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INVESTOR UPDATE

Bringing Orviglance to market – next steps towards launch

Ascelia Pharma | Investor Update | 14 March 2023, 14:00h CET

ADVANCING ORPHAN ONCOLOGY

ADVANCING
ORPHAN
ONCOLOGY

MOMENTUM FOR GROWTH

Magnus Corfitzen | CEO

Ascelia Pharma | Investor Update | 14 March 2023, 14:00h CET

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BRINGING ORVIGLANCE TO MARKET – NEXT STEPS TOWARDS LAUNCH

- Momentum for growth
  Magnus Corfitzen, CEO
- Completing clinical development
  Jennie Wilborgsson, VP Clinical Development
  Andreas Norlin, CSO
- Attractive commercial opportunity
  Julie Brogren, Deputy CEO & CCO
- Q&A

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ASCELIA PHARMA – COMPANY HIGHLIGHTS

ADVANCING ORPHAN ONCOLOGY

- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
  - **ORVIGLANCE** – Phase 3 patient enrollment completed; FDA Orphan Drug Designation
  - **ONCORAL** – Ready for Phase 2

BUILDING GLOBAL CAPABILITIES

- Based in Malmö (Sweden), US affiliate in New Jersey (US)
- Solid balance sheet and financed into Q4 2023
- Listed on NASDAQ Stockholm (Ticker: ACE)

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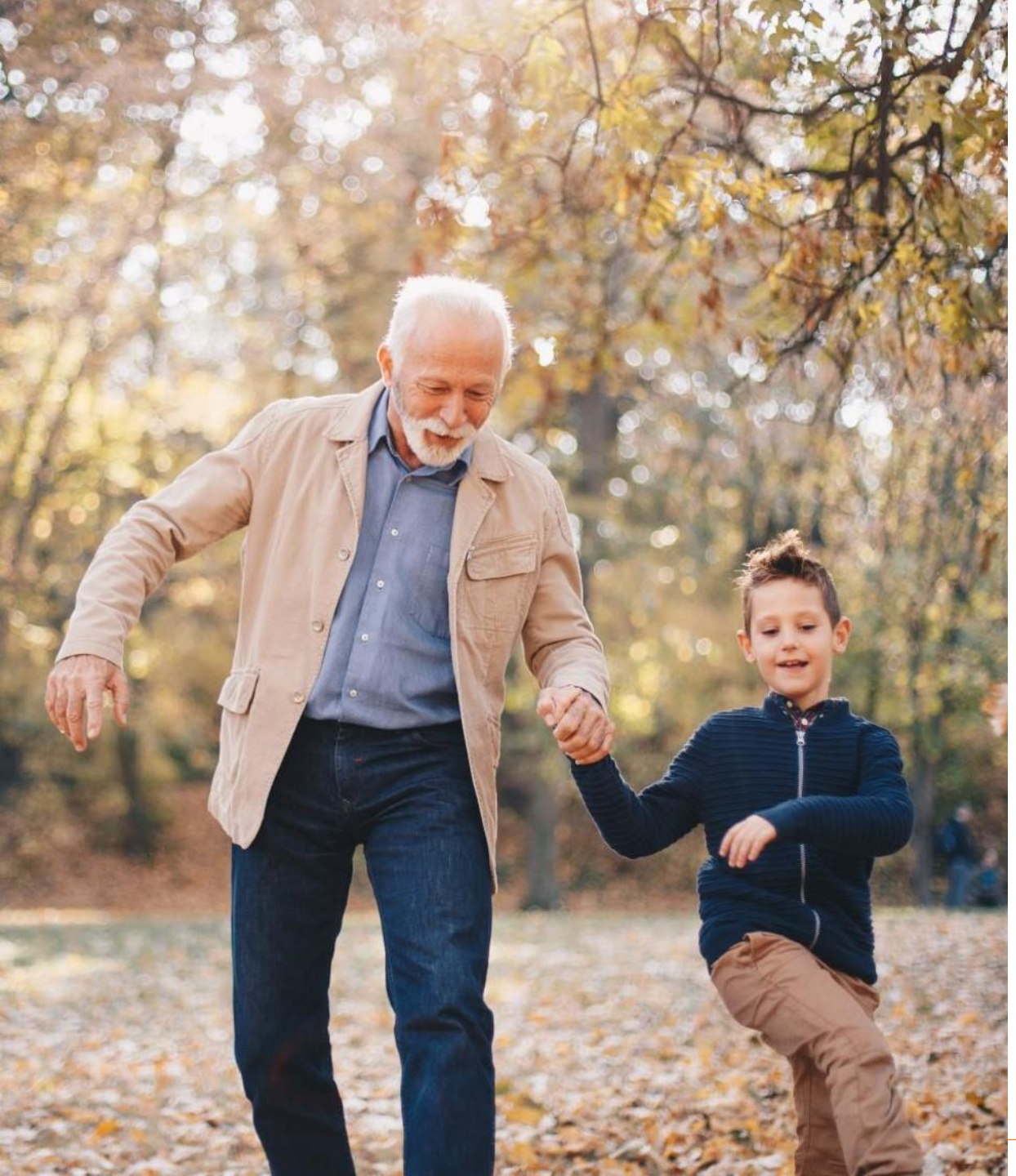

MAKING PROGRESS ON OUR MISSION

PRIORITIES 2023

- ✓ Orviglance Phase 3 patient enrollment - completed
- Generate SPARKLE headline results – mid 2023
- Prepare Orviglance launch – on track

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ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Liver metastases 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

Contrast enhanced MRI is gold standard

Contrast enhanced MRI

- Detection and visualization
- Surgery or drug treatment planning
- Post-treatment surveillance

A role for Orviglance in patients with kidney impairment

Healthy kidneys

MRI with gadolinium contrast agent

Severe kidney impairment

- All gadolinium contrast agents have regulatory Black Box warnings
- Risk of severe side effects, incl. Nephrogenic Systemic Fibrosis

Orviglance

Aims to be the liver imaging option without gadolinium-related safety risks for cancer patients with poor kidney function

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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ORVIGLANCE LEADS INNOVATION IN LIVER MRI

- Recent innovations within liver MRI have mostly been within technical/software – not imaging drugs or contrast agents

- Most recent FDA approval of a liver-specific gadolinium agent was in 2008

- Orviglance brings innovation to the MRI space:
  - ✓ First-in-class drug
  - ✓ Well-defined and vulnerable patient population
  - ✓ Proven business model

TIMING FOR ORVIGLANCE IS RIGHT

Historically, few have focused on the issues with gadolinium safety and environmental exposure

