ADVANCING
ORPHAN
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Ticker symbol: ACE
Nasdaq Stockholm
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Ascelia Pharma introduction

May 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

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 SUCCESSFULLY MEETS PRIMARY ENDPOINT

- Phase 3 study demonstrated strong superiority in visualization of focal liver lesions with Orviglance (CMRI) compared to unenhanced MRI
- All three readers meet the primary endpoint ($p<0.001$) with statistical significance
- The reliability of the data is strong and conclusive for all readers – including variability

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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SUBSTANTIAL VALUE CREATION OPPORTUNITIES

Advance Orviglance to approval

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

Progress Orviglance commercialization readiness

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

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

Develop pipeline potential

Demonstrate Oncoral efficacy and safety in Phase 2

Expand Orviglance franchise with 2nd generation

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

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

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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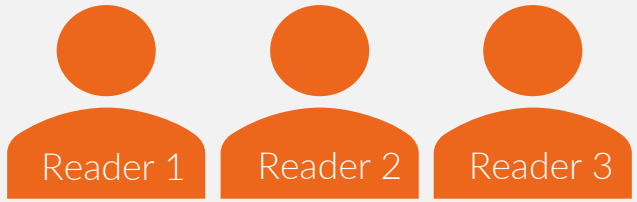
STRONG SUPERIORITY OF ORVIGLANCE IN PHASE 3

Primary endpoint met successfully

- Three out of three readers scored primary visualization variables significantly higher with Orviglance than without



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

Orviglance clinical development completed

- Primary efficacy and safety of Orviglance confirmed in pivotal Phase 3
- Consistent positive efficacy and safety results across all nine studies
- Phase 3 full study report in progress for early Q4 2024

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

CLINICAL DATA PACKAGE FOR REGULATORY SUBMISSION

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

286 patients and healthy volunteers

Phase 1 studies investigating safety, absorption and signal intensity

Total 4 studies with 126 healthy volunteers

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

Total 4 studies with 75 patients

Re-Evaluation Orviglance vs. Gadolinium & Unenhanced

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

Phase 3 study to confirm 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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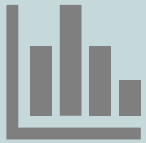
ADVANCING ORVIGLANCE TOWARDS APPROVAL

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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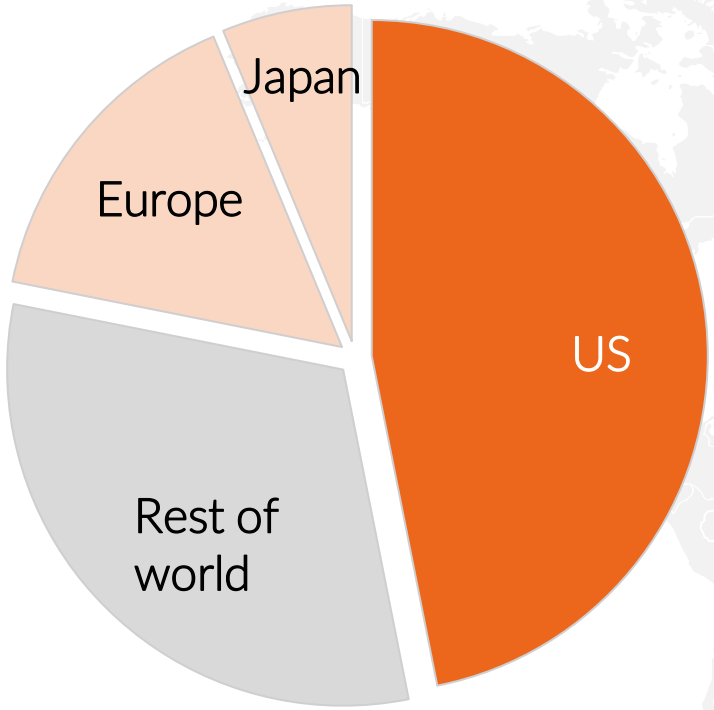
ATTRACTIVE ADDRESSABLE MARKET



