Ascelia Pharma

Økonomisk Ugebrev Investor Meeting
26 March 2025

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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 entity in New Jersey (US)
Listed on NASDAQ Stockholm (Ticker: ACE)

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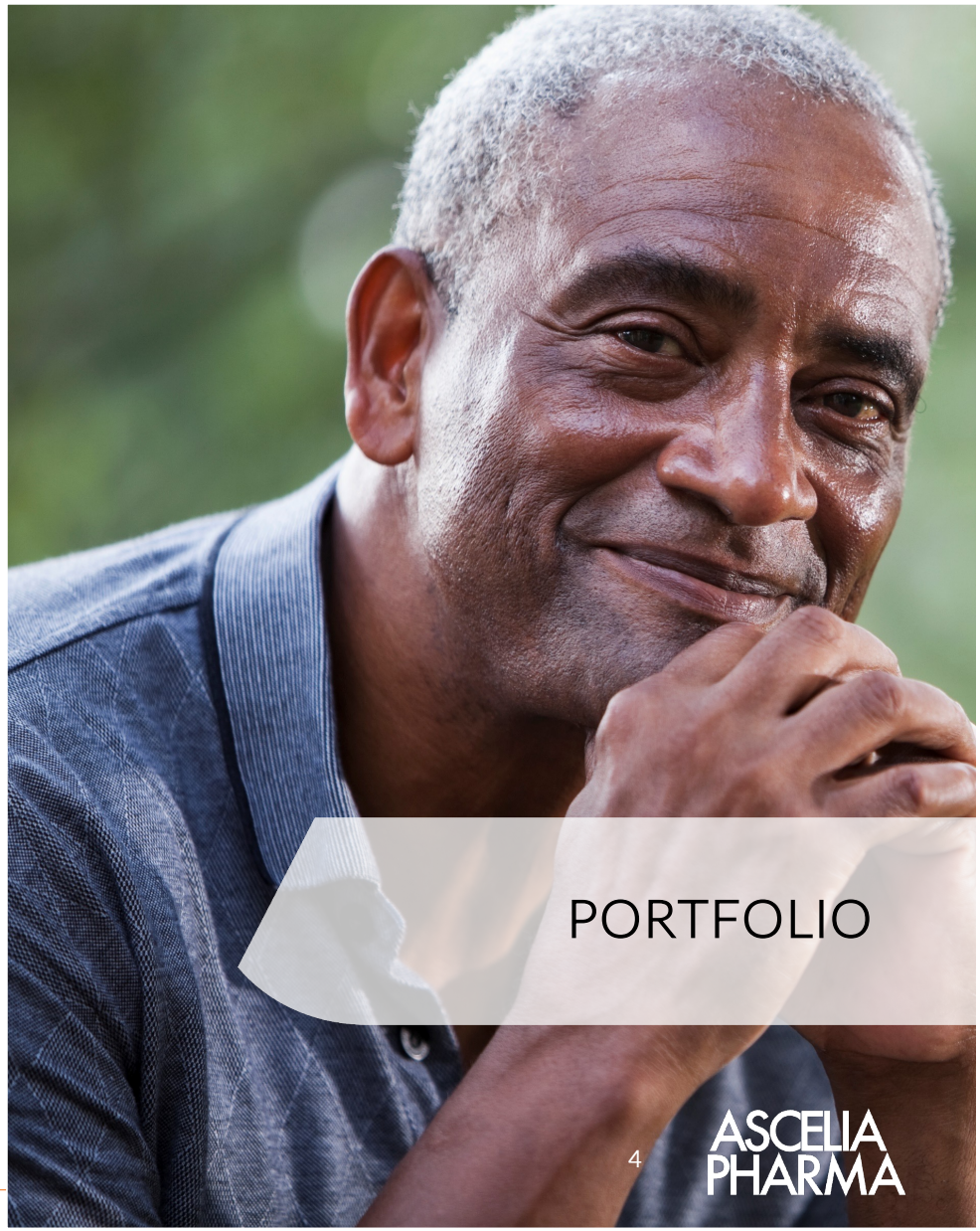
ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