Recently, focus has increased on the issues surrounding gadolinium exposure and the need for safer alternatives

Sources include:
Brünjes R. et al. Anthropogenic gadolinium in freshwater and drinking water systems, Water Research, Volume 182, 2020.
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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REDEFINING LIVER MRI IN PATIENTS WITH SEVERE RENAL DISEASE

- Patients with severe renal disease lack access to safe and effective contrast enhanced liver MRI
- Orviglance can redefine liver MRI in these patients
- Orviglance aims to become the preferred option by providing high quality liver MRI without any of the risks associated with gadolinium exposure for the patient or the environment

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COMPLETING CLINICAL DEVELOPMENT

Jennie Wilborgsson | VP Clinical Development
Andreas Norlin | CSO

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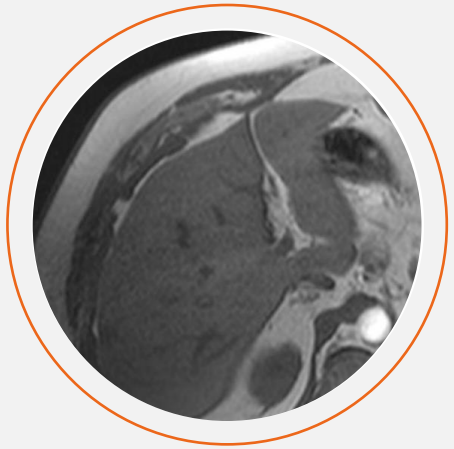
SPARKLE – PATIENT ENROLLMENT COMPLETED

The SPARKLE study is the last of 9 studies in the clinical development program for Orviglance



Designed to demonstrate that Orviglance improves the visualization of focal liver lesions in patients with severe renal disease or acute kidney injury and who have known or suspected focal liver lesions:

- Liver metastases
- Primary liver cancer
- Benign lesions

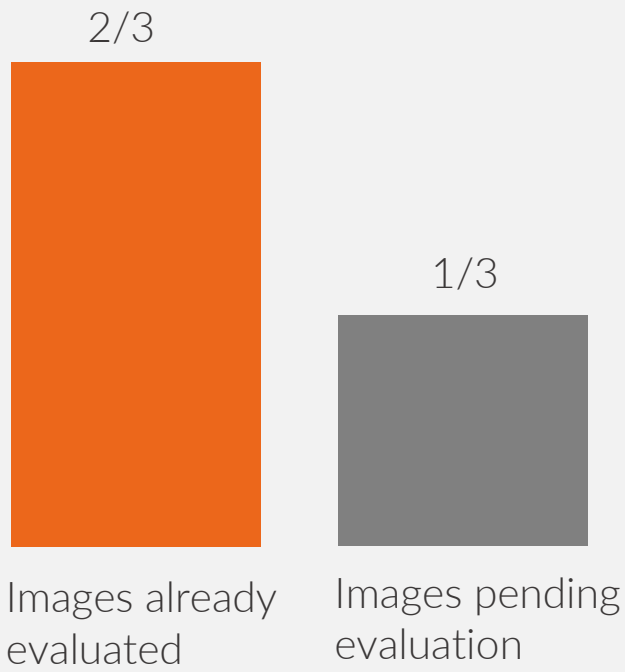
SPARKLE enrollment has been completed

- 85 patients were enrolled at 32 hospitals
- Enrollment speed in the final phase resembled the pre-study estimated enrollment speed of assumed 5-6 patients/site/year

NEXT STEPS TO OBTAIN HEADLINE RESULTS

Timeline for Headline Results

Status of MRI Image Evaluation by Independent Radiologists



* To enure integrety of the data reported, according to FDA guideline (FDA Guidance for Industry: Developing Medical Imaging Drug and Biological Products Part 3: Design, Analysis, and Interpretation of clinical studies) recall bias needs to be be mitigated by ensuring breaks for the radiologists between the evaluations

ORVIGLANCE CLINICAL ACTIVITIES BEYOND HEADLINE RESULTS

* Headline Results: Primary endpoint data and safety data
** Clinical Study Report: Primary endpoint data, secondary endpoint data and safety data

EXTENSIVE ORVIGLANCE CLINICAL PROGRAM

Phase 1 & 2

Six Studies Completed [1-6]

Evaluating safety and efficacy

Totally 127 subjects (2 placebo) healthy volunteers and patients

Evaluation Before Phase 3

Re-read of efficacy across all studies

Enriched with 68 patients from a compassionate use program

New Evaluation (P004A): Orviglance vs. Gadolinium and Unenhanced

Re-read of 20 patients with liver metastases, by 3 blinded, independent readers

Phase 3 Program

Food Effect Study

Effect of food intake on absorption and signal intensity (39 subjects)

Hepatic Impairment Study

Effect of liver impairment on the safety, pharmacokinetics (35 subjects)

SPARKLE - Phase 3 Pivotal Study

Evaluates the safety and efficacy in target patient population (85 patients)

Consistent positive efficacy and safety in completed studies[7]
Total Program of 286 patients and healthy volunteers

