ADVANCING
ORPHAN
ONCOLOGY

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ASCELIA PHARMA

INVESTOR PRESENTATION

April 2023

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ASCELIA PHARMA – 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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ORVIGLANCE

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

PORTFOLIO

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

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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 9 studies in 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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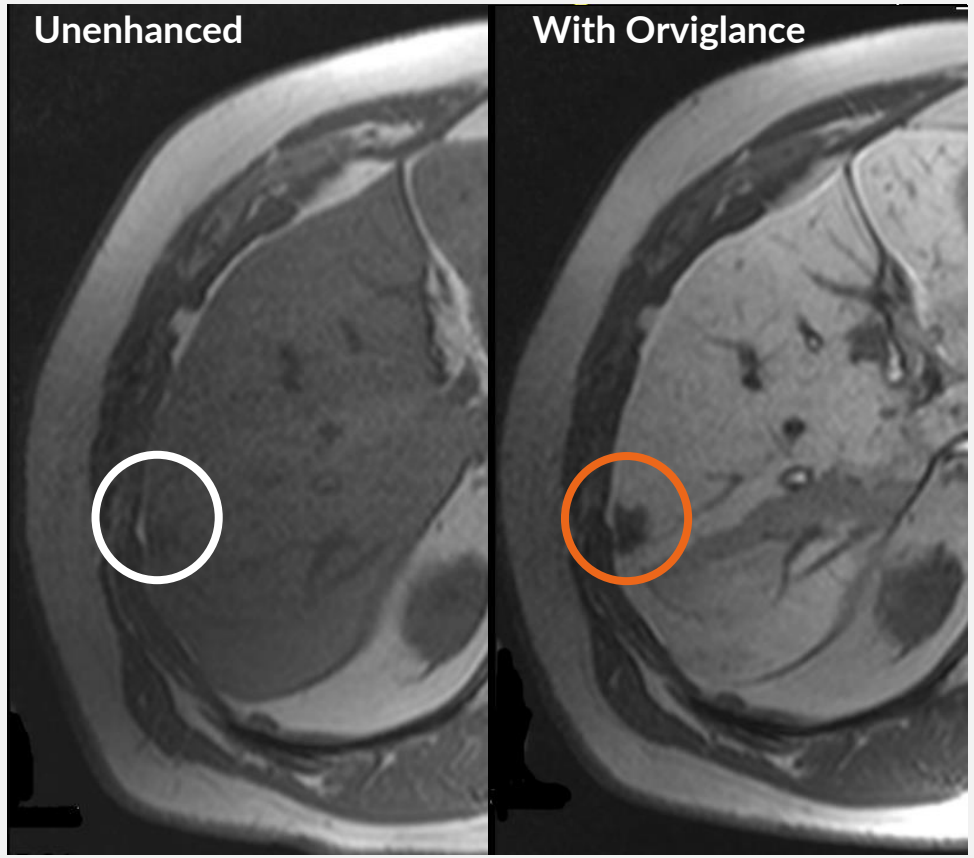
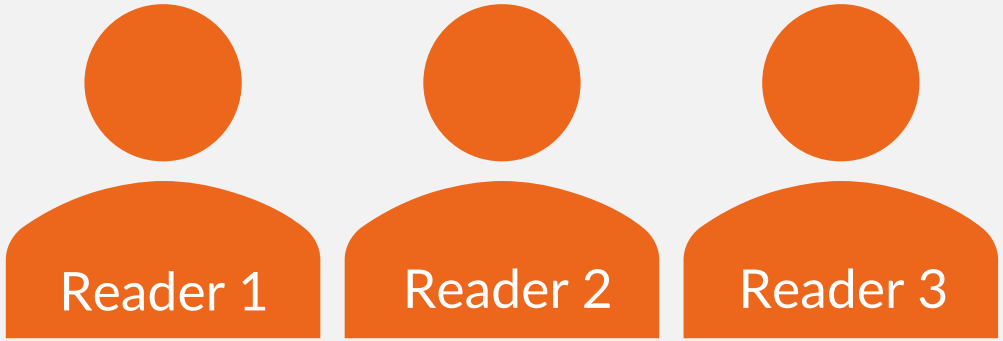
SPARKLE SUCCESS DETERMINED BY LESION VISUALIZATION