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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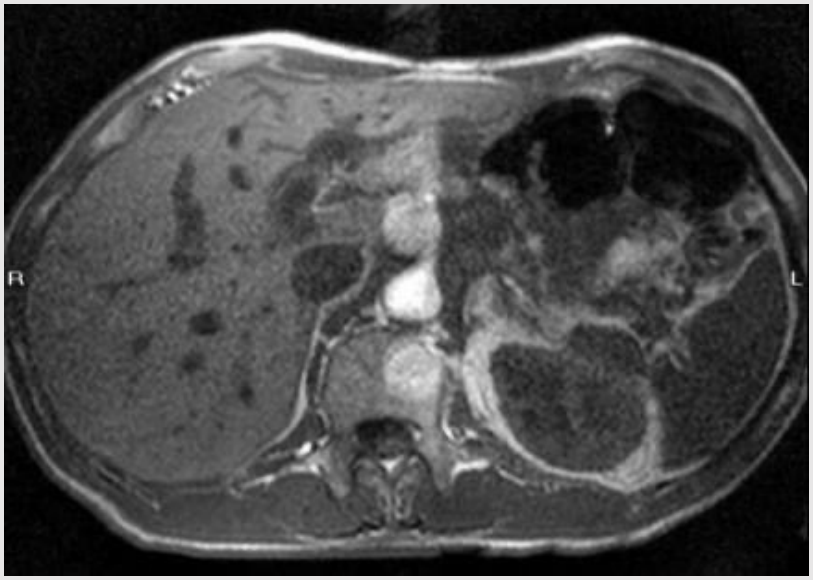
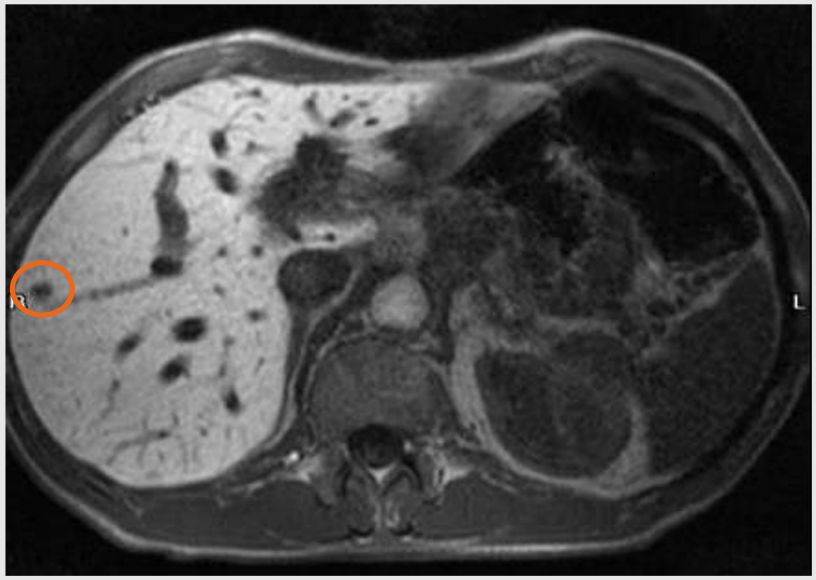
STRONG LIVER ENHANCEMENT WITH ORVIGLANCE

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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STRONG SUPERIORITY OF ORVIGLANCE IN PHASE 3

Successful Phase 3 Study

- 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

- **Secondary efficacy endpoints support** primary analysis and confirm the robustness of the positive results
- 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

ASCELIA PHARMA

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,

PRESS RELEASE

06 November 2024 22:40:00 CET

ASCELIA PHARMA

Ascelia Pharma Announces Completion of Full Study Report Reinforcing the Successful Outcomes of Orviglance Phase 3 Study SPARKLE

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced the completion of the Full Study Report for the pivotal Phase 3 Study for Orviglance® liver imaging drug candidate, which includes the previously announced strong results of primary endpoints. In addition, the results of secondary endpoints further reinforce the successful study outcomes and support the New Drug Application (NDA) process.