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 with potential for Ascelia Pharma led launch in the US

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

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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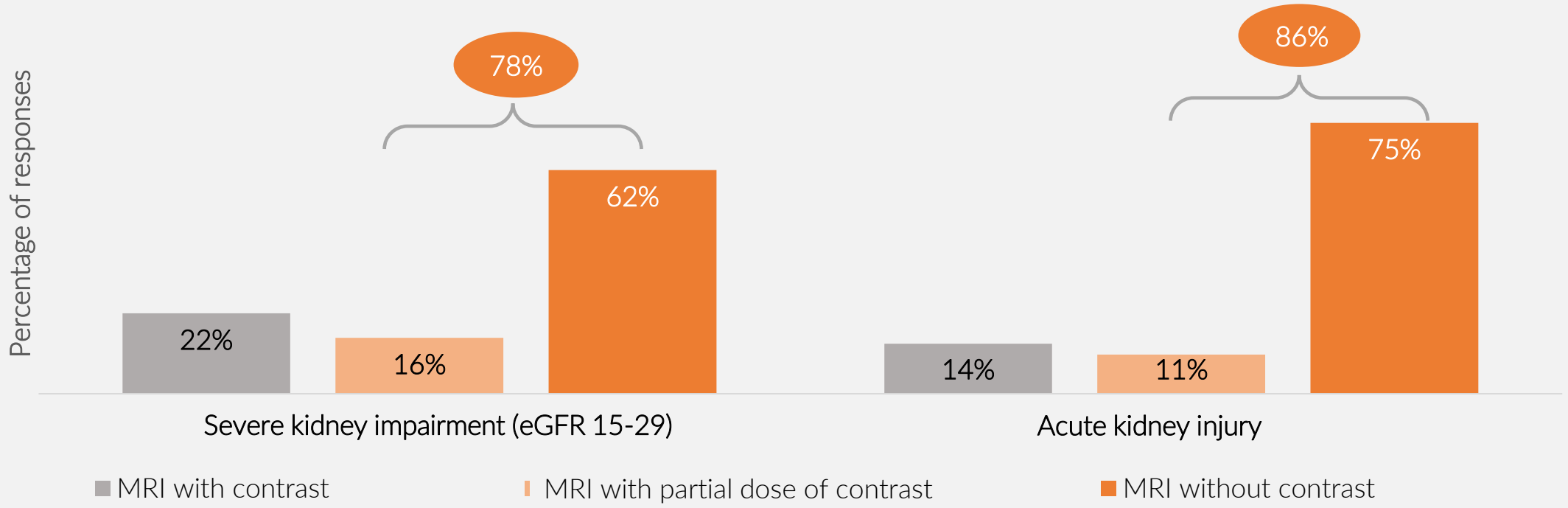
UNENHANCED MRI PREFERRED FOR TARGET PATIENTS TODAY

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)