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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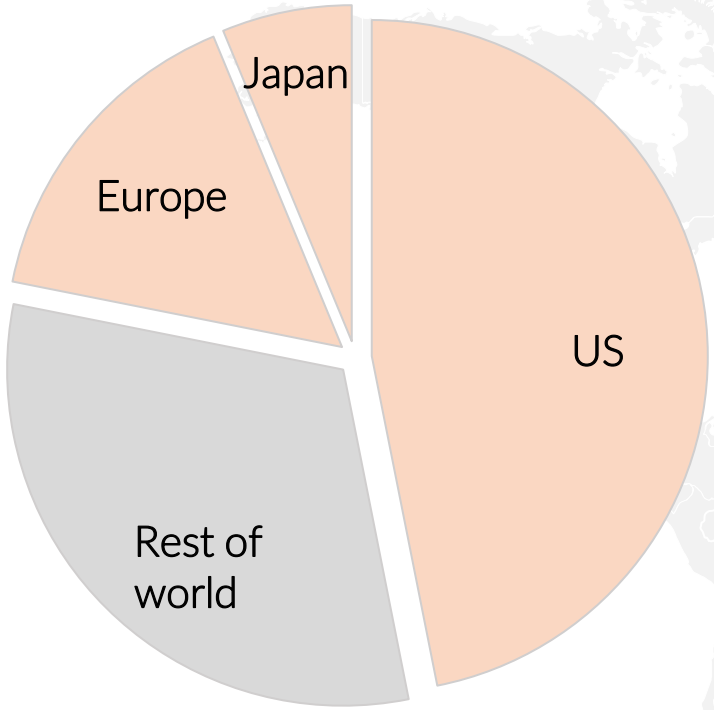
ATTRACTIVE ADDRESSABLE MARKET



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

CLEAR UNMET NEED

NSF risk
with warnings for target population

In patients with poor kidney function, all GBCAs have regulatory black box warning, as these patients have the highest risk of the severe and sometimes fatal side-effect, 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

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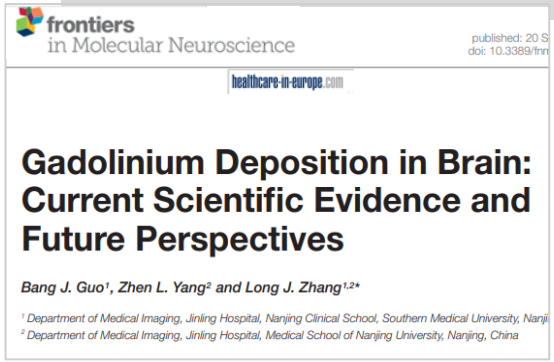
MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

Unknown safety impact

of deposition in the brain and organs

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)


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 Medical University, Nanji
[2] Department of Medical Imaging, Jinling Hospital, Medical School of Nanjing University, Nanjing, China

Environmental scrutiny

over gadolinium in sewage and drinking water

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"[1]

A future with alternatives

focus of 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)

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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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**