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POSITIVE FDA MEETING CONFIRMS NDA FILING ON TRACK

Meeting with the FDA

- Ascelia presented the plan for the submission including:
  - How to analyze and present the clinical data
  - Finalization of Statistical Analysis Plan
  - Manufacturing documentation
  - Structure of the NDA
- The FDA provided clear and concrete feedback which will allow Ascelia to finalize the NDA documentation package
- The NDA submission continues to be planned for mid-2025

PRESS RELEASE

18 March 2025 22:05:00 CET

ASCELIA PHARMA

Ascelia Pharma Announces Positive Outcomes of FDA Meeting and Confirms Plan to Submit the NDA for Orviglance mid-2025

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the Company has received final minutes from the meeting with the FDA, providing positive guidance for the Orviglance NDA to progress with the submission mid-2025 as planned.

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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 meeting by **Q1 2025**
- ❑ NDA submission **mid-2025**

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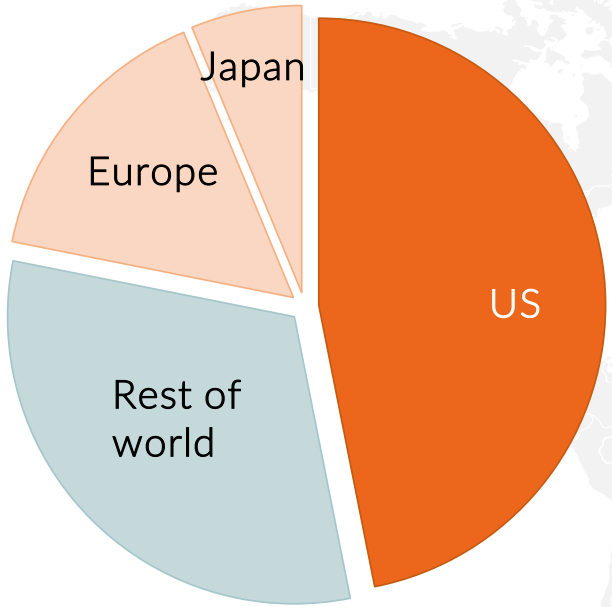
ATTRACTIVE GLOBAL ADDRESSABLE MARKET



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

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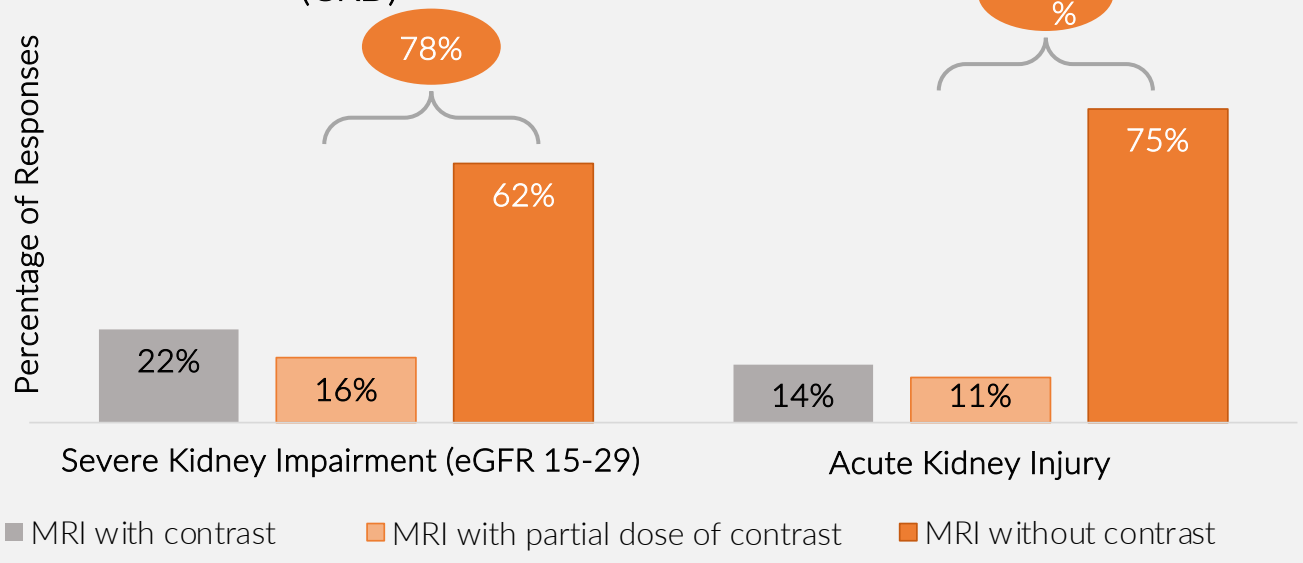
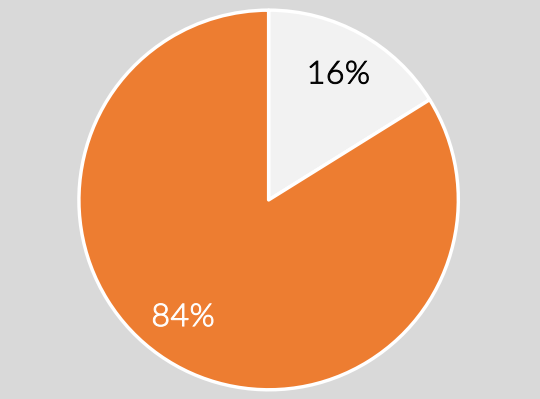
UNENHANCED MRI PREFERRED TODAY; 84% OF US PHYSICIANS LIKELY TO USE ORVIGLANCE