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 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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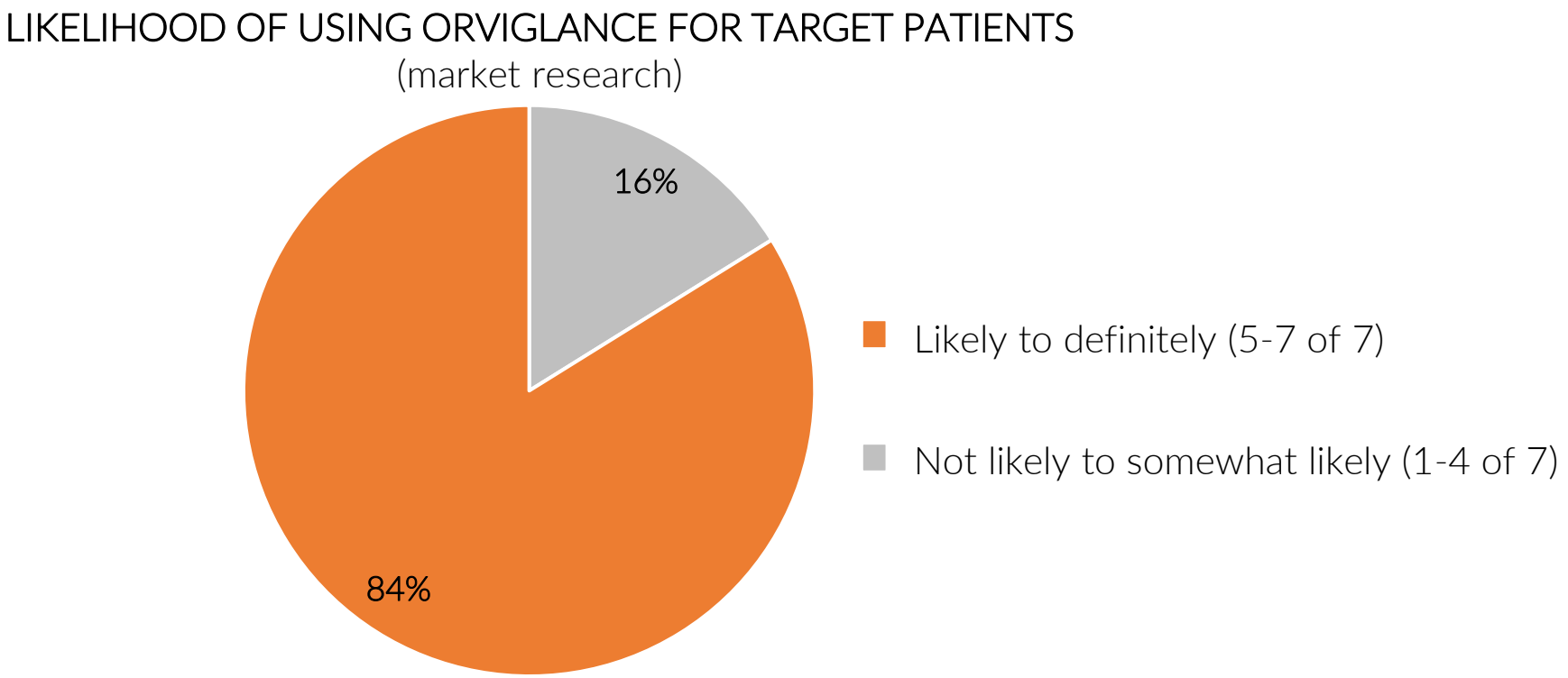
84% US HEALTHCARE PROFESSIONALS WILL USE ORVIGLANCE



Market research for Ascelia Pharma conducted in Q4 2021/Q1 2022 by Two Labs Pharma Services
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?

ON TRACK FOR OPTIMAL COMMERCIALIZATION

Strategic objectives for commercialization

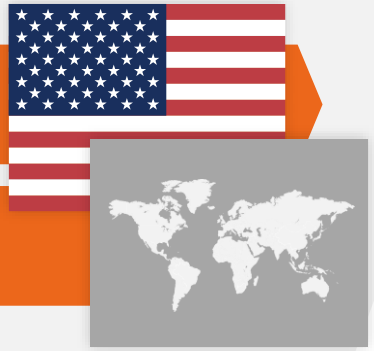
- Optimal balance between investment required and future revenues
- Maximize value with shared global launch strategy
- Focus on key strategic capabilities in Ascelia Pharma