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

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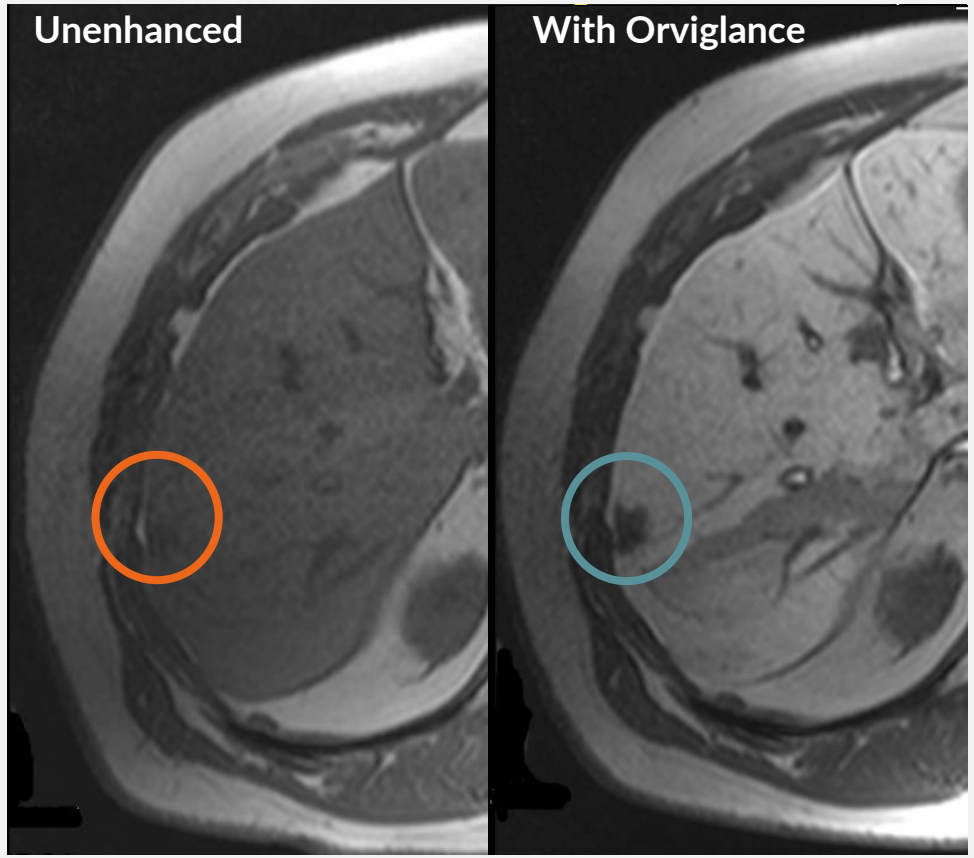
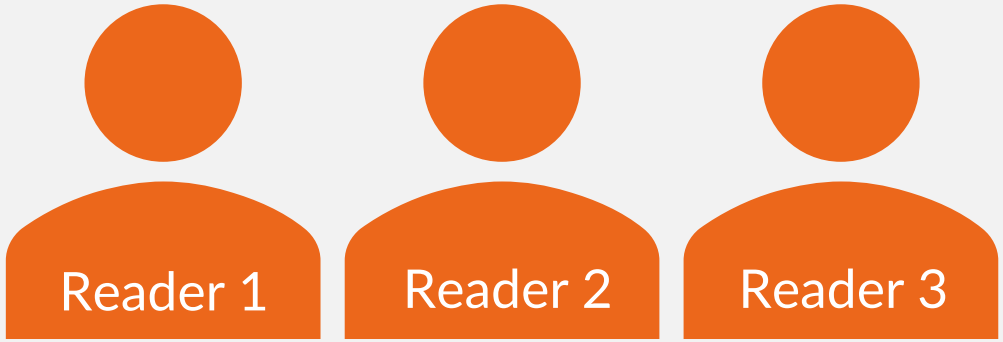
SPARKLE SUCCESS DETERMINED BY LESION VISUALIZATION



Criteria for statistical test of primary endpoint



Primary endpoint is met if 2 out of 3 independent radiologists rate both Border Delineation and Lesion Contrast (Conspicuity) for Orviglance MRI higher than unenhanced MRI with statistical significance

Images from Study CMC-P002, patient with colon cancer and liver metastasis.

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ASCELIA EXPERIENCE WITH EVALUATION METHODOLOGY

	Number of Patients	Liver Lesion Types*	Number of Radiologist Readers	Primary Endpoint	Orviglance Superior to Unenhanced	Statistical Significance
P004A Re-read	20	Metastases	3	Co-primary: Border delineation, Lesion contrast	Yes	(P=0.009)
SPARKLE	85	Known or suspected lesion (metastases, primary tumors, benign lesions)	3	Co-primary: Border delineation, Lesion contrast	?	?

* Apart from the difference in population heterogeneity, other differences between P004A Re-read and SPARKLE includes e.g., dose and MR hardware/software technology

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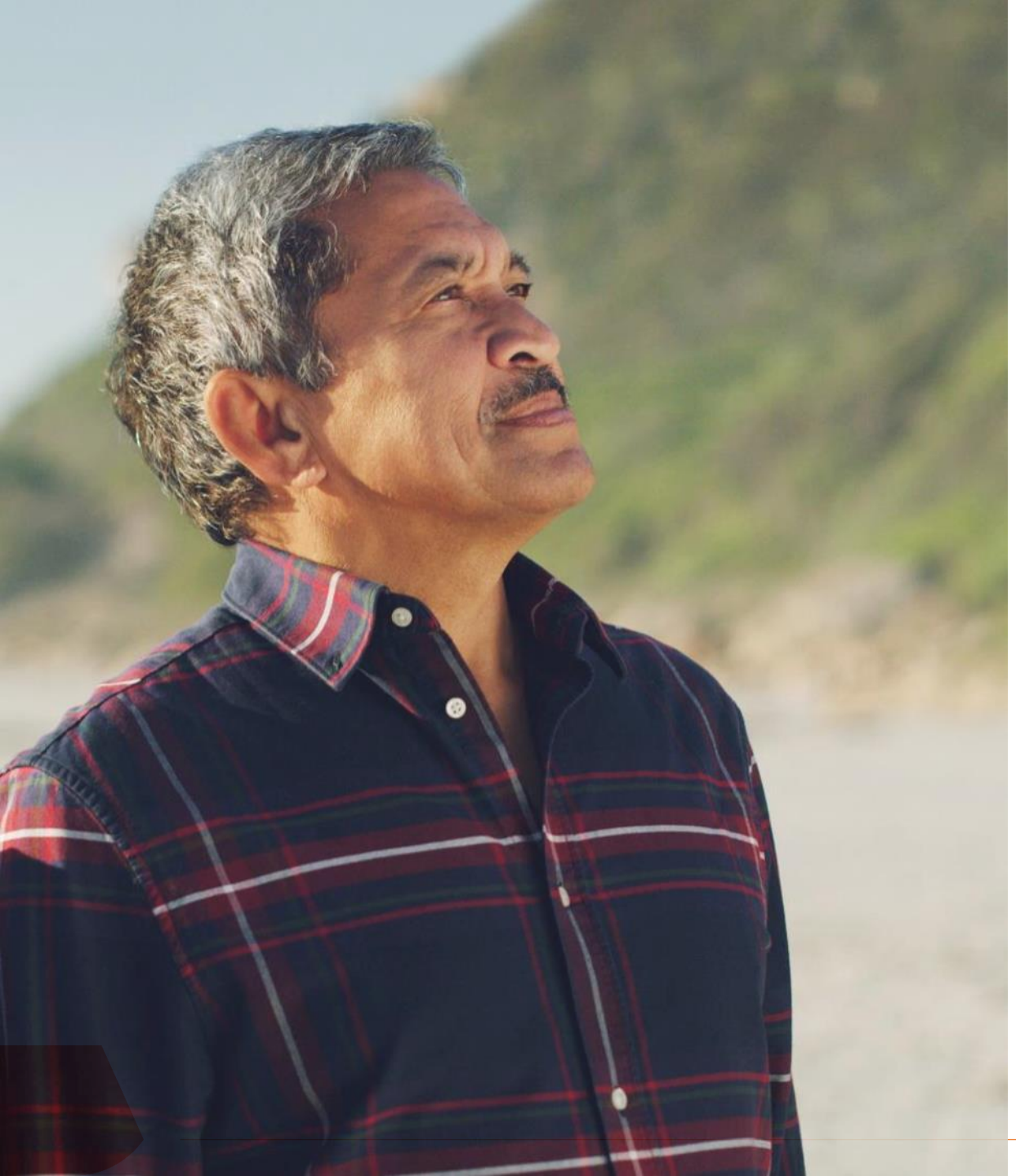