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



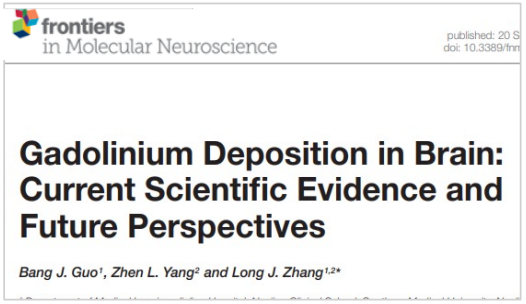
Source: Independent research by Two Labs Pharma Services for Ascelia Pharma in the USA conducted in Q4 2021/Q1 2022 included 16 in depth interviews and a survey of 254 healthcare professionals (HCPs), including 154 radiologists N =103 oncologist, nephrologist, and radiologist responses. Q: Please assign priority to the imaging tests in the sequence or order in which you would recommend or perform them

MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

Deposition in Brain & Organs

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

FDA required study on GBCA effect on movement and mental skills (ODYSSEY)


frontiers in Molecular Neuroscience

published: 20 S
doi: 10.3389/fnn

Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives

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

Water Contamination

scrutiny of environmental impact

Gadolinium is excreted in urine and discharged into environment and water

Future with Less Gadolinium

focus of leading gadolinium manufactures

Lower dose full-body gadolinium contrast agents

- FDA approved in priority review (2022) and EMA (2023) approved (gadopiclenol, Guerbet/Bracco)
- Completion of Phase 3 (gadoquatrane, Bayer 2024)

Completion of Phase 1 for IV manganese-based contrast agent (GE HealthCare 2023)

Sources include:
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)
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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RECOGNITION IN THE SCIENTIFIC COMMUNITY

SPARKLE data accepted at major conferences so far with
4 oral presentations and 3 abstract presentations

American Society of Nephrology (ASN) Kidney Week, October 2024

SPARKLE: A Multicenter, Open-Label Study to Evaluate the Safety and Diagnostic Efficacy of ACE-MBCA in Patients with Known or Suspected Focal Liver Lesions and Severe Renal Impairment

Session Information

» Late-Breaking Science Posters
October 24, 2024 | Location: Exhibit Hall, Convention Center
Abstract Time: 10:00 AM - 12:00 PM

Category: Diversity and Equity in Kidney Health

- 900 Diversity and Equity in Kidney Health

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- Ortiz Melo, David I., Duke University, Durham, North Carolina, United States

Ascelia Pharma Announces Acceptance of SPARKLE Phase 3 Data for Presentation at the Society of Abdominal Radiology Congress 2025

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that two scientific abstracts with clinical data from the SPARKLE Phase 3 study with Orviglance have been accepted as an oral presentation and a scientific poster at the Society of Abdominal Radiology Congress, taking place from 16-21 February 2025 in Tucson, AZ, US.