Global commercialization through partners

with potential for Ascelia Pharma led launch in the US

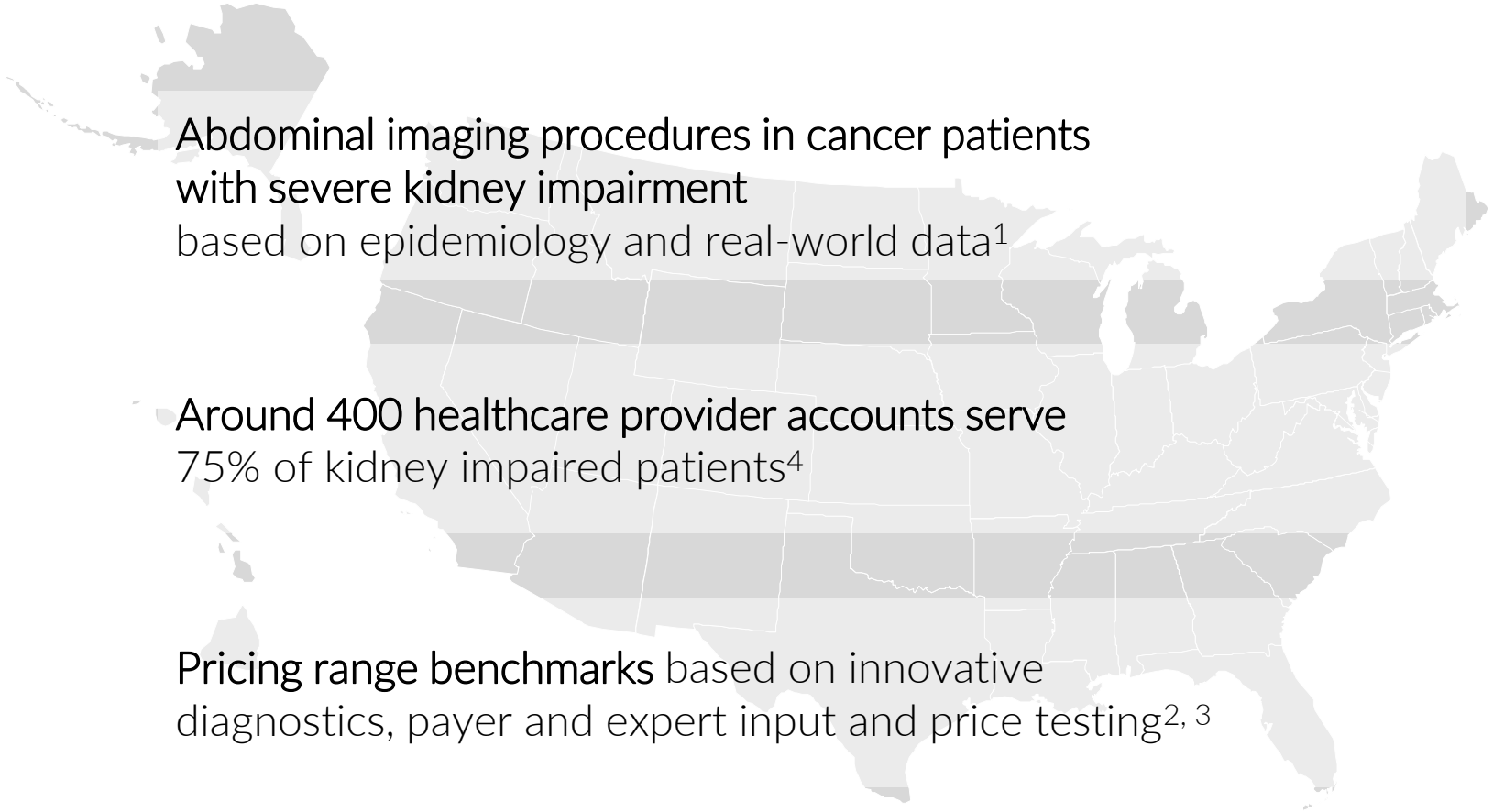
Secure launch readiness

Establish commercial partnerships



Progress launch readiness securing VALUE CREATION

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]

