadolinium Exposure (SAGE, Am. College of Rad., 2022)

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

Water contamination
scrutiny of environmental impact

Gadolinium excreted in urine is discharged into our environment and drinking water

A future with less gadolinium

Manganese

First in class oral manganese agent targeting patients with severe renal impairment (Ascelia Pharma)

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

Gadolinium

Low dose full-body gadolinium contrast agents pursued by GBCA players with one approved by the FDA (Guerbet/Bracco) and another in regulatory review (Bayer)

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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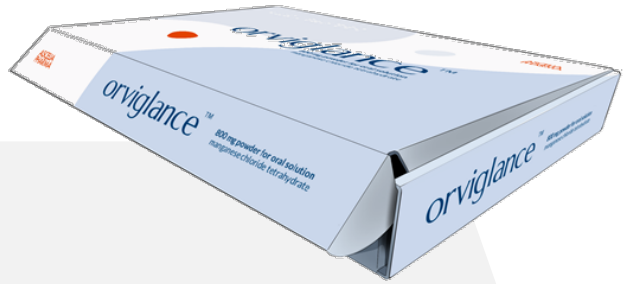
OPTIMAL COMMERCIALIZATION THROUGH PARTNERS



Partner led commercialization

Maximizes overall value of Orviglance by leveraging established capabilities

Optimizes capital requirements vs. future revenues

Attractive partner opportunity

De-risked asset in registration phase

Unmet need with high value for payers – high value per patient

Clear decision maker value - patients, physicians and payers

Focused launch efforts for hospital/imaging units

Wide synergy potential within e.g. radiology/nephrology/oncology or high-value/orphan drug

Dialogue with potential partners progressing

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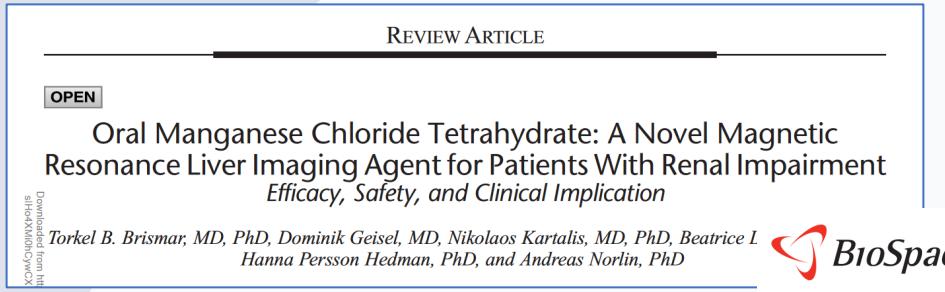
Reimagine imaging for people with poor kidney function



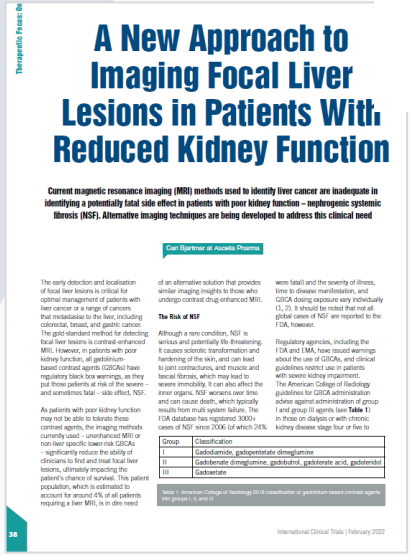
REVIEW ARTICLE

OPEN

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

Efficacy, Safety, and Clinical Implication

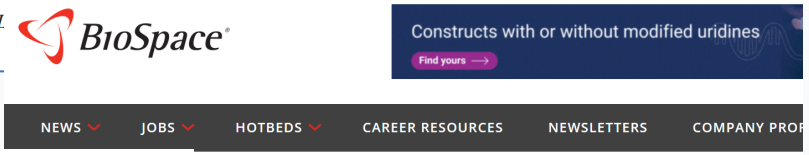
Torkel B. Brismar, MD, PhD, Dominik Geisel, MD, Nikolaos Kartalis, MD, PhD, Beatrice L
Hanna Persson Hedman, PhD, and Andreas Norlin, PhD