Radiological Society of North America (RSNA), Annual Meeting, December 2024

Science Session (Value Based, Equitable and Sustainable Radiology) | M6-STCE2

Session Type: Learning Center Theater Presentations

Monday, Dec 2 | 1:30 PM - 2:00 PM CST | LEARNING CENTER THEATER 2

SPARKLE: A MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE SAFETY AND DIAGNOSTIC EFFICACY OF ACE-MBCA IN PATIENTS WITH KNOWN OR SUSPECTED FOCAL LIVER LESIONS AND SEVERE RENAL IMPAIRMENT | M6-STCE2-3

Alvin C. Silva, MD, Presenter

Ascelia Pharma Announces Acceptance of Three Scientific Abstracts with SPARKLE Phase 3 Data at the European Society of Gastrointestinal and Abdominal Radiology Annual Meeting

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that two oral presentations and one scientific poster with clinical data from the SPARKLE Phase 3 study with Orviglance have been accepted for presentation at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting, taking place 13-16 May in Amsterdam, Netherlands.

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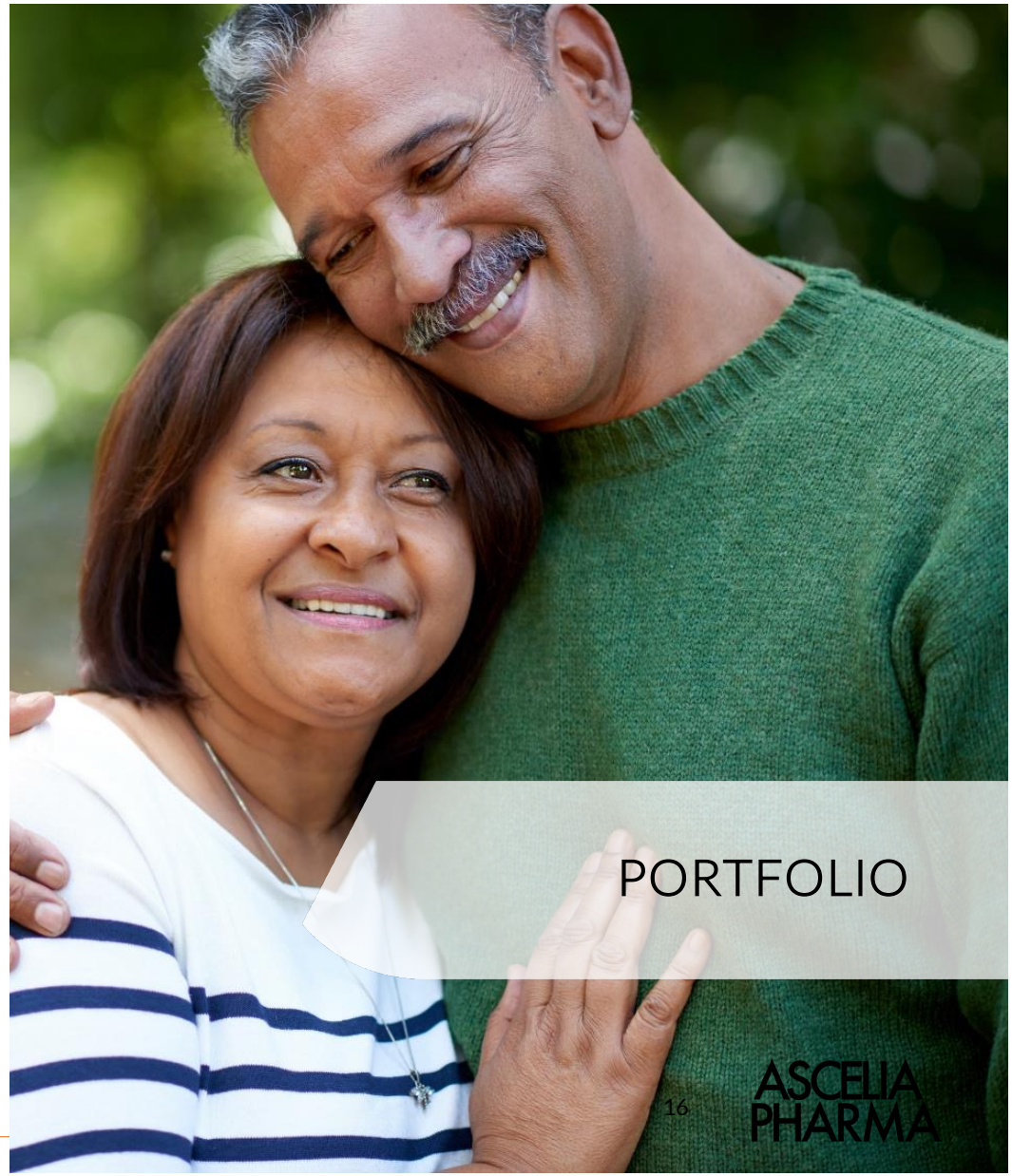
ORVIGLANCE®