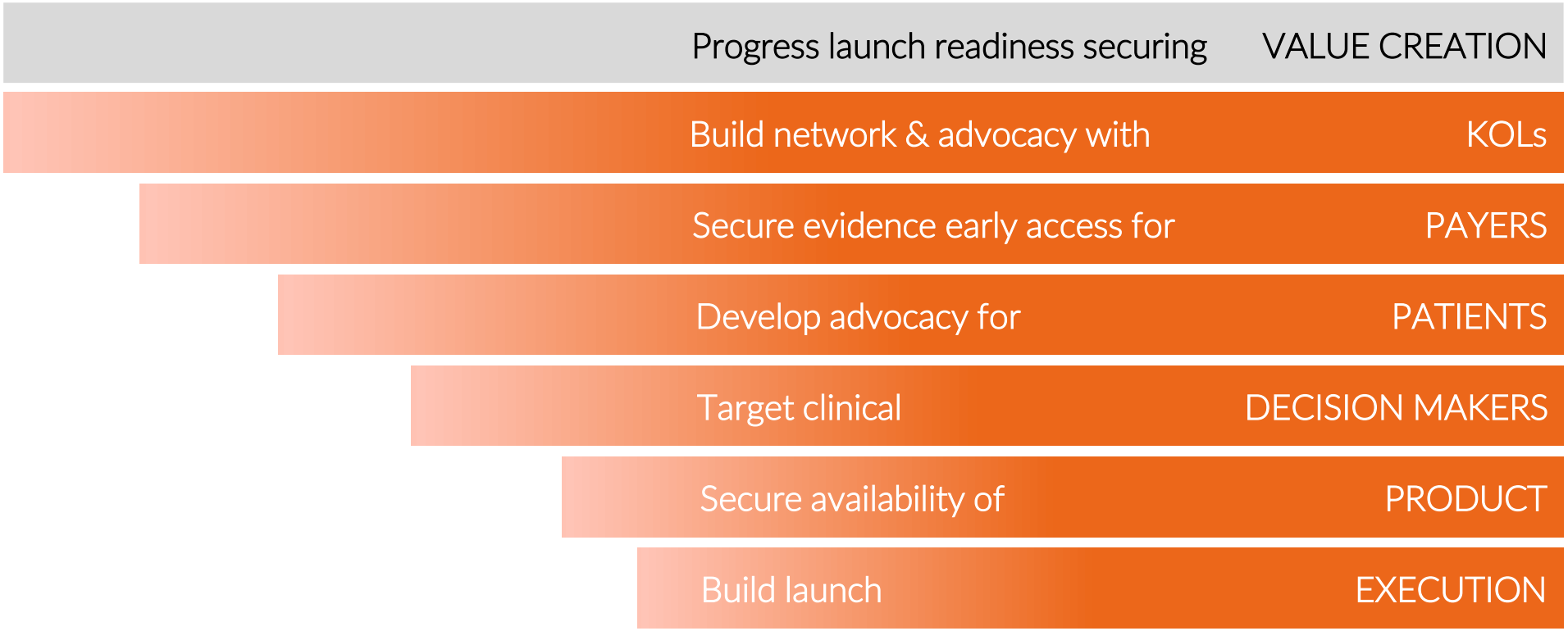
~100,000
procedures annually

~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

CLEAR ROADMAP FOR OPTIMAL LAUNCH



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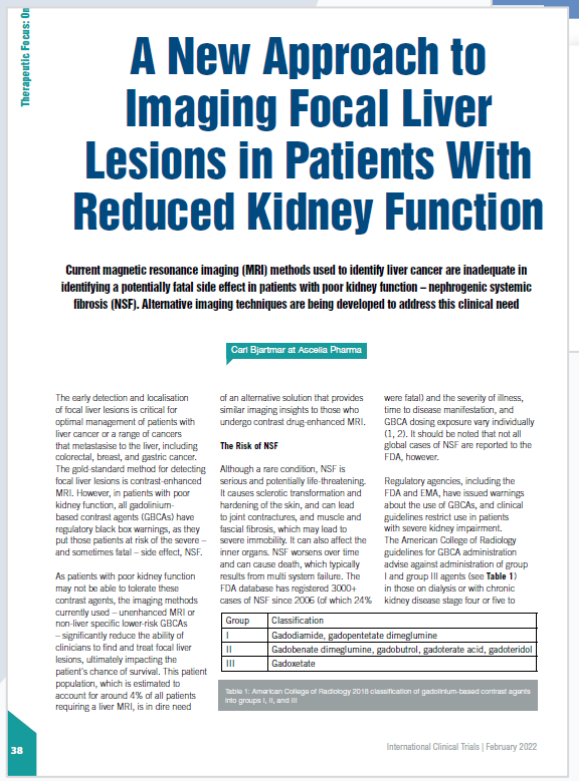
Progress launch readiness securing VALUE CREATION