CAPTURING US MARKET VALUE

~2,000

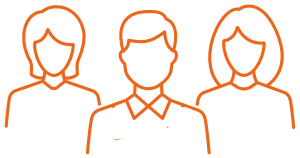
RADIOLOGISTS

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

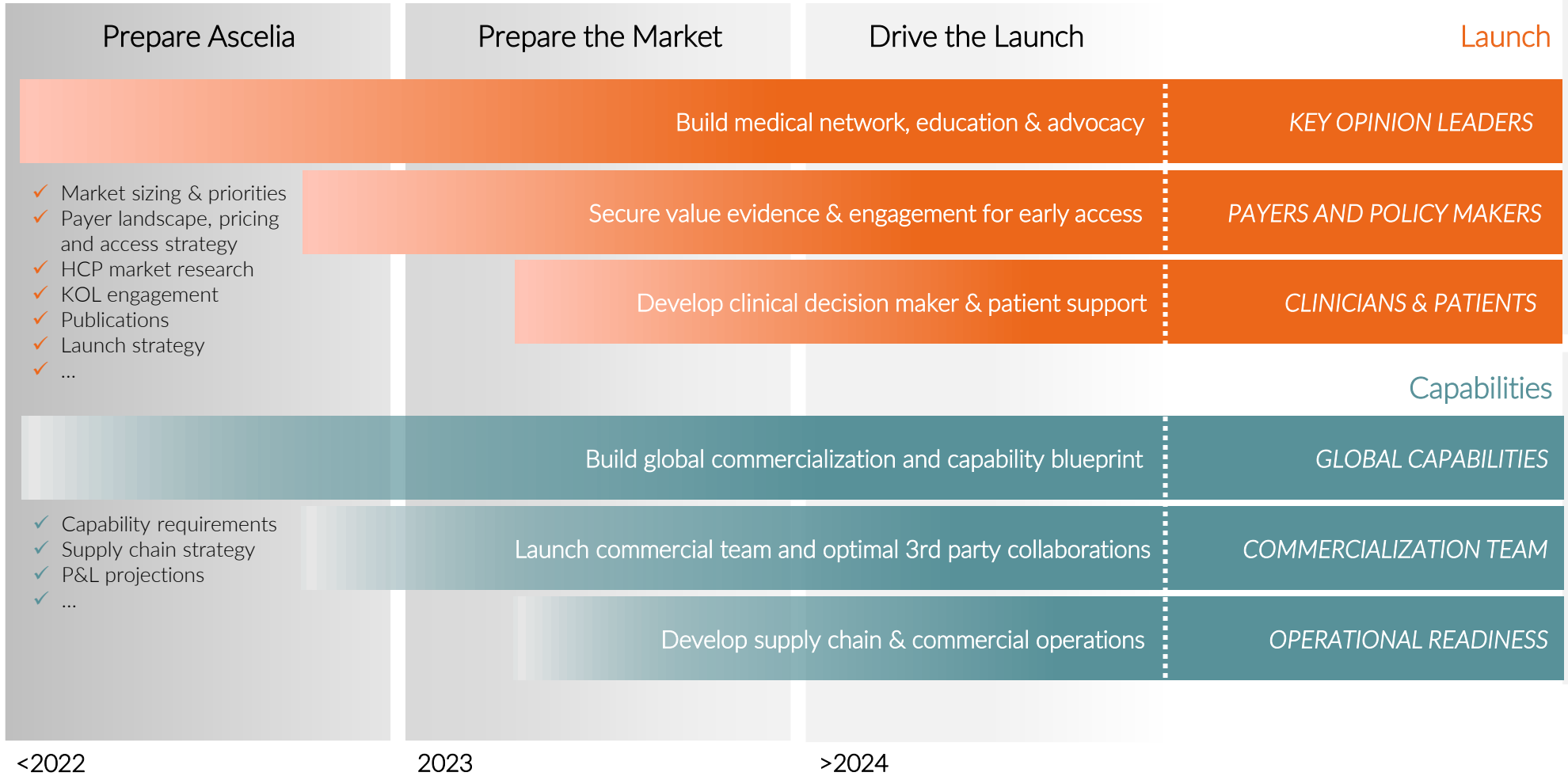
US LAUNCH DESIGN

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

ORVIGLANCE LAUNCH: GRADUAL, FOCUSED, AMBITIOUS



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

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]

"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

+33%
more lesions

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

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

84%
clinicians

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

"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; Head of Radiology at US hospital