CLINICAL DEVELOPMENT NEAR COMPLETION

- Strong and encouraging data package from phase 1 and 2 studies
- Orviglance Phase 3 patient enrollment - completed
- SPARKLE headline results – mid 2023

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ATTRACTIVE COMMERCIAL OPPORTUNITY

Julie Waras Brogren | Deputy CEO & CCO

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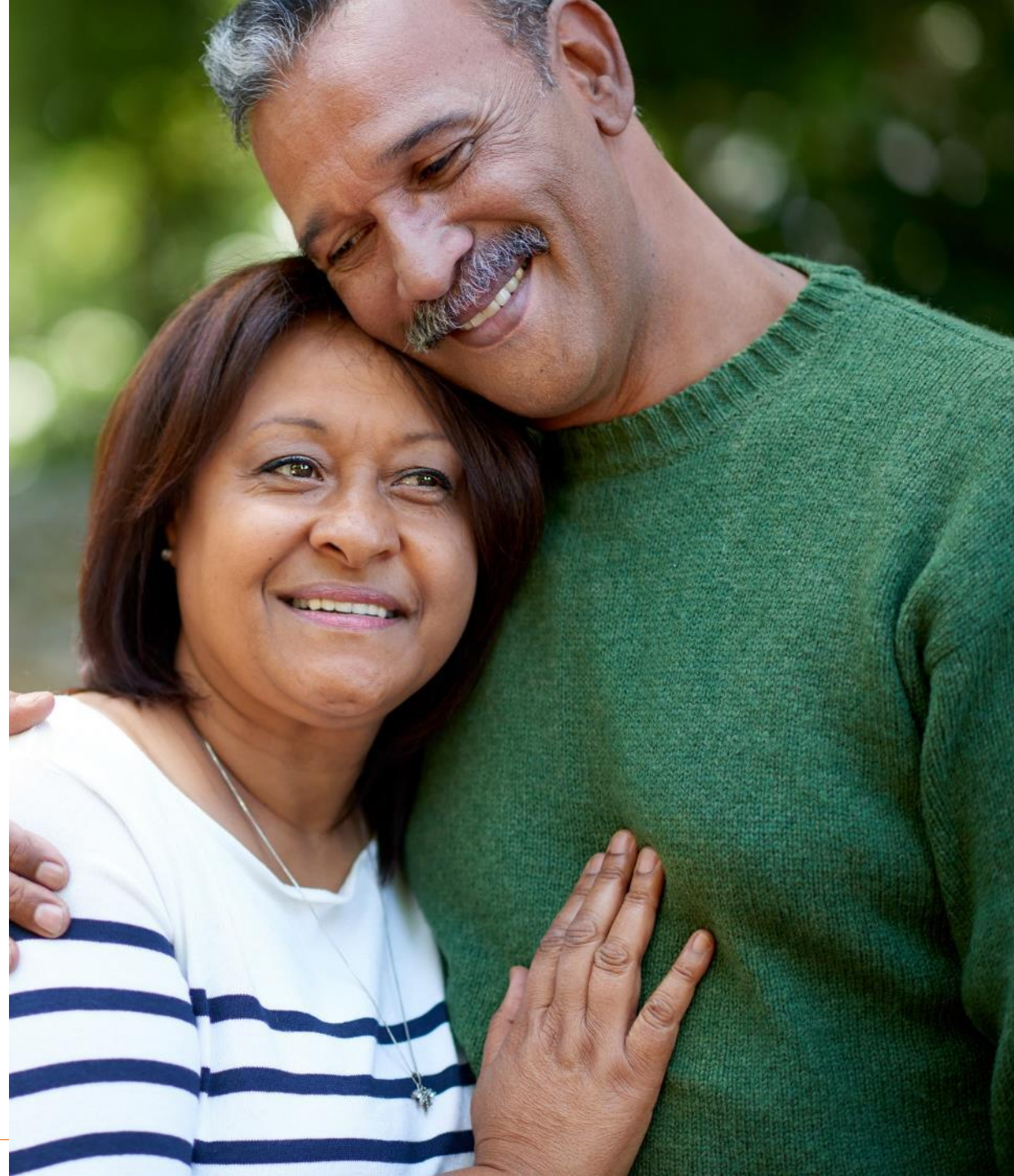
ATTRACTIVE COMMERCIAL OPPORTUNITY FOR ORVIGLANCE

- A global addressable market opportunity of USD 800 million
- Addressing a well defined patient population with 100,000 procedures annually in the US
- Focused preparations for a successful launch progress as planned



ORVIGLANCE – WELL DEFINED, ATTRACTIVE OPPORTUNITY

orviglance®
800 mg powder for oral solution
manganese chloride tetrahydrate

Unique opportunity

Clear unmet need for well-defined patient population

Orphan drug designation

A strong value proposition for regulators, payers, physicians and patients

Attractive market

Liver imaging for cancer patients with poor kidney function

- not associated with gadolinium safety risks for patients with poor kidney function
- addressing the increasing demand for alternatives to toxic gadolinium

Clear ambition

Become standard of care liver imaging choice for target patient population

Focused, ambitious launch

Ensure optimal label and timely supply and operations readiness

Drive early adoption & preference by payers and decision makers with focused efforts and a strong value proposition