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

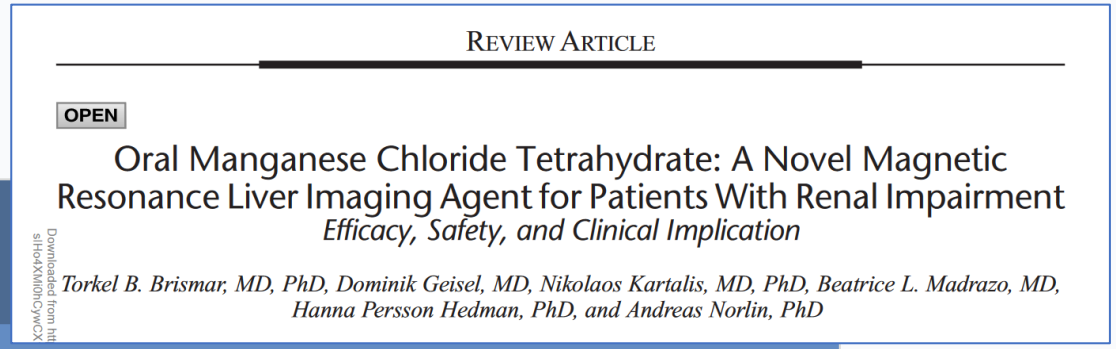
itn IMAGING TECHNOLOGY NEWS

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.



