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Ascelia Pharma

October 2024

ASCELIA
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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

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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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**
- **Clinical development completed** with 9 studies and strong phase 3 results
- Commercial scale **manufacturing**
- Orviglance advances to **regulatory filing and approval** phase
- Commercialization with **partner**

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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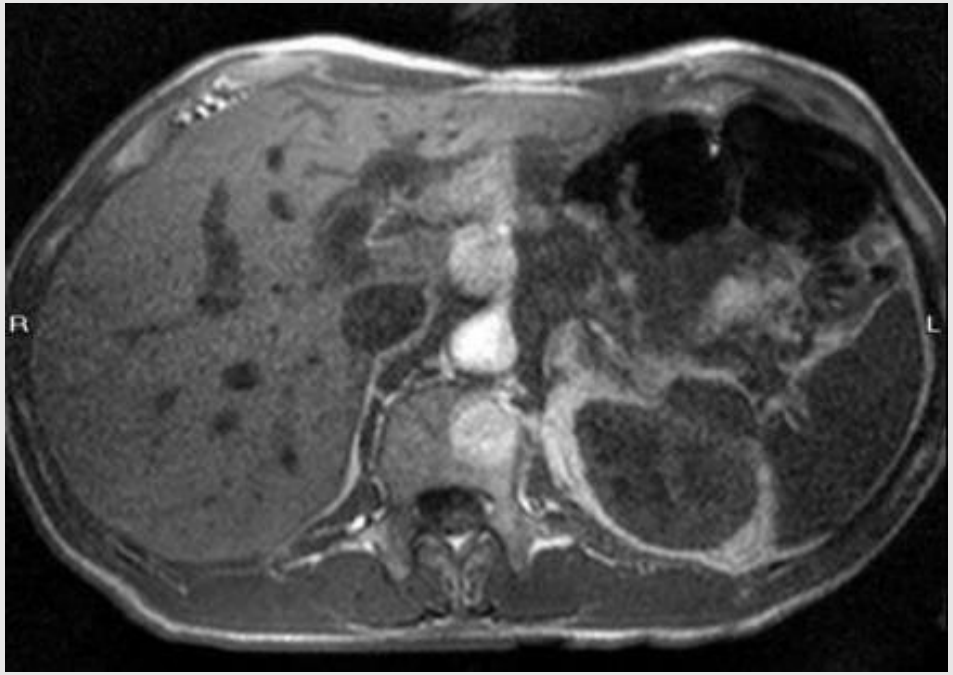
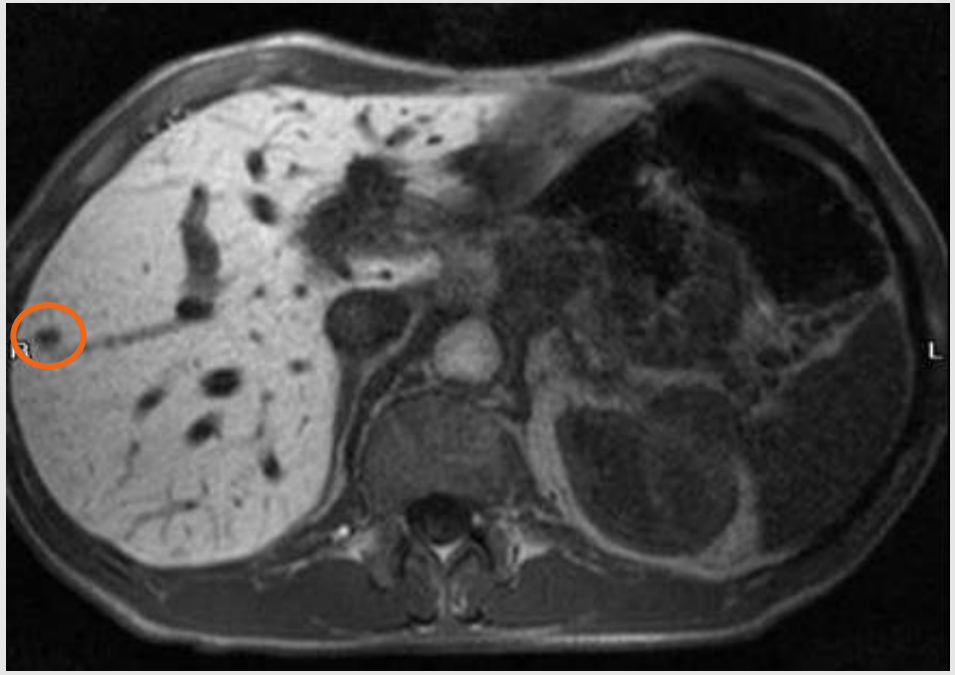
STRONG LIVER ENHANCEMENT WITH ORVIGLANCE

PATIENT EXAMPLE FROM PHASE 2 STUDY



UNENHANCED liver MRI (without contrast agent)



ORVIGLANCE contrast enhanced liver MRI

Liver metastasis appears with ORVIGLANCE

Source: Patient with colorectal cancer. (Study CMC-P002)