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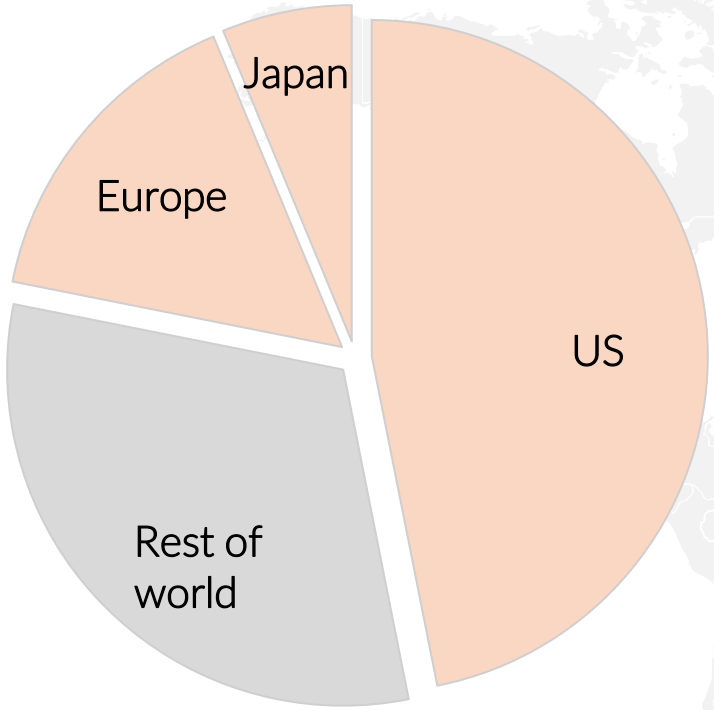
ATTRACTIVE ADDRESSABLE MARKET



Global addressable market of USD 800 million (US, Europe and Japan USD 500-600 million)

Well defined unmet need for liver imaging in cancer patients with severe kidney impairment

Attractive pricing and access opportunity based on recognized value proposition[1]

Underlying growth driven by prevalence and cancer survival as well as access and quality of care in rest of world markets[2]

Sources:
Ascelia Pharma market research 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
2) In rest of world markets addressable market patient population incorporates restricted access to care, with market-based assumptions ranging from 10% upwards

ATTRACTIVE US OPPORTUNITY

Abdominal imaging procedures in cancer patients with severe kidney impairment (CKD 4/5/AKI)
based on epidemiology and real-world data[1]

~100,000 procedures annually

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

$3,000-4,500

Volume growth driven by demographics as well as prevalence and long-term care in cancers and kidney disease

4-5% vol. annually

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

ATTRACTIVE COMMERCIAL OPPORTUNITY FOR ORVIGLANCE

- A global addressable market opportunity of USD 800 million
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- Focused preparations for a successful launch progress as planned

WELL DEFINED PATIENT POPULATION

~1,000,000

cancer patients referred to abdominal imaging

Liver cancer or liver metastases is common in many cancer types and often the cause of mortality

~2,200,000

abdominal imaging procedures (2.2 per patient/year)

Contrast-enhanced imaging is standard of care for detecting and visualizing metastases

~100,000

severe renal impairment (4.2% of procedures)

Severe kidney impairment patients risk severe adverse events from gadolinium-based contrast agents

Sources: Ascelia Pharma analysis based on DRG Clarivate analysis with 2019 US claims. Ascelia Pharma market research with 270 HCPs (radiologists, oncologists and nephrologists) by Two Labs Pharma Services Dec 2021-Jan 2022. The Global Cancer Observatory, 2020 (https://gco.iarc.fr). B. Stengel. (2010). Chronic kidney disease and cancer: a troubling connection. J Nephrol. 2010; 23(3): 253–262. Ann Surg Oncol (2013) 20:3885–3891, Risk of Colorectal Cancer in Chronic Kidney Disease., Wu et al. N. Hill et al. (2016). Global Prevalence of Chronic Kidney Disease – A Systematic Review and Meta-Analysis
Comment: CT iodinated contrast carry similar risk for 4/5/AKI patients. Unenhanced/partial dose MRI is preferred vs. unenhanced CT

MULTIPLE IMAGING NEEDS FOR TARGET PATIENTS

Detect suspected liver metastases or liver cancer

Liver metastases common in many cancer types[1-3]

Plan surgery

Locate lesions

Visualize lesions

Therapeutic intervention

Investigational

Approved

Post treatment monitoring

Effect of treatment

New lesions

TYPICAL ORVIGLANCE PATIENT

A 68-year-old male with colorectal cancer has a ~70% risk of developing liver metastases

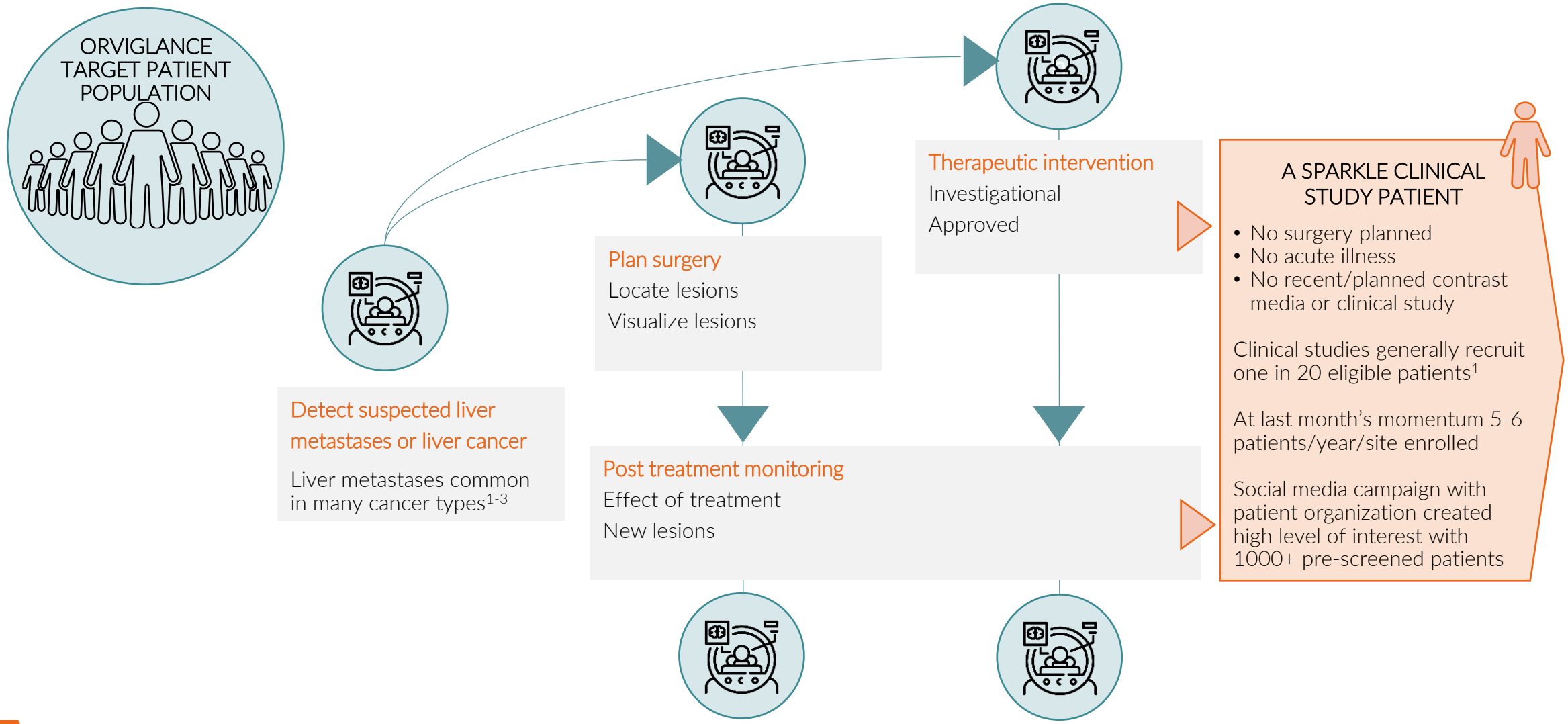
Real-world-liver imaging in cancer patients:

~50%+ male
~60%+ of patients above 65
~60%+ outpatient imaging
~15% of US adults have kidney disease; some severe

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

SPARKLE CLINICAL STUDY

SPARKLE CLINICAL STUDY PATIENTS



1) LaHucik. 'Even as pandemic recedes, short-staffed trial sites leave cancer patients waiting' EndpointsNews. Sept. 27, 2022

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CLEAR UNMET NEED

THE RISKS ASSOCIATED WITH GBCA

In patients with poor kidney function, all GBCAs have regulatory black box warning, as they put patients have the highest risk of the severe and sometimes fatal side-effects, nephrogenic systemic fibrosis

+90%

of HCPs are concerned by issues relating to GBCAs (including NSF)

+16%

of providers have experienced GBCA-induced NSF

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

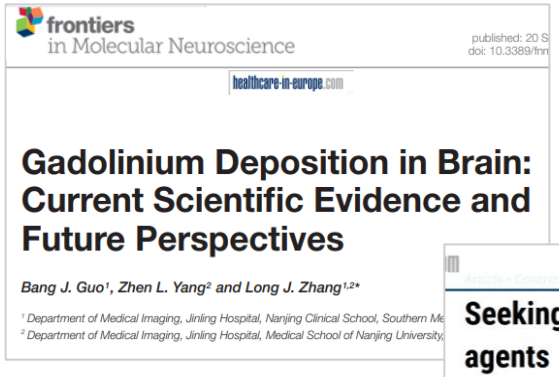
MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

NSF risk

with warnings for target population

Black-box warnings and GBCA label changes from 2007 onwards in major markets

Clinical practice preference for unenhanced or partial dose GBCA for at risk patients[1]


frontiers in Molecular Neuroscience

published: 20 S
doi: 10.3389/fnn

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]

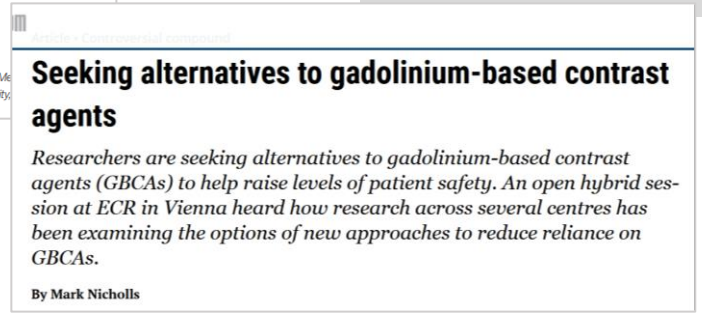
[1] Department of Medical Imaging, Jinling Hospital, Nanjing Clinical School, Southern Me
[2] Department of Medical Imaging, Jinling Hospital, Medical School of Nanjing University,

Unknown safety impact

of deposition in the brain and tissue

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

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


Seeking alternatives to gadolinium-based contrast agents

Researchers are seeking alternatives to gadolinium-based contrast agents (GBCAs) to help raise levels of patient safety. An open hybrid session at ECR in Vienna heard how research across several centres has been examining the options of new approaches to reduce reliance on GBCAs.

By Mark Nicholls

Environmental scrutiny

increasing

Gadolinium used in MRI is excreted in urine. It is difficult to remove in our sewage systems and discharged into the environment and drinking water

"The increasing use of gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging is leading to widespread contamination of freshwater and drinking water systems"[2]

1)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

2) Brünjes R. et al. Anthropogenic gadolinium in freshwater and drinking water systems, Water Research, Volume 182, 2020.
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Bang G. Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives. Mol. Neurosci., 20 September 2018.

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INDUSTRY INNOVATION CENTERED AROUND ALTERNATIVES

A future with alternatives to gadolinium

Trends among leading gadolinium manufactures

Half dose full-body gadolinium contrast agent FDA approved in priority review (gadopiclenol, Guerbet/Bracco 2022)

Completion of Phase 1 of full-body low dose gadolinium (gadoquatrane, Bayer 2022)

Completion of Phase 1 patient enrollment in full-body IV manganese-based contrast agent (GE HealthCare 2023)

Source: Company websites

VALUE RECOGNIZED BY STAKEHOLDERS

Well-defined
target patient population

No MRI contrast agent advised
for patients with severe renal impairment or acute kidney failure[1]

+33%
more lesions

Improved visualization
of focal liver lesions (incl. metastases) compared to unenhanced MRI[2]

84%
clinicians

Are likely to or definitely will use
Orviglance at launch for the target patient population[3]

1) Based on ACR clinical guidelines and regulatory drug class warning for gadolinium-based contract agents in patients with severe renal impairment (an eGFR <30 ml/min/1.73 m^2) or acute kidney failure.
2) Outcomes from re-read of Phase 1 and 2 studies
3) 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?