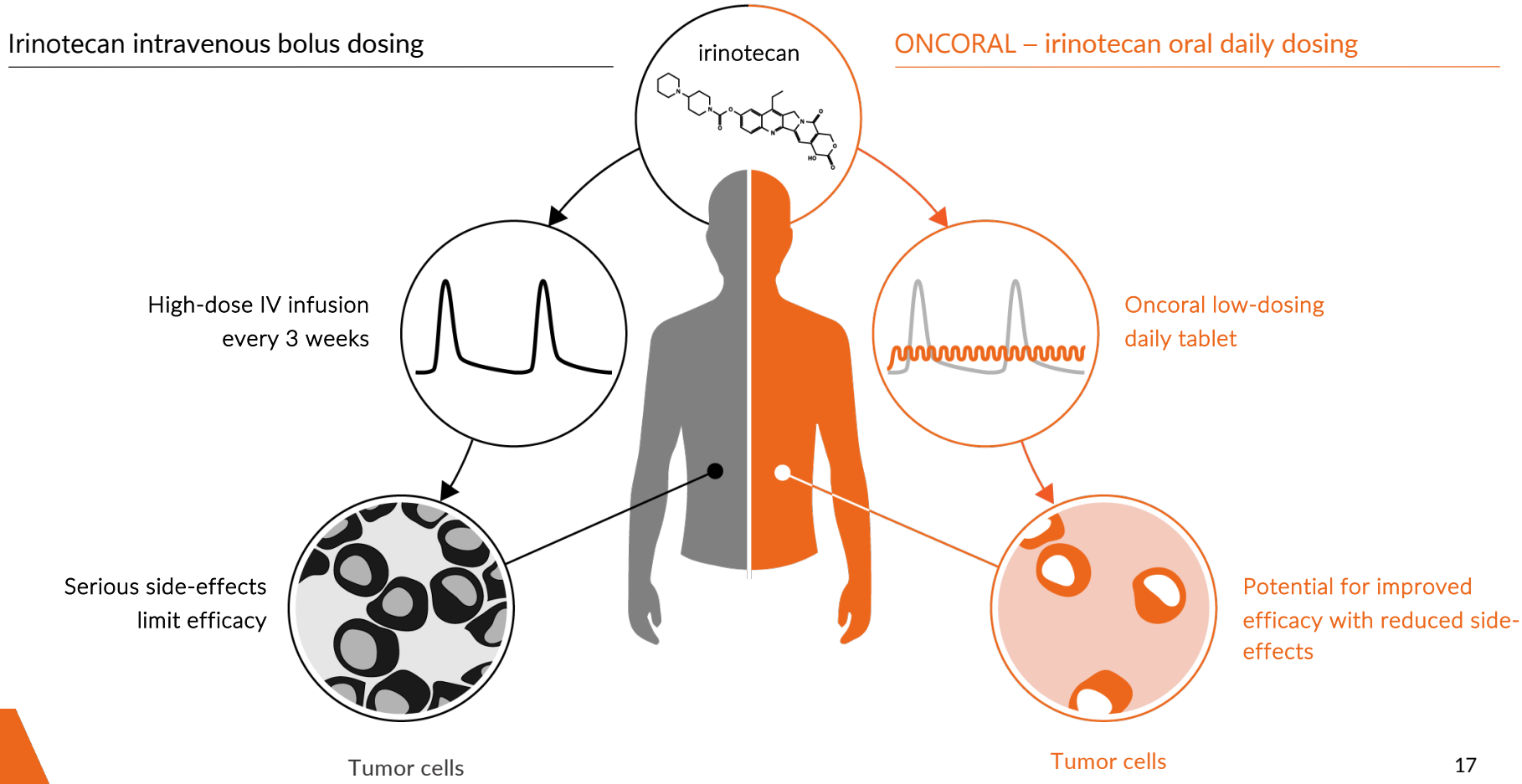
Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