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

Carl Bjartmar at Ascelia Pharma



BioSpace

Constructs with or without modified uridines

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ORIGINAL ARTICLE

Lesion Visualization of an Oral Manganese Contrast Agent Compared to Unenhanced MRI and Gadobenate Dimeglumine in Patients Undergoing Liver Magnetic Resonance Imaging for Evaluation of Colorectal Cancer Metastases

Centralized Assessment of a Randomized, Crossover, Phase II Study

Torkel B. Brismar, MD, PhD, Nikolaos Kartalis, MD, PhD,
Nadilka Hettiarachchige, MD, and Andreas Norlin, PhD

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

Published: May 02, 2024

ASCELIA PHARMA AB (PUBL) (TICKER: ACE), A BIOTECH FOCUSED ON IMPROVING THE

Orviglance data accepted for
4 oral and 5 poster presentations
at major conferences since Phase 3

orviglance®

800 mg powder for oral solution
manganese chloride tetrahydrate

ORVIGLANCE NDA SUBMITTED TO THE FDA

Obtain approval for Orviglance

as a liver MRI contrast agent for patients with severe kidney impairment or when gadolinium may be otherwise medically inadvisable

NDA submitted 3 September 2025

- Attractive benefit-risk profile
- Established commercial-scale manufacturing
- Orphan Drug Designation granted, offering regulatory and commercial benefits

NDA SUPPORTED BY ROBUST CLINICAL PROGRAM

Nine studies with consistent positive efficacy and safety results[1-8]

286 patients and healthy volunteers

Superior efficacy compared to unenhanced imaging

- Superior visualization of focal liver lesions
- More lesions detected, in particular small lesions (< 1cm)
- Consistent improvement of visualization across main patient groups
- Efficacy further supported by secondary endpoints across studies

Favorable safety profile

- Robust safety data from nonclinical and clinical studies with no concerning findings
- Minimal systemic exposure of manganese
- Mild GI-related adverse reactions most frequently reported
- No serious drug-related reactions