ATTRACTIVE COMMERCIAL OPPORTUNITY FOR ORVIGLANCE

- A global addressable market opportunity of USD 800 million
- Addressing a well defined patient population with 100,000 procedures annually in the US
- Focused preparations for a successful launch progress as planned

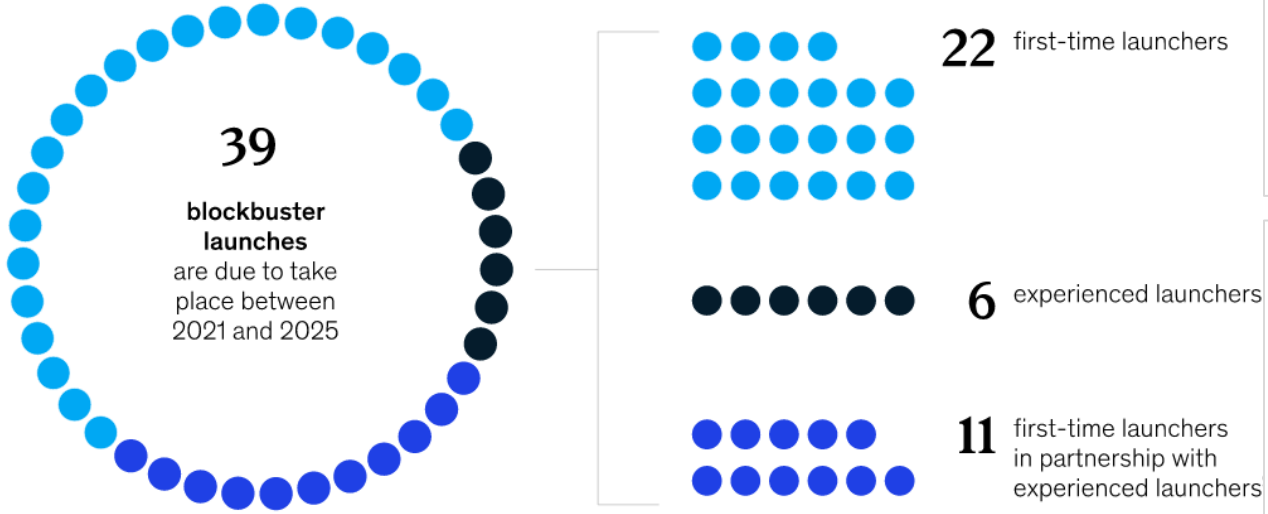
MARKET SPECIFIC VALUE DRIVEN COMMERCIALIZATION

Go-to-market model		Value drivers
	Ascelia Pharma led commercialization	• Retain **topline** • Build **strategic capabilities** • Optimize selected outsourcing **operations** • **Milestone** based investment approach
Rest of World	Ascelia Pharma strategy with global synergies → Partner led commercial operations	• **Low Ascelia investment** for launch • Leverage **established** commercial capabilities • Use global internal **strategic competencies**

EMERGING PHARMA – WHY AND HOW THEY SUCCEED

More than half of the 39 'blockbuster' launches in the next five years will come from first-time launchers.

Projected blockbuster launches,[1] number



Why launchers go alone

- Narrow indications
- KOL and Payer driven adoption (vs. salesforce size)
- Leverage the value of small and control
- Vendors and selected outsourcing available

How successful emerging pharma succeed

- Ensure market insights and relationships
- Invest in targeted pre-launch
- Build the core team early with emphasis on strategic competencies
- Track, learn and adjust

Source: First-time launchers in the pharmaceutical industry, Feb 2021, McKinsey & Company

CAPTURING US MARKET VALUE

~2,000

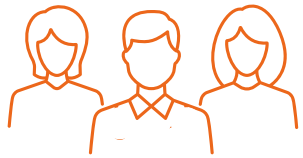
RADIOLOGISTS

Perform regular liver MRIs in kidney impaired patients[1]

~400

CLINIC ACCOUNTS

Serve ~75% of kidney impaired patients[1]



FOCUSED

FIELD TEAM

Reach priority decision makers for access and adoption

US LAUNCH DESIGN

Step-wise build-up with ~40 FTEs expected at launch with selected outsourcing operations

Manufacturing partner, Cambrex, in New Jersey

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

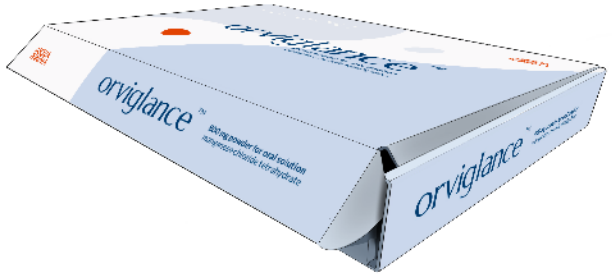
SUPPLY CHAIN PREPARATIONS ON TRACK

SUPPLY CHAIN

Ensuring quality with optimal ramp-up and seamless customer decisions

Manufacturing Partner,
Cambrex, New Jersey (US)

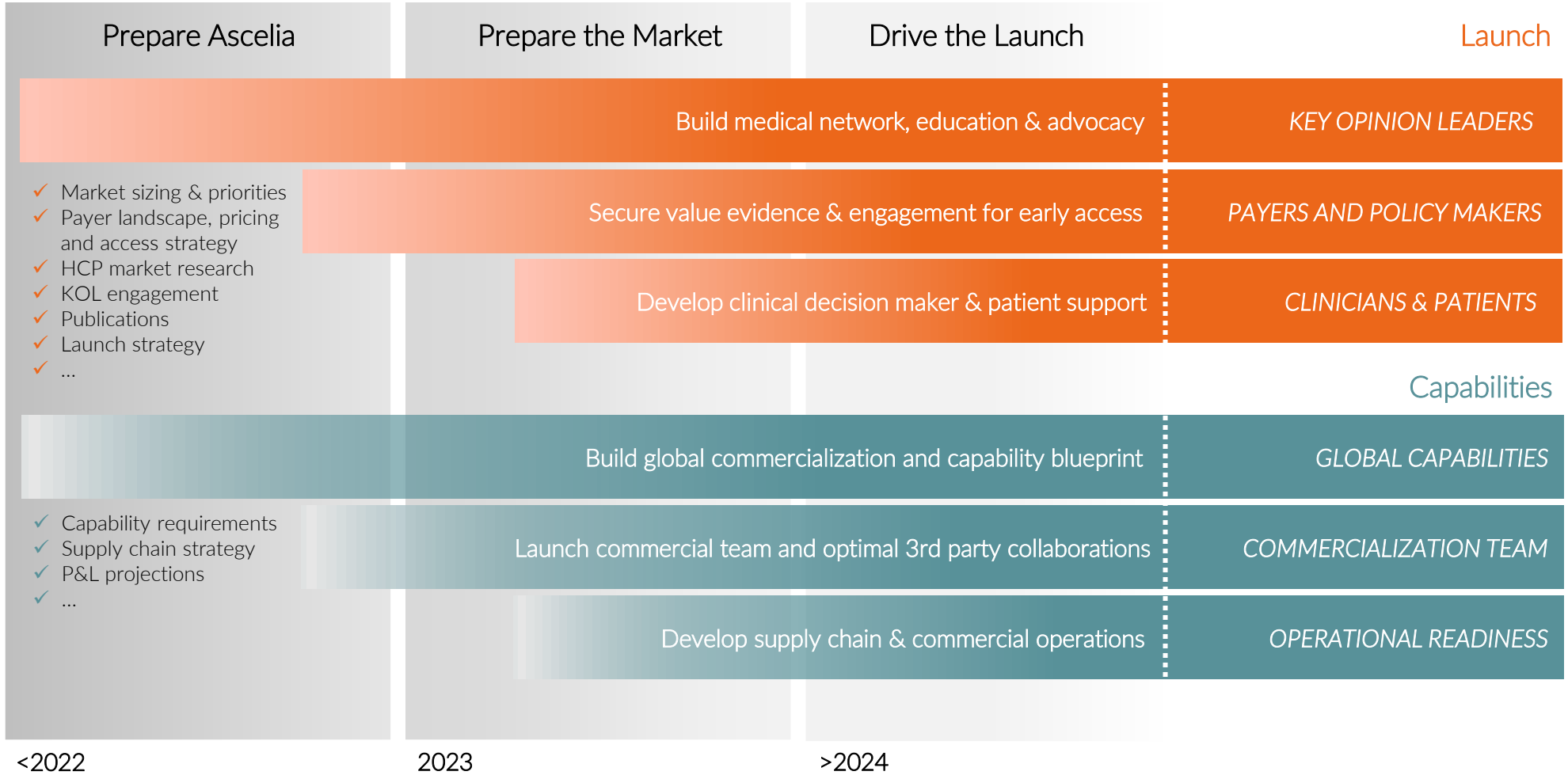
- ✓ Supply chain strategy
- ✓ Scale up & validation on track
- ✓ Capacity for global supply