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?
Quotes come from general observations and experience with Orviglance and the medical unmet need from dialogue with investigators and KOLs, i.e. they not specifically a comment to the data point mentioned on the slide

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ORVIGLANCE

Liver diagnostic drug in ongoing Phase 3

ONCORAL

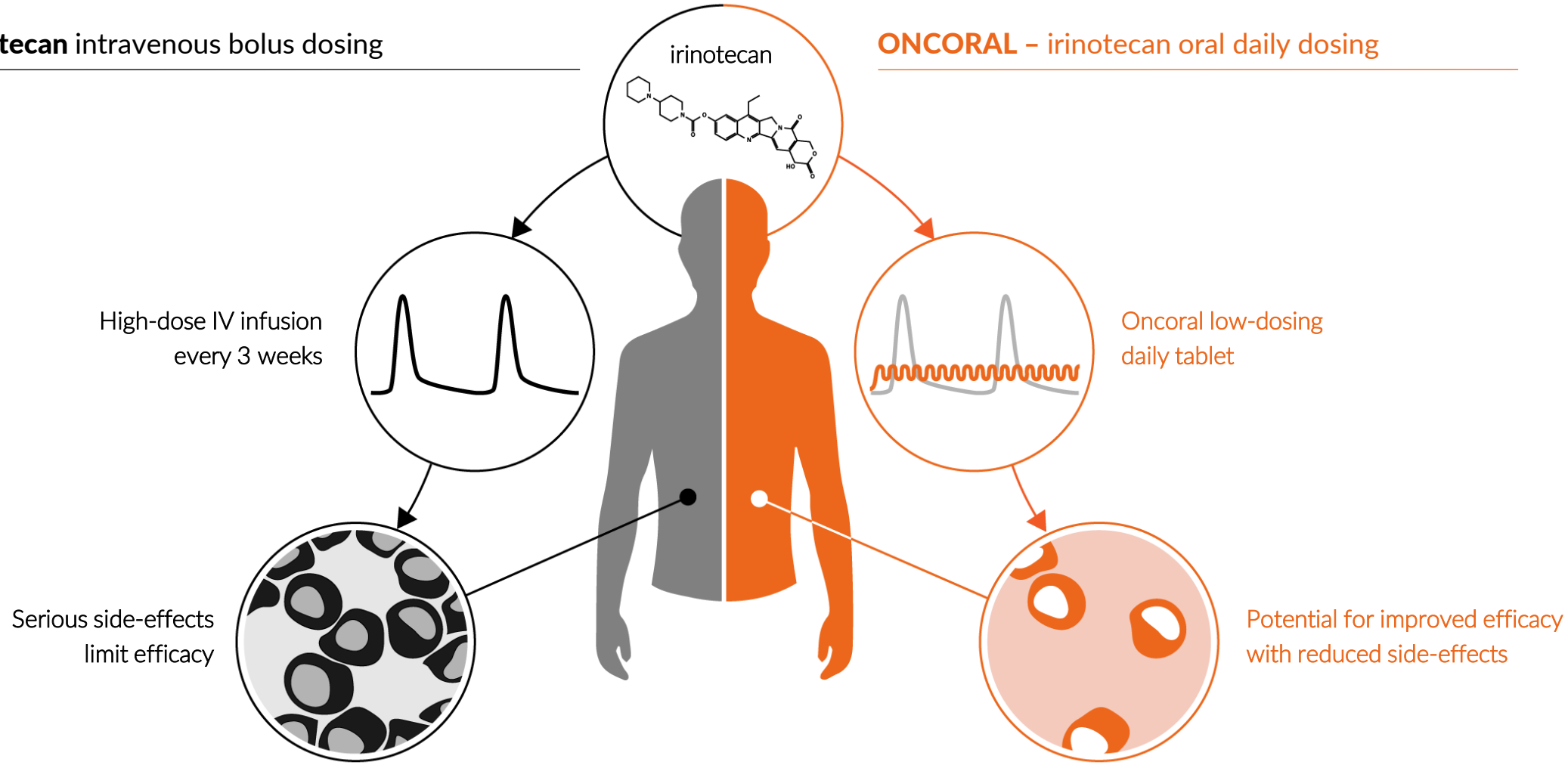
Daily oral chemotherapy ready for Phase 2