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) Brismar TB, et al., Invest Radiol 2025: Apr 8. doi: 10.1097/RLI.0000000000001184. Online ahead of print.
7) Study CMC-P005, primary objective to study of Orviglance for imaging of bile ducts (not published)
8) 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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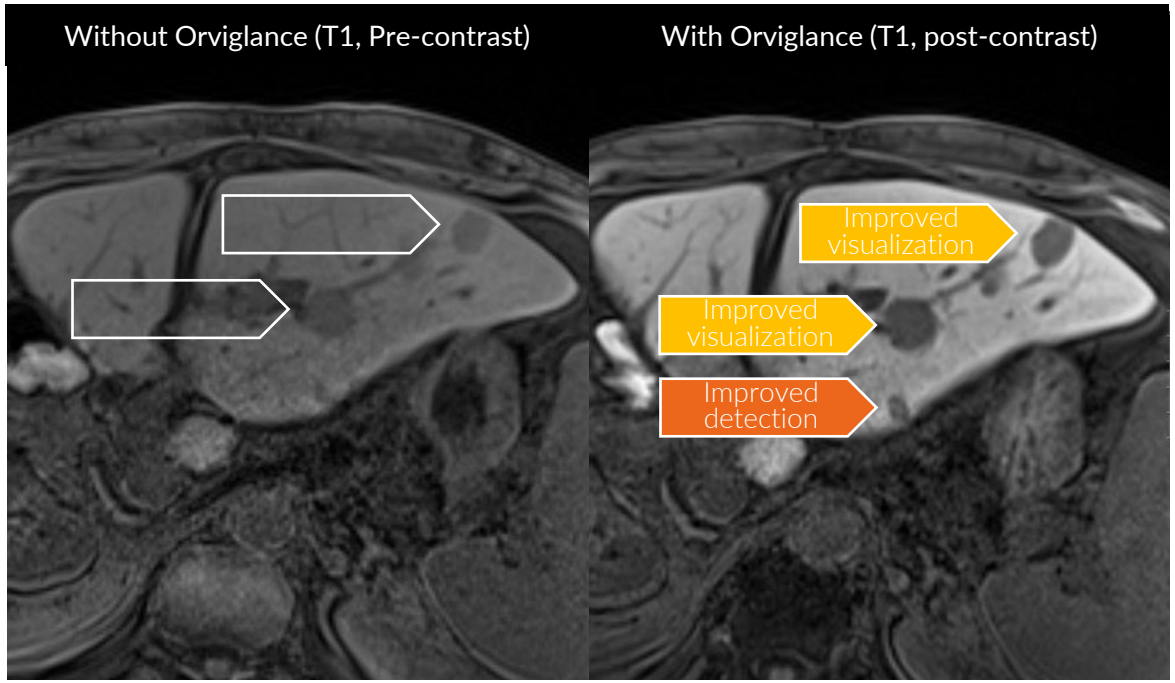
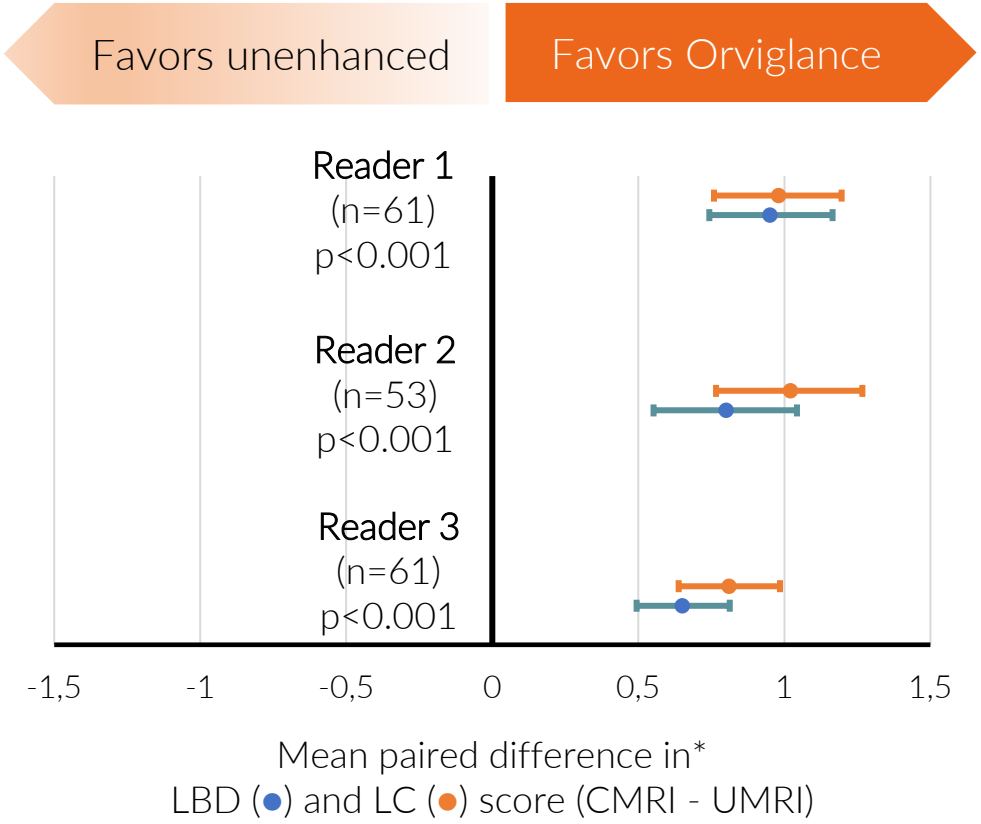
SUPERIORITY OF ORVIGLANCE DEMONSTRATED IN PHASE 3