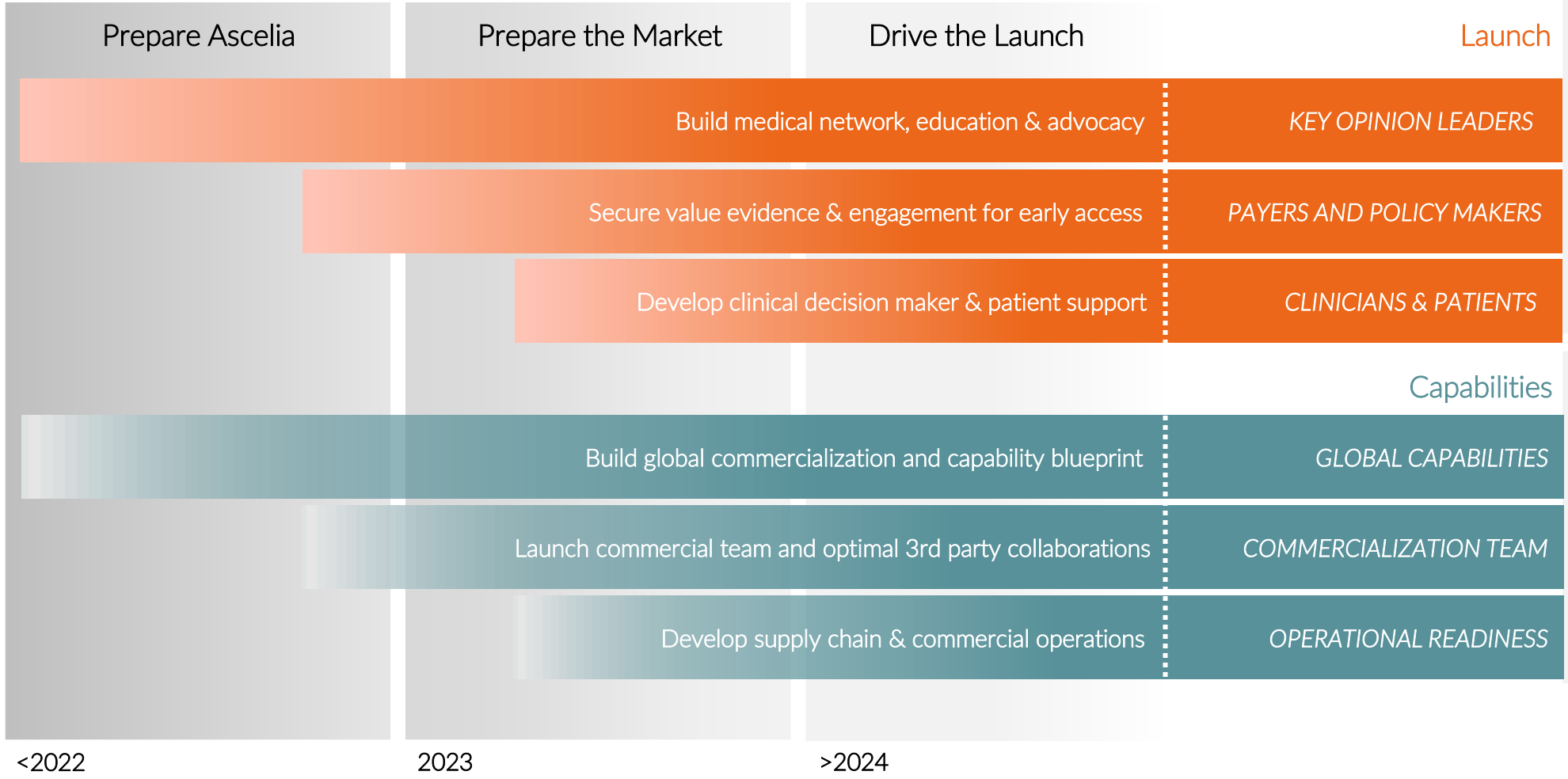
Specialty distribution partners

- ✓ Distribution for seamless procurement

ORVIGLANCE LAUNCH: GRADUAL, FOCUSED, AMBITIOUS



ORVIGLANCE LAUNCH: OPTIMAL MIX OF CAPABILITIES



Key Success Factors

Focus and quality leveraging leadership experience from **20+ global/US launches**

Key Success Factors

Succeed through **strategic leadership** and **operational optimization** through selected outsourcing collaborations

Reimagine imaging for people with poor kidney function.

IN THE MEDIA

ASCELIA PHARMA

WORDS FROM THE FIELD

""The college [American Colleague of Radiology] is beginning to get a bit nervous… and they 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

"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

"..we strictly followed the imaging guidelines, images are fantastic"
- SPARKLE Investigator

American Kidney Fund®
FIGHTING ON ALL FRONTS

COLLABORATIONS

orviglance®
800 mg powder for oral solution
manganese chloride tetrahydrate

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