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PIVOTAL ORVIGLANCE PHASE 3 SUCCESSFULLY COMPLETED

SPARKLE CLINICAL STUDY

- Oral manganese-based liver-specific MRI contrast agent
- Orphan Drug designation (US) for patients for which current gadolinium-based contrast agents are medically inadvisable

Patients
- Global study, 85 patients from 32 study sites in USA, Europe, and Latin America
- Known or suspected focal liver lesions and severe kidney impairment

Endpoints
- **Primary:** Improved lesion visualization (Lesion border delineation + lesions contrast)
- **Secondary:** Other efficacy endpoints, incl. quantitative image improvement, and safety

Comparator
- Unenhanced MRI + Orviglance MRI vs Unenhanced MRI
- Each patient their own control

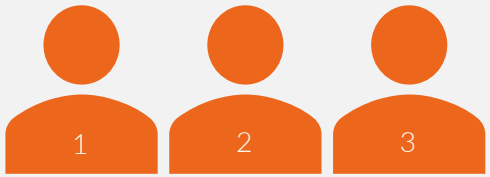
Evaluation
- Centralized evaluation by 3 independent radiologists

Follow-up
- Up to 7 days for safety

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, incl. dose-finding, hepatic impairment and food effect

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 centralized evaluation

Centralized evaluation with 3 readers of phase 2 study (20 patients) with liver metastases using 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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PHASE 1 & 2 PROVIDE STRONG EVIDENCE FOR ORVIGLANCE

Trial #	Phase	Subjects	Study design	Key results
CMC-P001	I	18 healthy subjects (+2 placebo)	Open-label dose-escalation study	Data suggested that Orviglance may be an effective MRI contrast medium
CMC-P010		32 healthy subjects	Randomised, double-blind, cross-over, dose-response	Liver signal intensity increase most pronounced at 800 mg dose (highest dose tested)
0188-20		39 healthy subjects	Open-label, randomized, 2-period, 2-way cross-over	Intake of light meal prior to Orviglance MRI provides similar liver image enhancement as in a fasting condition
ACE-MAN-P017		35 healthy subjects	Open-label, single dose, sequential cohort	Orviglance was well tolerated in patients with liver impairment. Confirms excretion primarily via the liver and not the kidney
CMC-P002	II	18 patients with liver metastasis	Open-label – each patient own control	Diagnostic quality scores improved after Orviglance
CMC-P003		20 patients with liver metastasis	Randomized, parallel group, open-label	Improved MRI quality of Orviglance most pronounced at 3 and 6 hours
CMC-P004a		20 patients with liver metastasis	Centralized evaluation of randomized cross-over	Strong superiority in visualization of focal liver lesions with Orviglance (CMRI) compared to unenhanced MRI and no significant difference vs. gadobenate (MultiHance; gadolinium-based MRI contrast agent)
CMC-P005		17 patients with liver lesions	Randomized, parallel group, open-label	Improvement of the delineation of focal liver lesions after Orviglance

Publications based on the studies: Thomsen HS *et al*, Acad Radiol 2004: 11: 630-636. Thomsen HS et al. Eur Radiol 2007, 17: 273-278. Rief M *et al*. Invest Radiol. 2010; 45: 565-71. Brismar TB *et al*.. Eur Radiol 2012; 22:633-41. Albiin N *et al*. MAGMA. 2012; 25:361-368. Study CMC-P005, primary objective to study of Orviglance for imaging of bile ducts (not published). 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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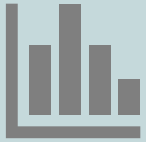
ADVANCING ORVIGLANCE TOWARDS APPROVAL

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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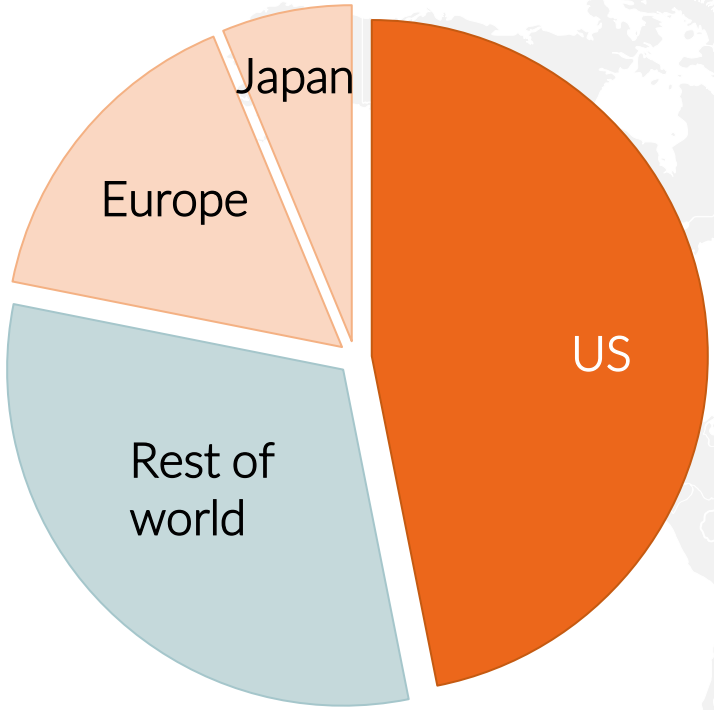
ATTRACTIVE GLOBAL ADDRESSABLE MARKET