PORTFOLIO

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

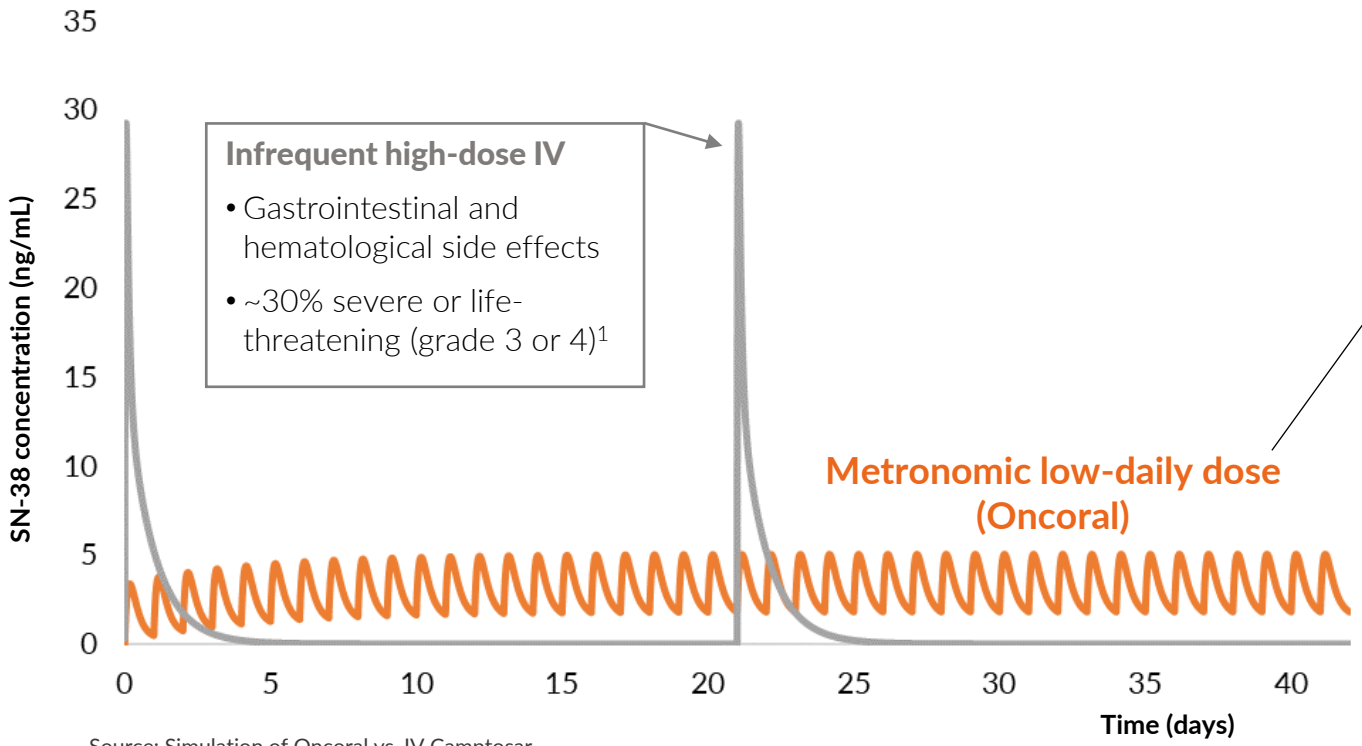
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar

Frequent (metronomic) low-dose irinotecan

- Several studies show improved tolerability[2,3]
- Daily dosing – adjust quickly if acute toxicity