Improved visualization of focal liver lesions with Orviglance



Example from a patient with metastases in the SPARKLE Phase 3 study



*Visualization assessed by 3 independent readers as the improvement of Lesion border delineation (LBD) and Lesion contrast (LC) on combined Orviglance-enhanced + unenhanced (CMRI) images compared to unenhanced (UMRI) images for all matched lesions, using a 4-point scale (from 1 ("poor") to 4 ("excellent")).
Data presented as mean paired differences for matched lesions per patient for CMRI and UMRI with 95% Confidence Intervals. One-sided paired t-test (α=0.025).
Total N=85, n=number of patients with matched lesions (per reader).

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ORVIGLANCE TOWARDS US APPROVAL IN 2026

Current priority: Timely approval by the US FDA as an orphan drug for the use in liver MRI for patients with severe renal impairment or when gadolinium may otherwise be medically inadvisable

Milestones:

3 Sept 2025: NDA submission

November 2025: Day 74 (PDUFA announced)

July 2026:Approval

Future opportunities: Apply for marketing approval in EU and other ex-US regions

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ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

PORTFOLIO

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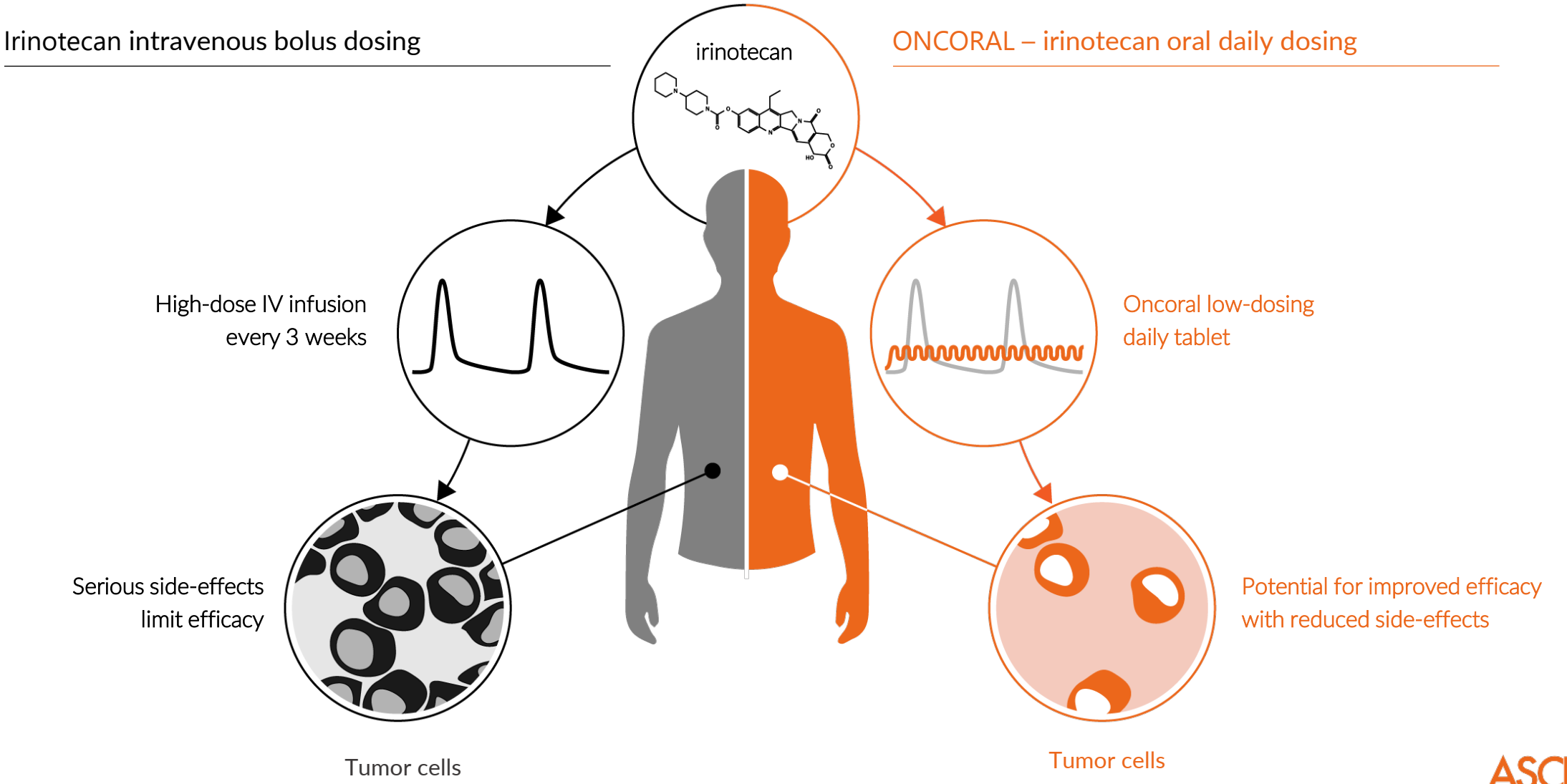
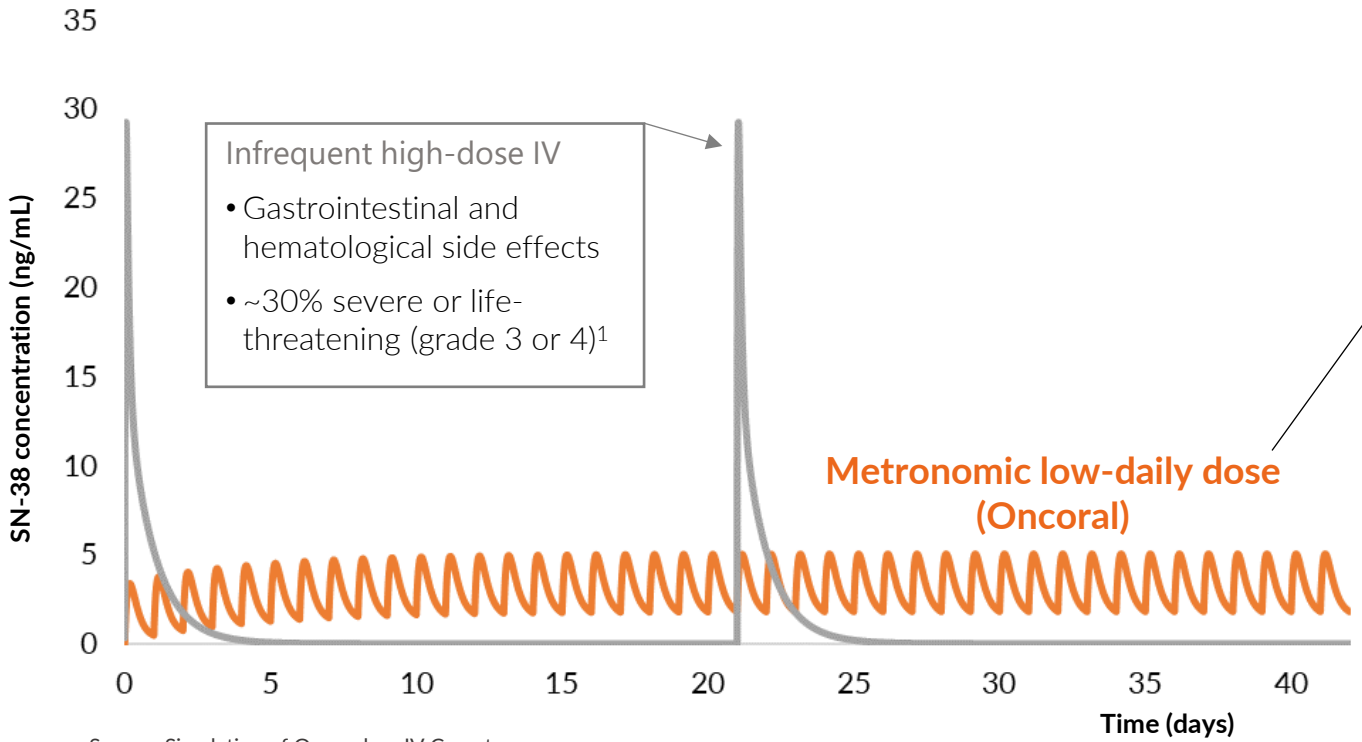
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**