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

CREATING VALUE BY PARTNERING FOR COMMERCIALIZATION

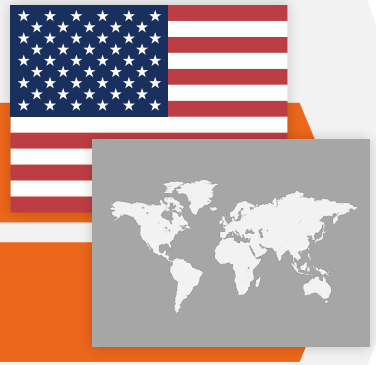
Objectives for commercialization

- Create revenue stream with limited investment required
- Leverage established commercialization capabilities and scale
- Maximize value with globally optimized launch efforts

Global commercialization through partners

Establish commercial partnerships

Secure launch readiness



Secure LAUNCH READINESS and PARTNERING

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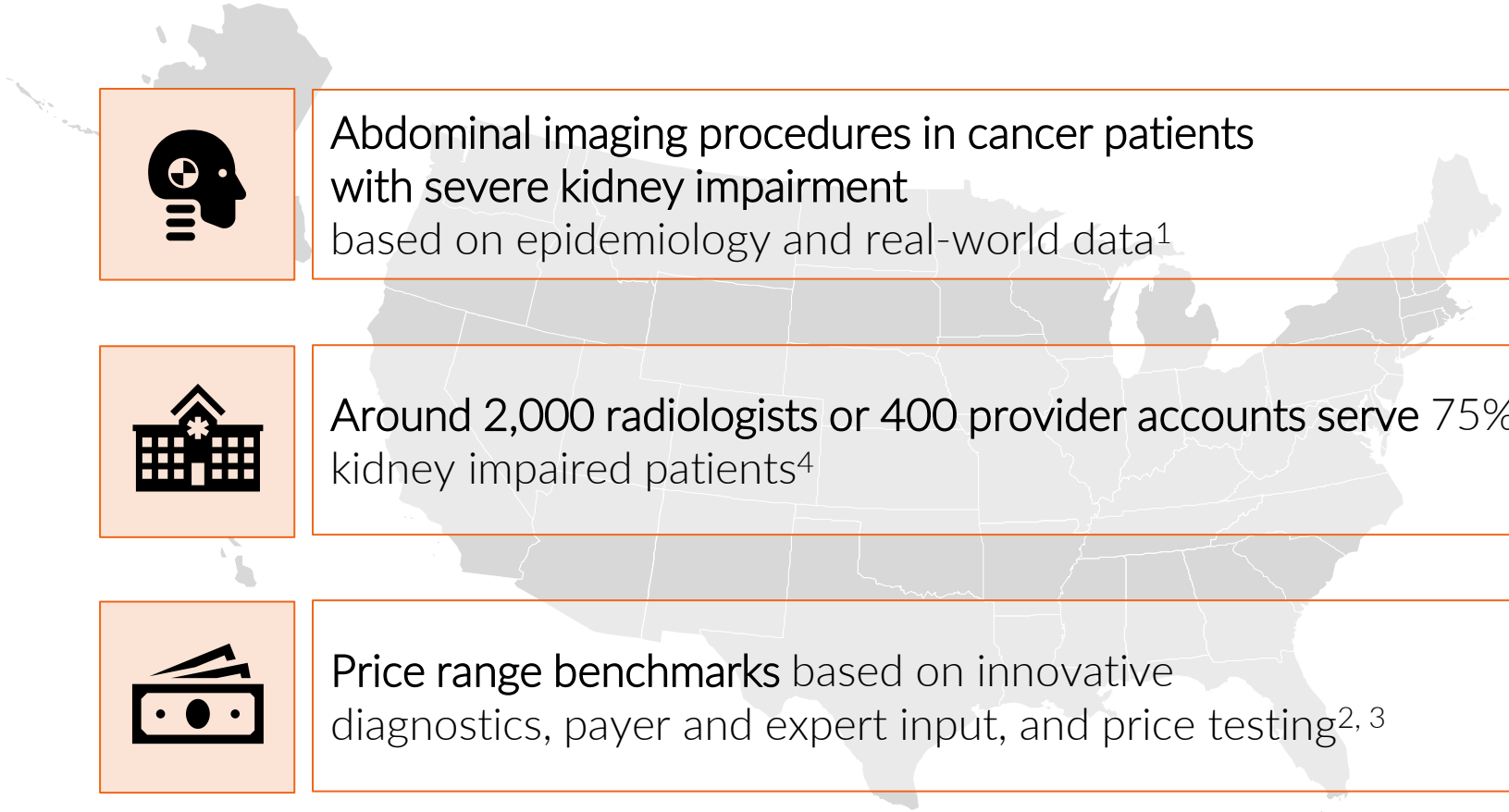
US MARKET OPPORTUNITY



Abdominal imaging procedures in cancer patients with severe kidney impairment
based on epidemiology and real-world data[1]