Oncoral Phase 1 results

- Well tolerated, no unexpected side-effects
- Hematological toxicities mild-moderate (grade 1 or 2)[4]
- Efficacy: Stable disease even in patients previously treated with IV irinotecan

1) Camptosar prescribing information 2) Furman et al 1999 3) Perez et al 2004 4) Kumler et al 2018

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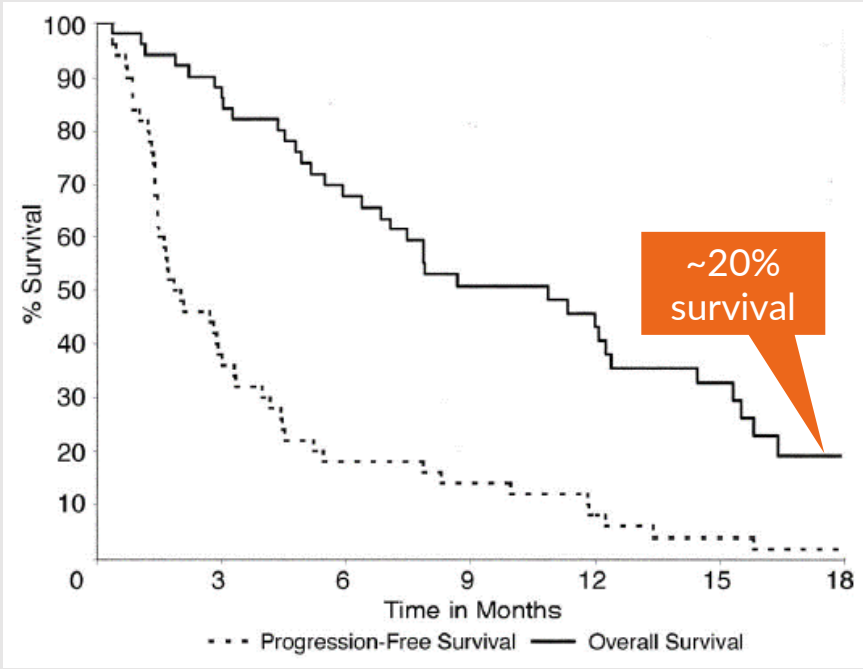
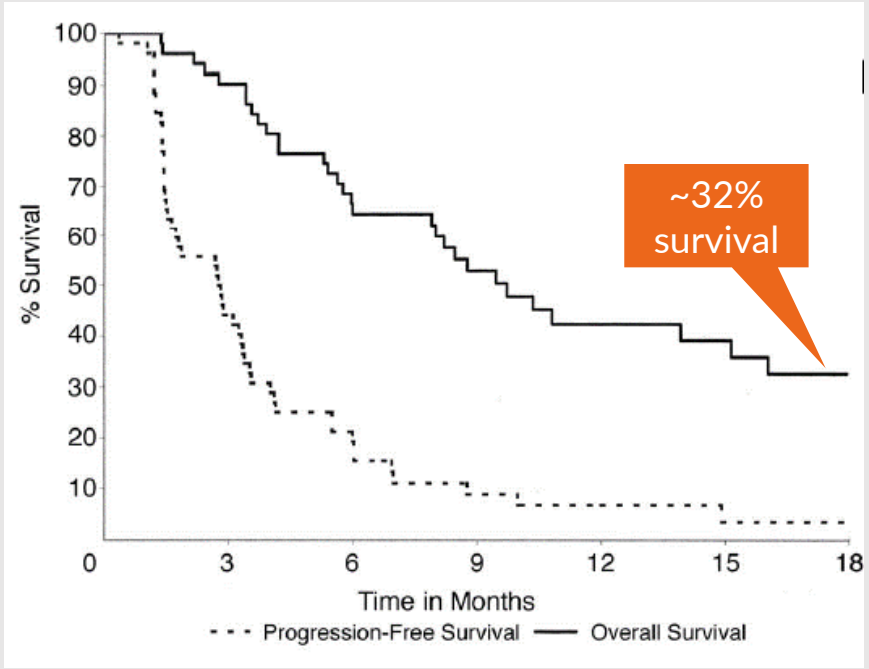
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