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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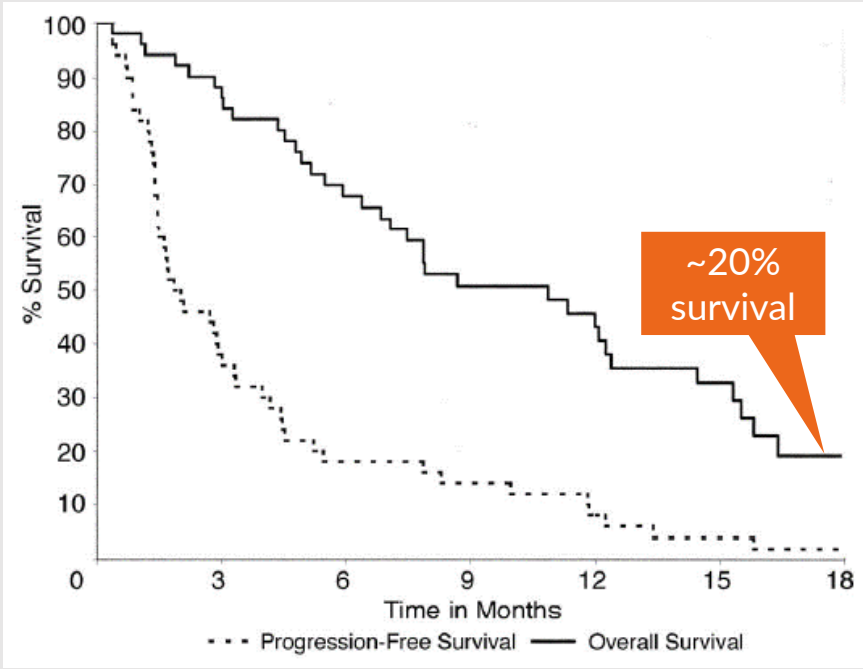
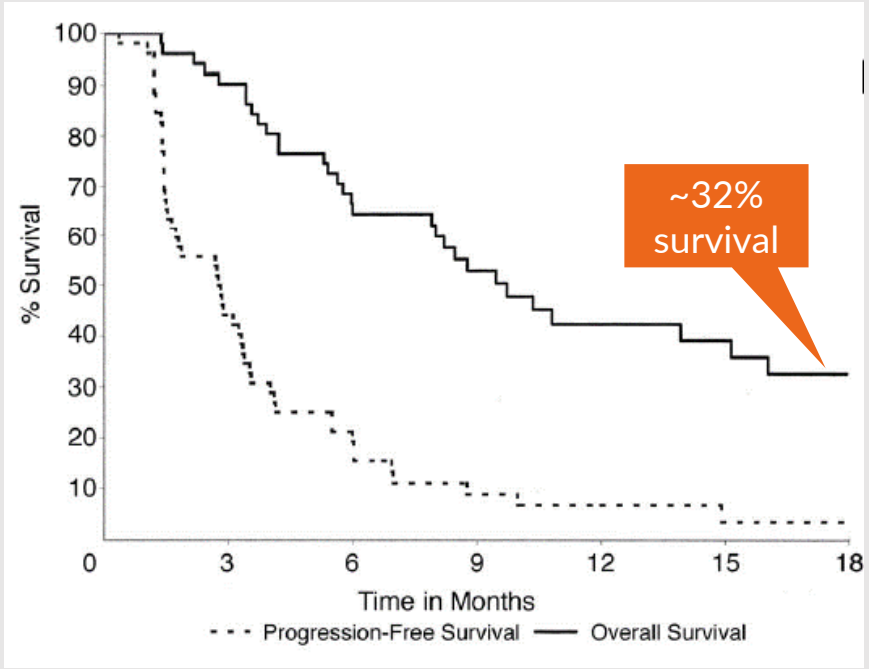
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