~100,000
procedures annually

Around 2,000 radiologists or 400 provider accounts serve 75% of kidney impaired patients[4]

~400
accounts

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

$3,000 - $4,500
price range

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

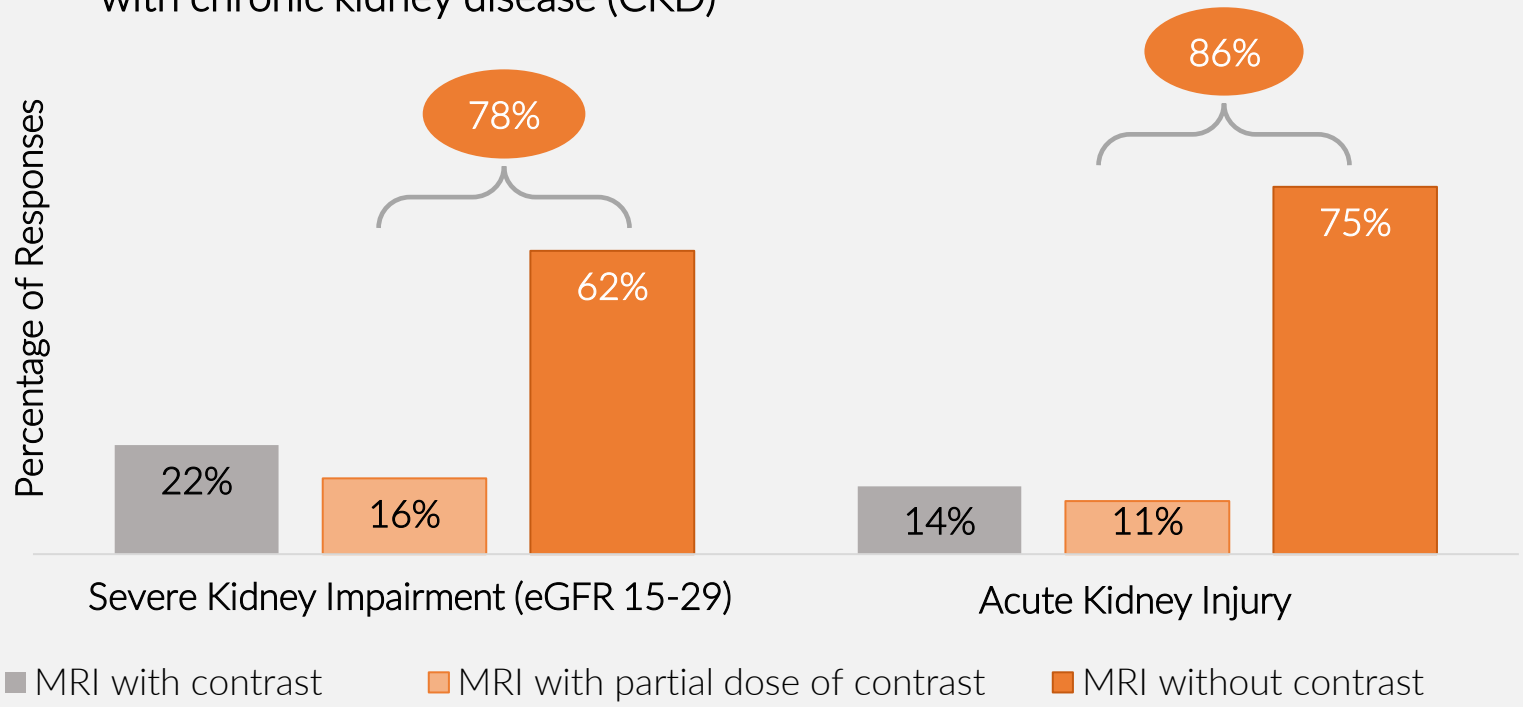
*nephrogenic systemic fibrosis

""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

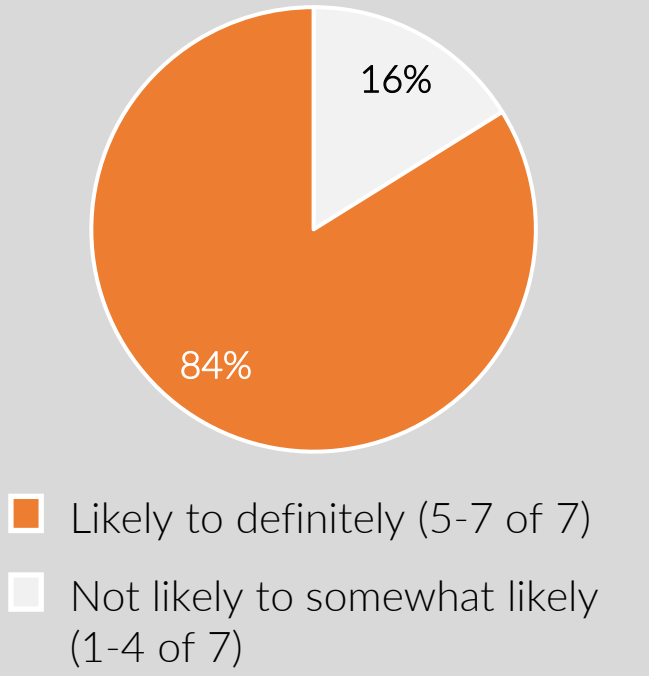
UNENHANCED MRI PREFERRED TODAY; 84% OF US PHYSICIANS LIKELY TO USE ORVIGLANCE

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

ORVIGLANCE MEDICAL ADVISORY BOARD

Nine leading US experts in liver disease and imaging shared their experience and advice