Overall survival: Improved from 20% (dosing every third week) to 32% (weekly dosing)[1]

Irinotecan every 3 weeks (IV)



Irinotecan weekly (IV)



Study in patients with metastatic refractory breast cancer, N=103

1) Perez et al. J Clin Oncol 2004: Randomized Phase II Study of Two Irinotecan Schedules for Patients With Metastatic Breast Cancer Refractory to an Anthracycline, a Taxane, or Both

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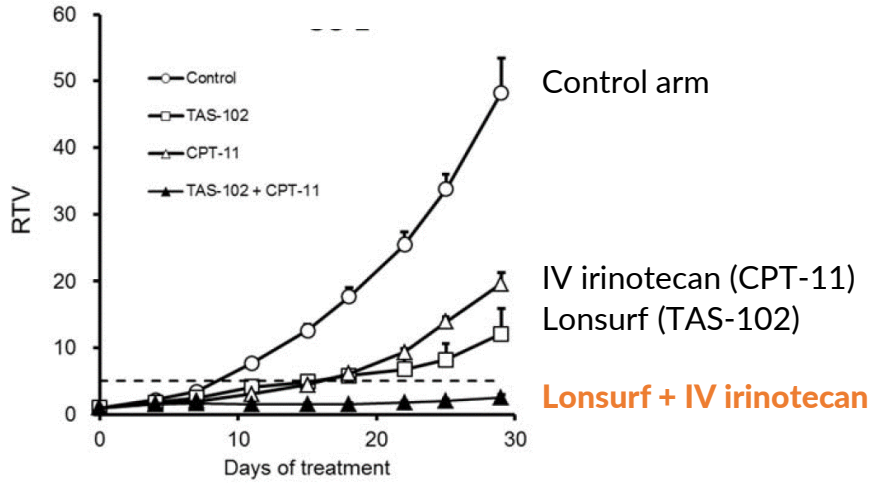
ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

- High unmet need and clinically demonstrated
- Potential for synergistic effect between Lonsurf and irinotecan

Efficacy study in an animal model of gastric cancer[1]
(Relative Tumor Volume, RTV)



Control arm

IV irinotecan (CPT-11)
Lonsurf (TAS-102)

Lonsurf + IV irinotecan

LONSURF AND IRINOTECAN COMBINATION

RANDOMIZED CONTROLLED PHASE 2 STUDY

- ~100 patients with metastatic gastric cancer
- Study arms: Oncoral + Lonsurf vs. Lonsurf
- Endpoints: Progression Free Survival (Primary), Response Rate, PK, Safety (Secondary) and Overall Survival (follow-up)
- IND approved in the US
- To focus all resources on Orviglance, patient enrollment is not initiated until it can be done effectively

Clinical collaboration with

TAIHO ONCOLOGY

LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

1) Nukatsuka et al: Combination Chemotherapy Using TAS-102 and Irinotecan Hydrochloride, ANTICANCER RESEARCH 35: 1437-1446 (2015)