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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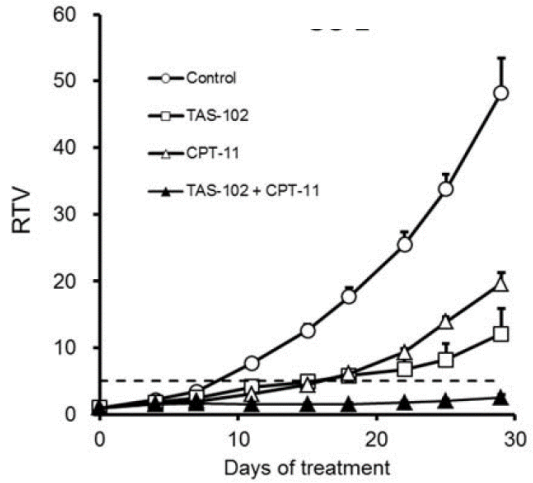
ONCORAL PHASE 2 IN GASTRIC CANCER

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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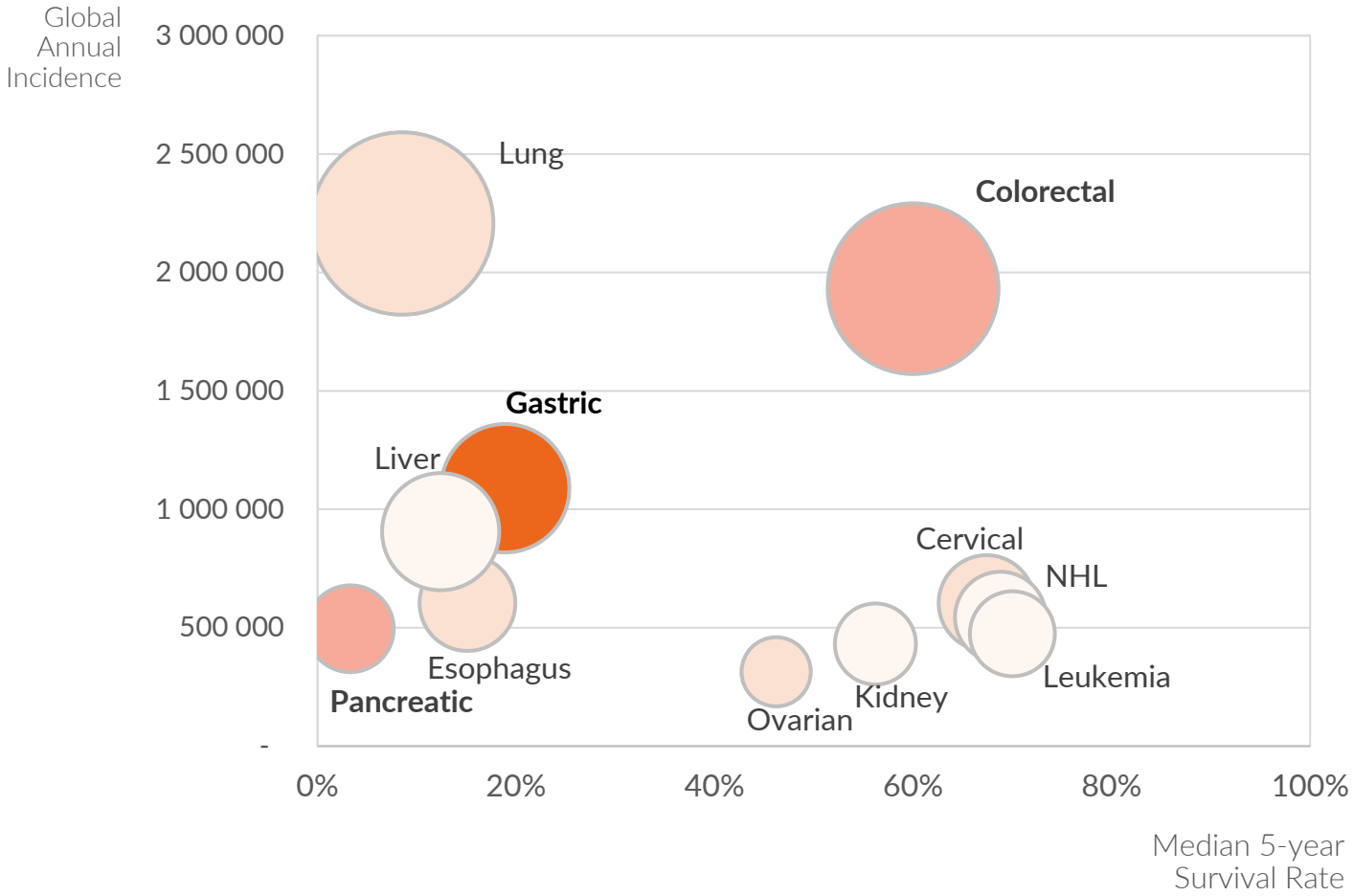
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