Key topics included

- Trends in liver imaging
  - SAGE (Symptoms Associated with Gadolinium Exposure)
  - LI-RADS (Liver Reporting & Data System)
  - Abbreviated Protocols (Shortened MRI by eliminating selected steps)
- Guidelines
- The journey of a patient with liver lesions
- The role of ORVIGLANCE in clinical practice

Advisors include

- Dr. Alessandro Furlan (Radiology, University of Pittsburgh Medical Center)
- Dr. Alvin Silva (Radiology, Mayo Arizona)
- Dr. Amit Singal (Hepatology, University of Texas Southwestern Medical Center)
- Dr. Bachir Touli (Radiology, Mount Sinai New York)
- Dr. Claude Sirlin (Radiology, University of California, San Diego)
- Dr. Jeffrey Weinreb (Radiology, Yale University)
- Dr. Kathryn Fowler (Radiology, University of California, San Diego)
- Dr. Richard Do (Radiology, Memorial Sloan Kettering Cancer Center)
- Dr. Victoria Chernyak (Radiology, Memorial Sloan Kettering Cancer Center)

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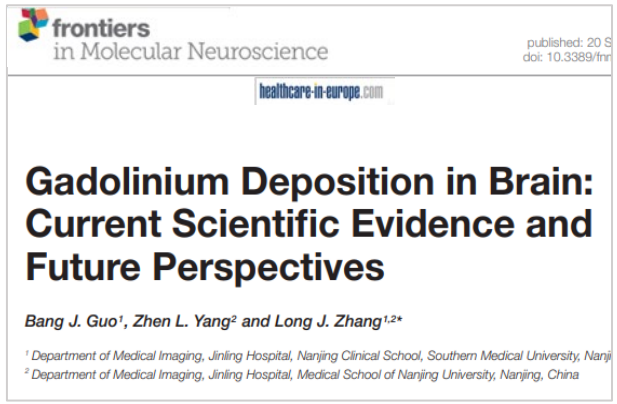
MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

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/fnr

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 gadolinium-anomaly in Tone River [Japan] increased from 851% (sampled in 1996) to 6,545% i.e. 7.7 times, reflecting the increased use of gadolinium-based contrast agents (GBCAs) in hospitals"[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) Kumasaka et al. Anthropogenic gadolinium in the Tone River (Japan): an update showing a 7.7-fold increase from 1996 to 2020, European Radiology Experimental 8, Article number 64 (2024)
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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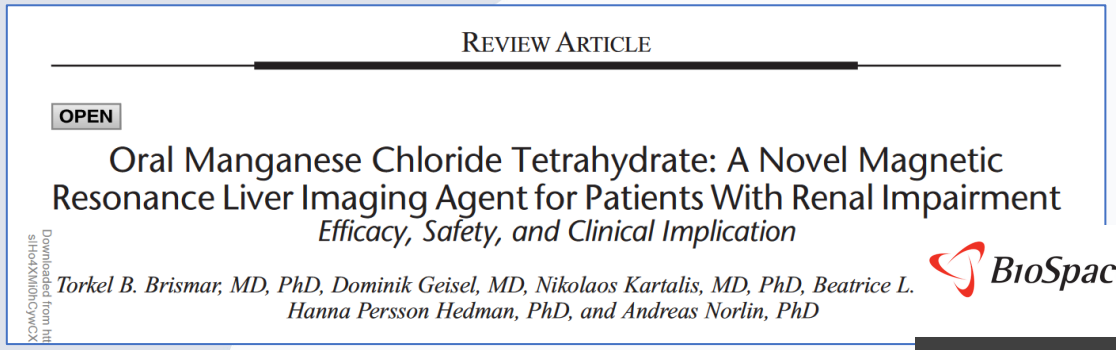
Reimagine imaging for people with poor kidney function



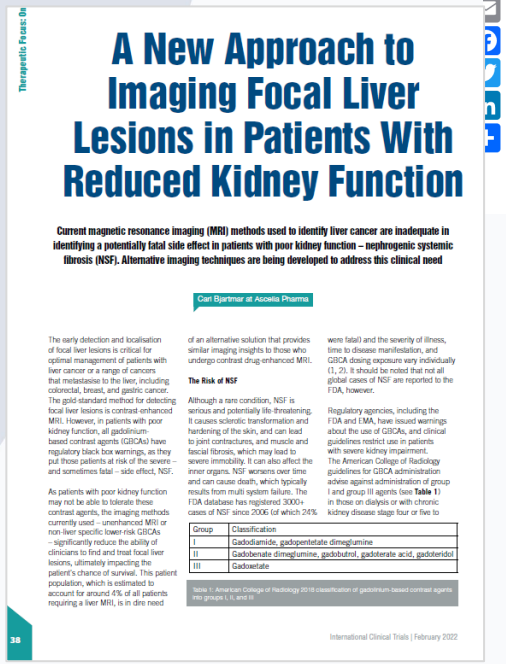
REVIEW ARTICLE

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

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

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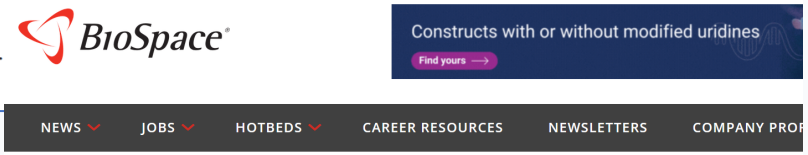
International Clinical Trials | February 2022