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

orviglance®

800 mg powder for oral solution

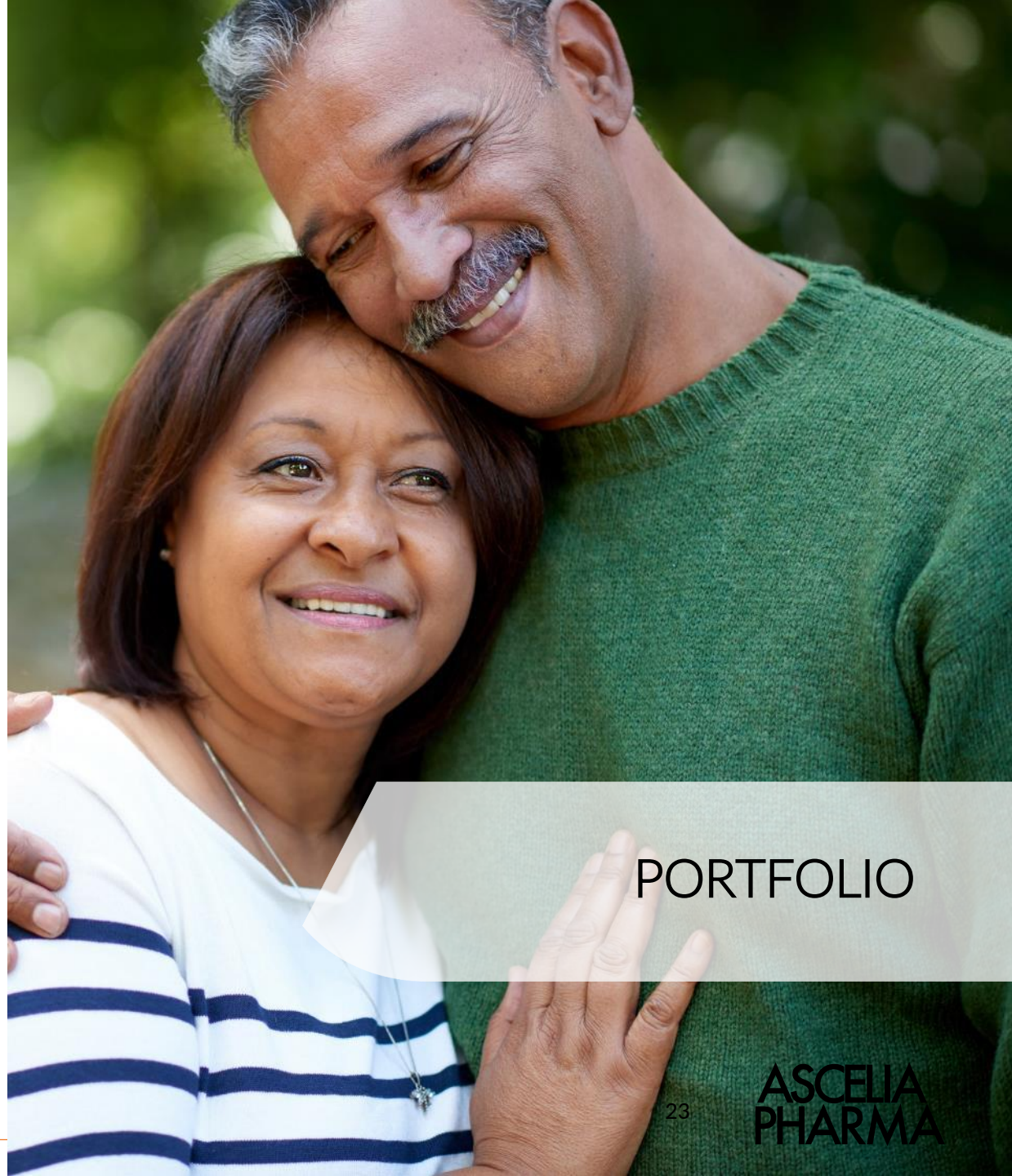
manganese chloride tetrahydrate

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



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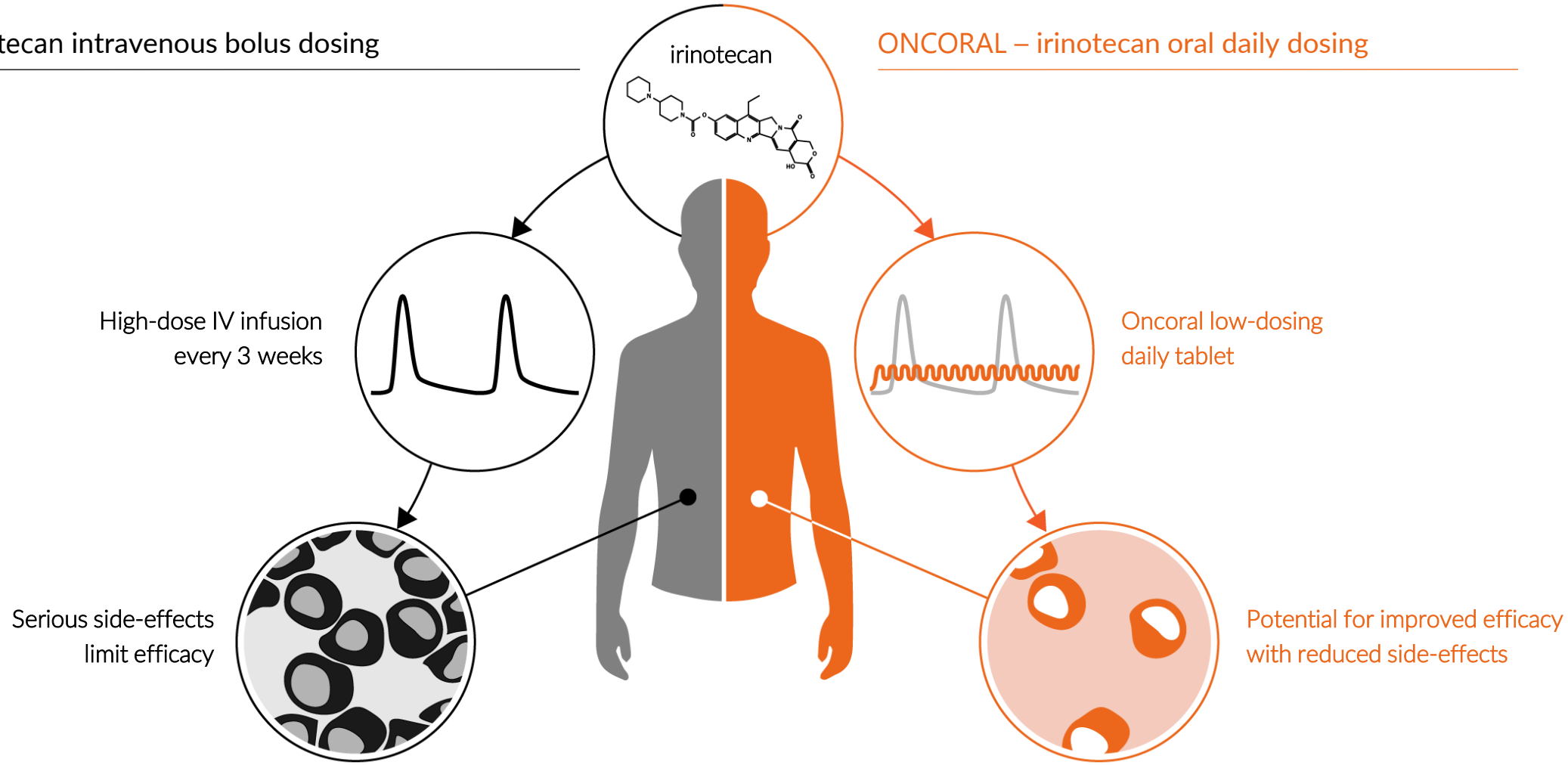
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