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

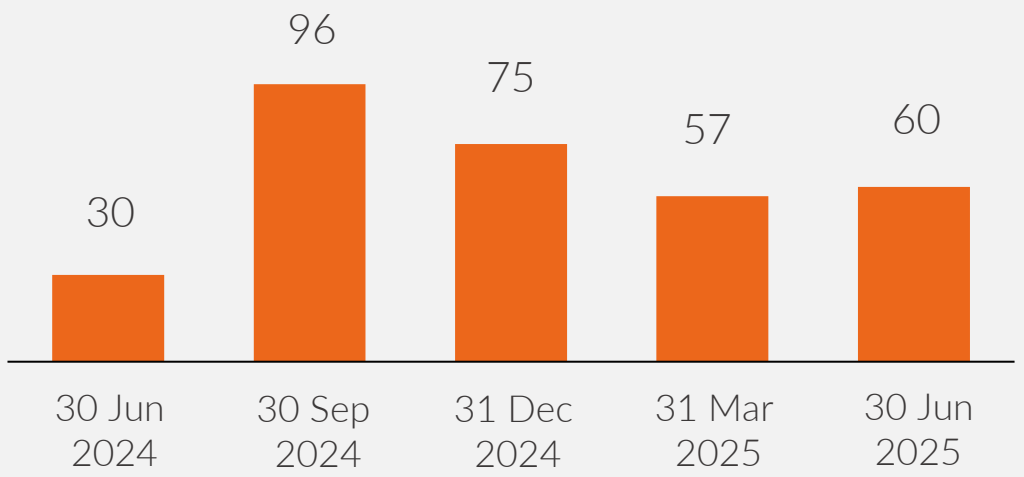
LIQUIDITY - CASH RUNWAY TO AT LEAST END 2025

Liquid assets of SEK 60 million (30 Jun 2025)

- No outstanding debt following conversion of 7.5 MSEK loan from Fenja (Sept 2025)

Cash runway into Q2 2025 with focus on Orviglance NDA review

Liquid assets including marketable securities
(SEK million)



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