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NEWS | CONTRAST MEDIA | MAY 08, 2024

Ascelia Pharma Meets Primary Endpoint in Phase 3 Study of Orviglance Liver Imaging Contrast Agent Drug Candidate

Swedish biotech company Ascelia Pharma has announced that its liver imaging drug candidate, Orviglance, significantly improved visualization of focal liver lesions, successfully meeting the primary endpoint in the pivotal Phase 3 study SPARKLE. Orviglance, whose CEO Magnus Corftizen is shown here, is in development as a first-in-class contrast agent for use in liver MRI in patients with severely impaired kidney function and has been granted FDA Orphan Drug Designation.

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

Published: May 02, 2024

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orviglance®

800 mg powder for oral solution

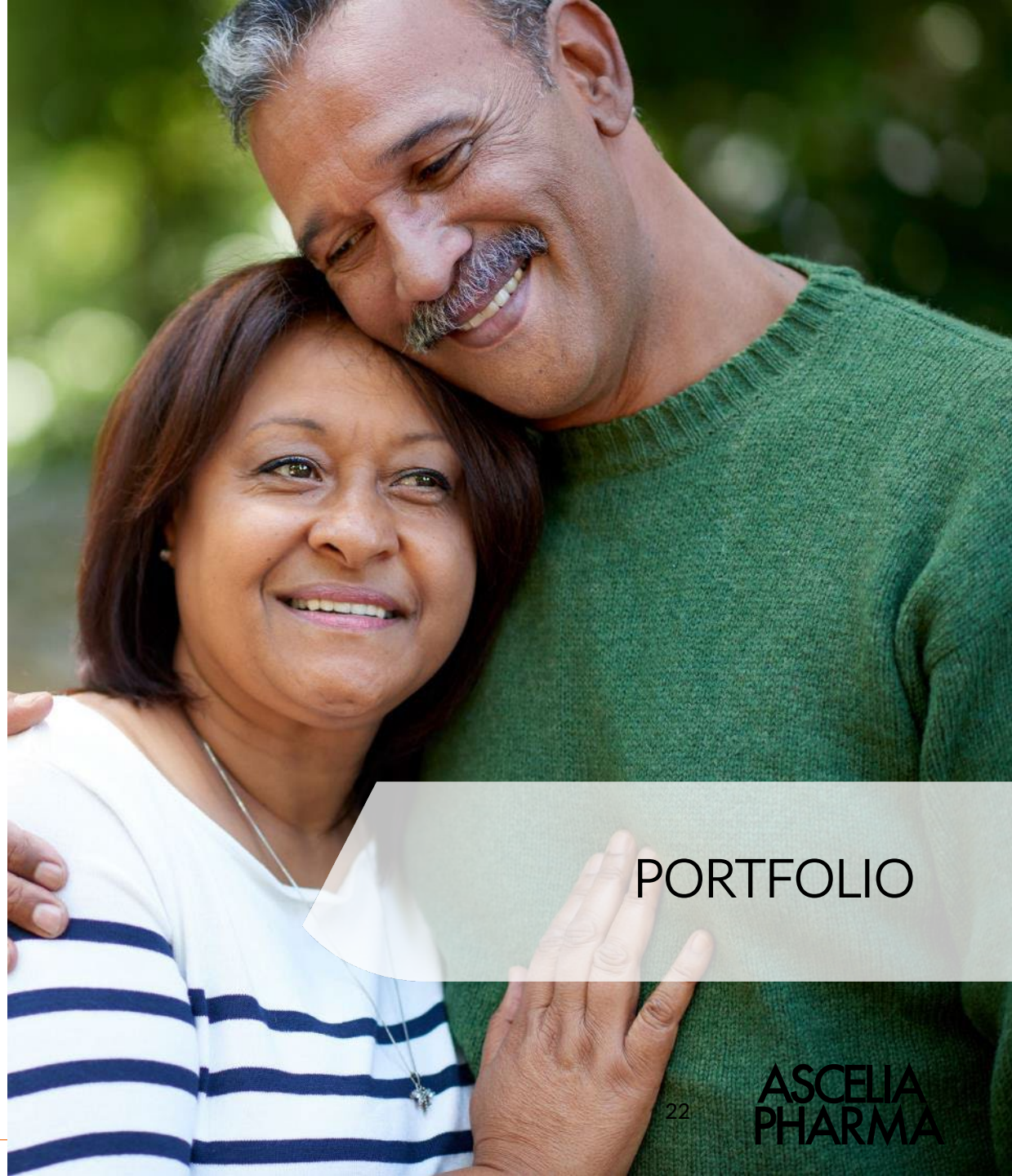
manganese chloride tetrahydrate

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



PORTFOLIO

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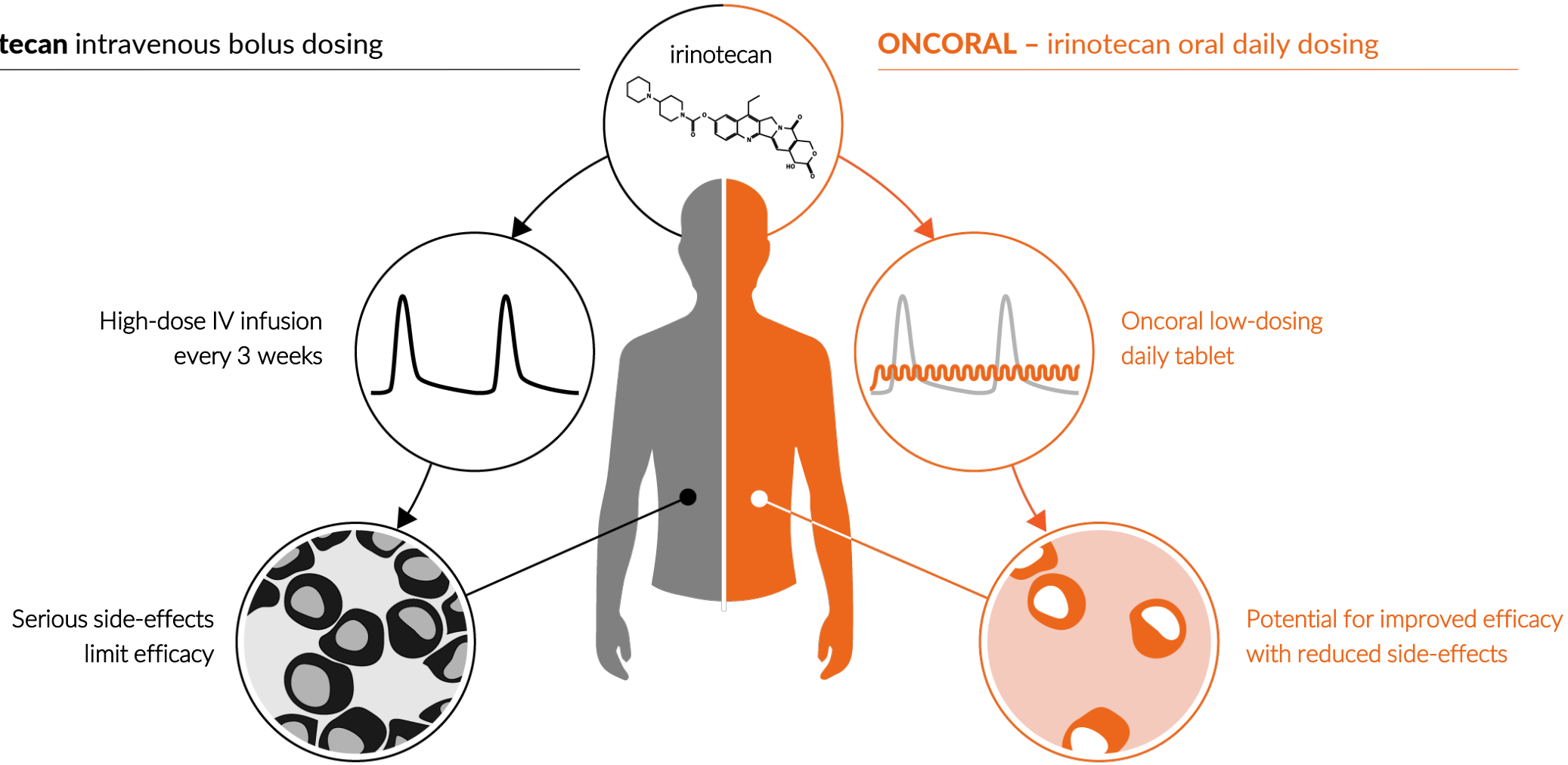
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing

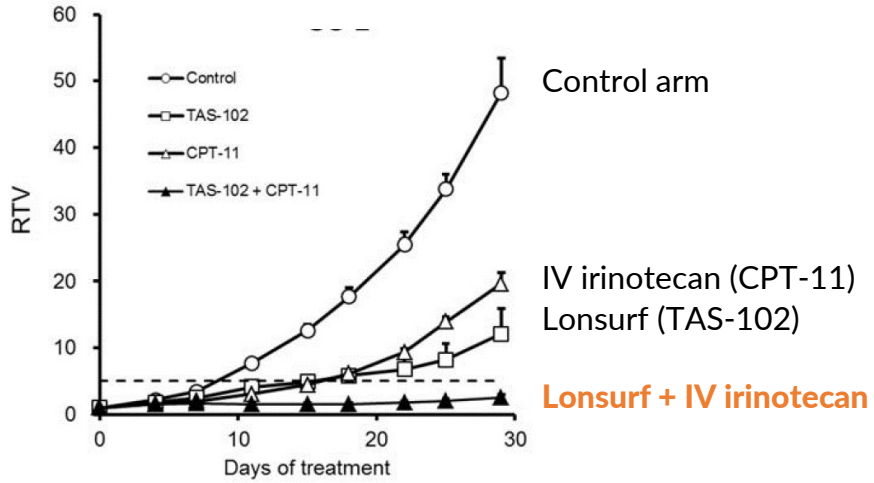


ONCORAL PHASE 2 IN GASTRIC CANCER

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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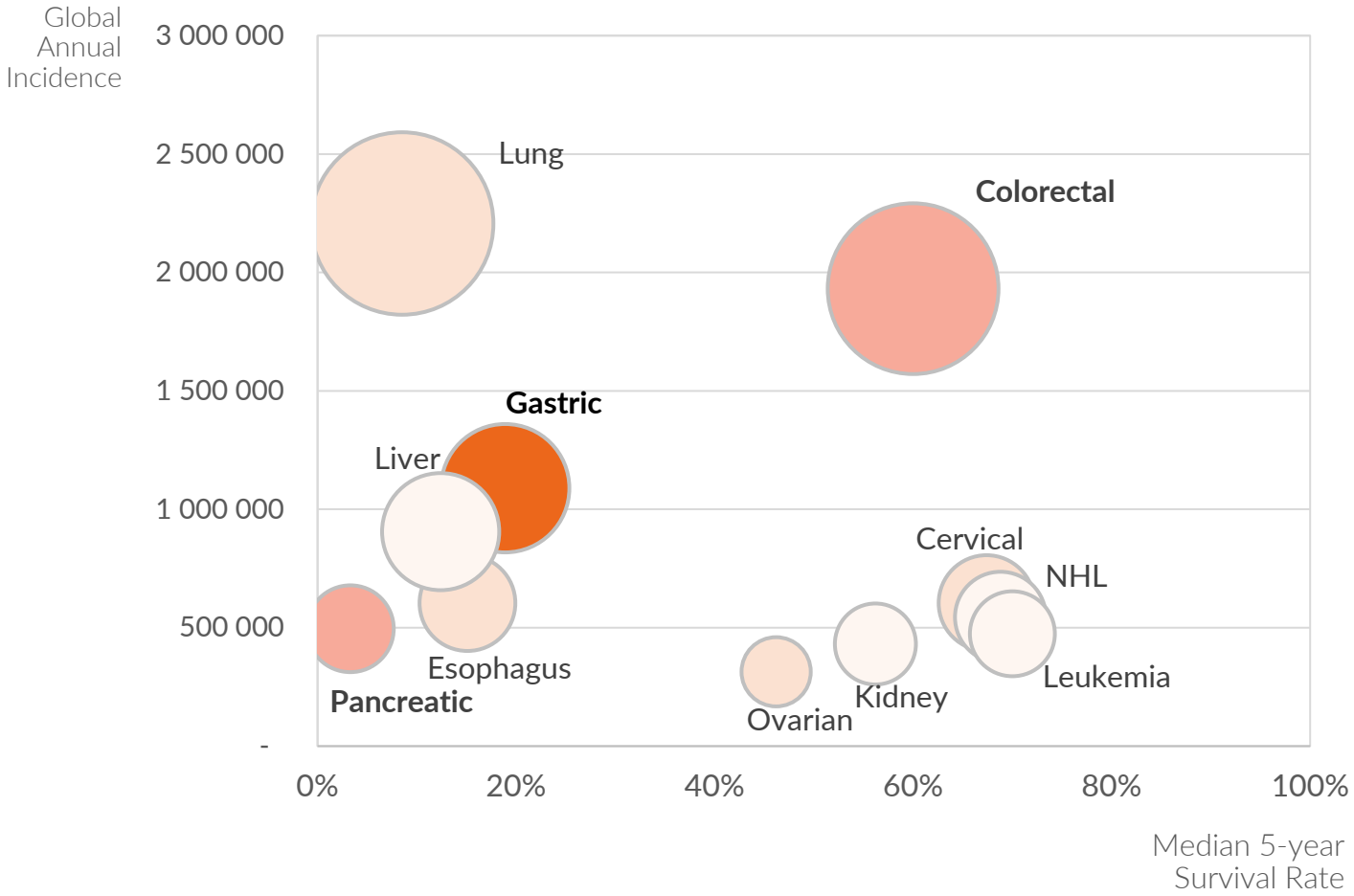
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

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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OUTLOOK

SUBSTANTIAL ORVIGLANCE VALUE CREATION OPPORTUNITIES

	Advance to approval	Secure partnering and commercialization readiness
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 with 800 MUSD annual addressable market **Partner** driven global commercialization
Milestones	▪ Full SPARKLE Clinical Study Report early **Q4 2024** ▪ Conclusions from FDA pre-submission meeting by **Q1 2025** ▪ NDA submission **mid-2025** with Ascelia Pharma and partner readiness	▪ Advance **launch readiness** ▪ Establish commercialization **partnership(s)**

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

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