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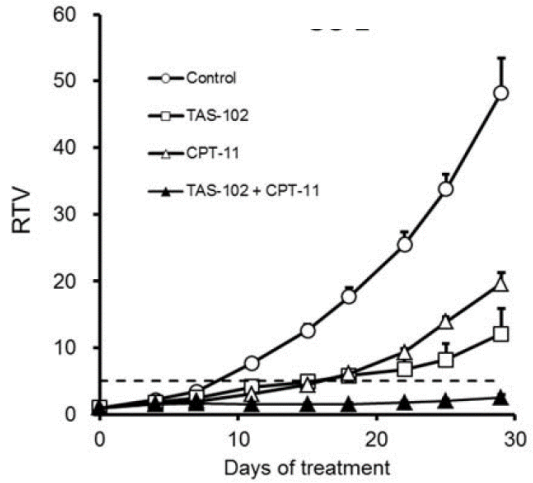
ONCORAL PHASE 2 IN GASTRIC CANCER

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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FINANCIALS & OUTLOOK

ASCELIA PHARMA SECURES FINANCING OF 35 MILLION

PRESS RELEASE

04 February 2024 20:54:00 CET

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Ascelia Pharma Secures Financing of up to SEK 35 Million

Ascelia Pharma AB (publ) (ticker:ACE) ("Ascelia Pharma" or the "Company"), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the board of directors has resolved on a directed issue of convertibles to Formue Nord Fokus A/S ("Formue") raising gross proceeds of SEK 15 million (the "Convertibles"). Further, the Company has also entered into an agreement with Formue for a loan facility of up to SEK 20 million (the "Loan Facility" and together with the Convertibles, the "Financing"). The transaction ensures financial and strategic flexibility, with the full Financing extending the cash runway into the second quarter of 2025.

Strengthened financial position

- Ensures financial and strategic flexibility
- Extends cash runway into Q2 2025
- Limited dilution of current shareholders (around 4 percent)

Attractive and competitive terms

- First tranche financing of SEK 20 million
  - SEK 15 million is convertibles (10.53 SEK per share)
  - SEK 20 million loan

- Repayment by 20 May 2025, with option to repay at any time at no additional costs

SUBSTANTIAL VALUE CREATION OPPORTUNITIES

Advance Orviglance to approval

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

Progress Orviglance commercialization readiness

- Advance launch readiness
- Commercialization partnership

Develop pipeline potential

- Initiate Phase 2 clinical study when financing allows

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

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