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

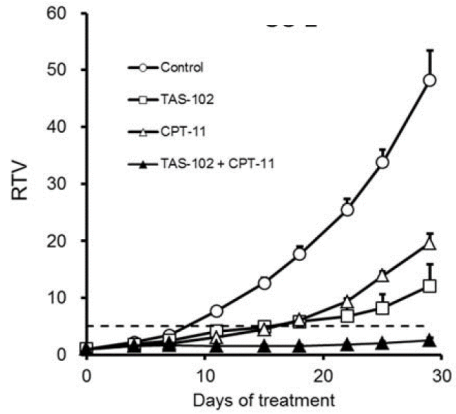


ONCORAL PHASE 2 IN GASTRIC CANCER

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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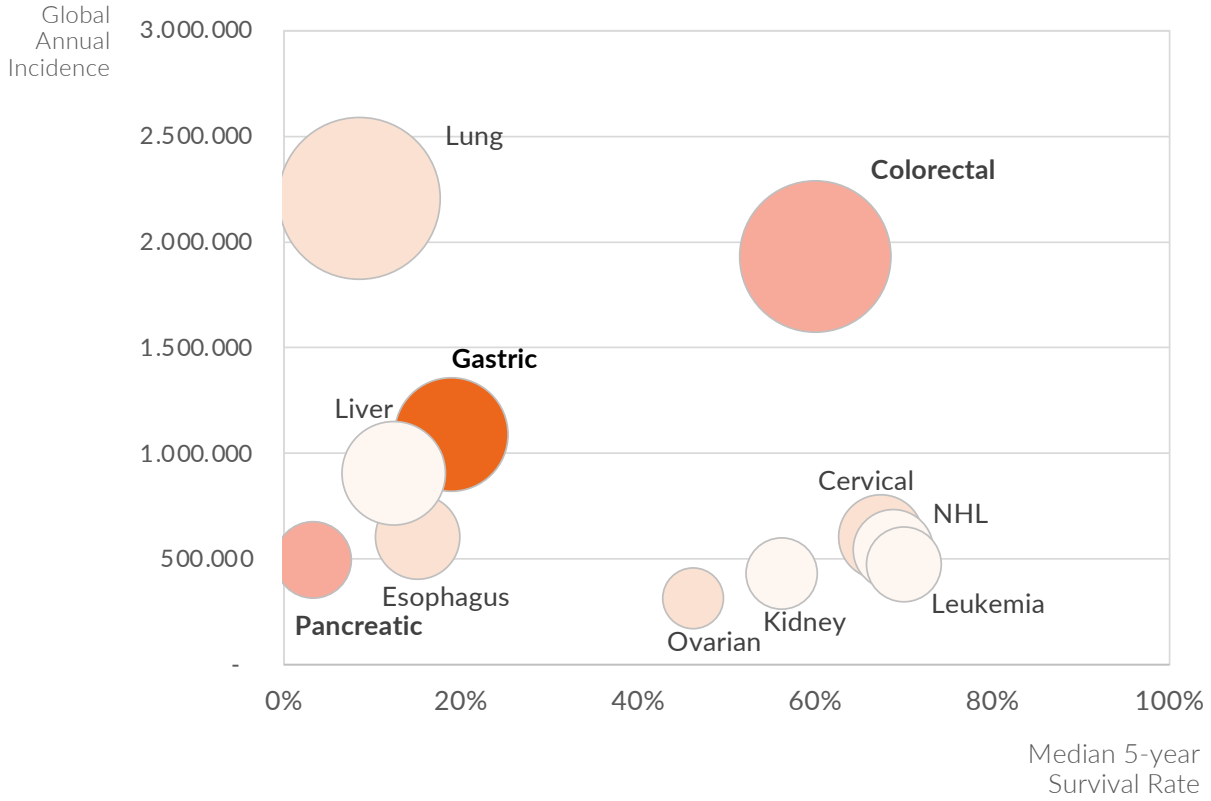
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

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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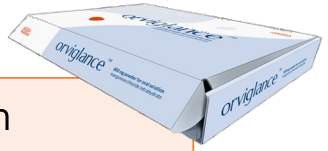
OUTLOOK

SUBSTANTIAL ORVIGLANCE VALUE CREATION OPPORTUNITIES



	Advance orphan diagnostic drug 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 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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