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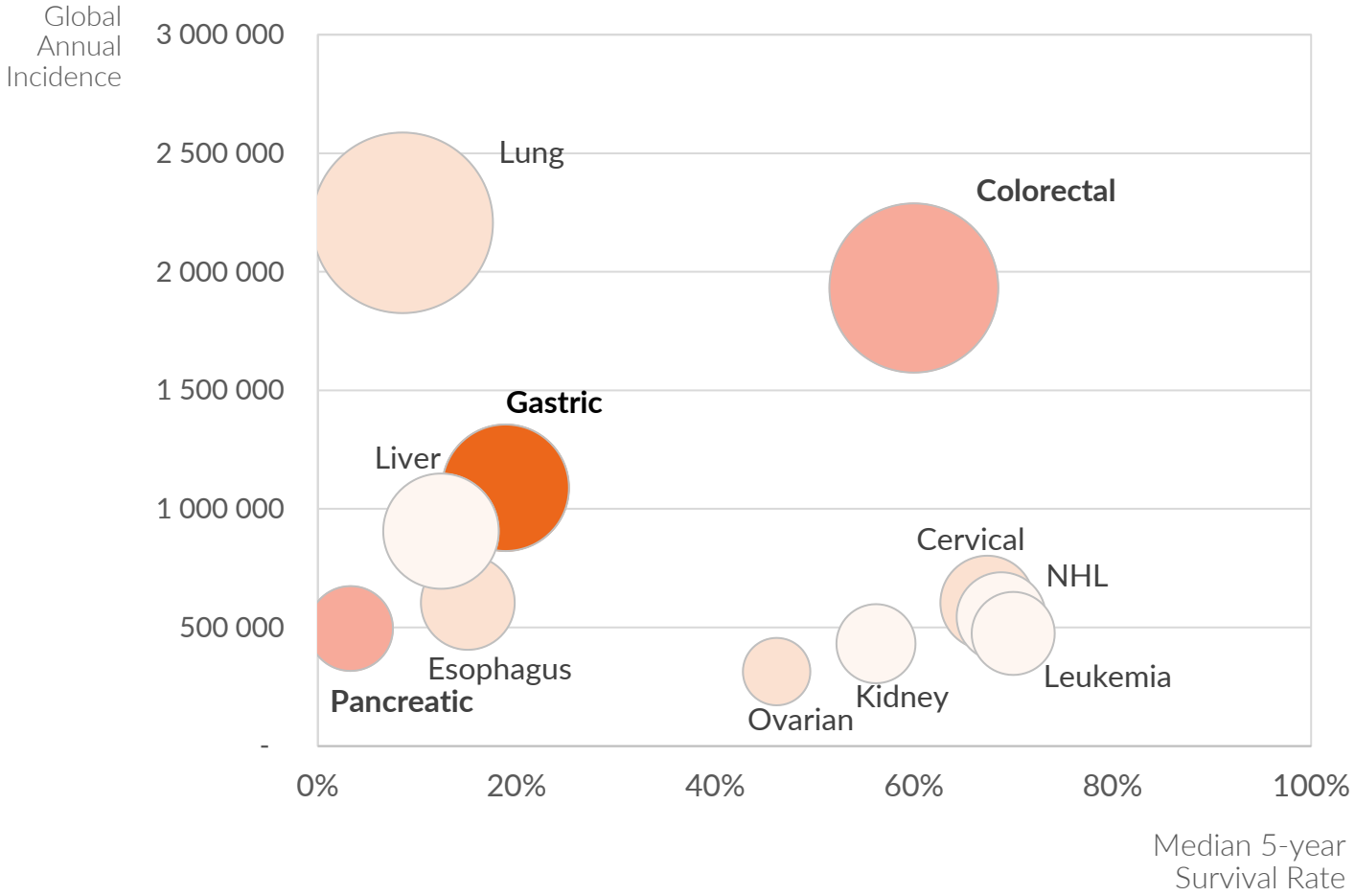
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN[3]



A WELL-ESTABLISHED CHEMOTHERAPY
with recognized anti-tumor effect in solid tumors

- Current focus: **Gastric cancer**
  - Clinically demonstrated
  - Guidelines recognized
  - 3rd highest cancer deaths[1]
  - Orphan disease (US and EU)
  - $3-4bn market[2]
- **Approved indications** for IV irinotecan
- Indications where IV irinotecan are clinically demonstrated & guidelines recognized
- Indications where IV irinotecan are clinically demonstrated

1) International Agency for Research on Cancer (IARC, 2021)
2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024
3) Globocan 2020, WHO, Cancer Research UK

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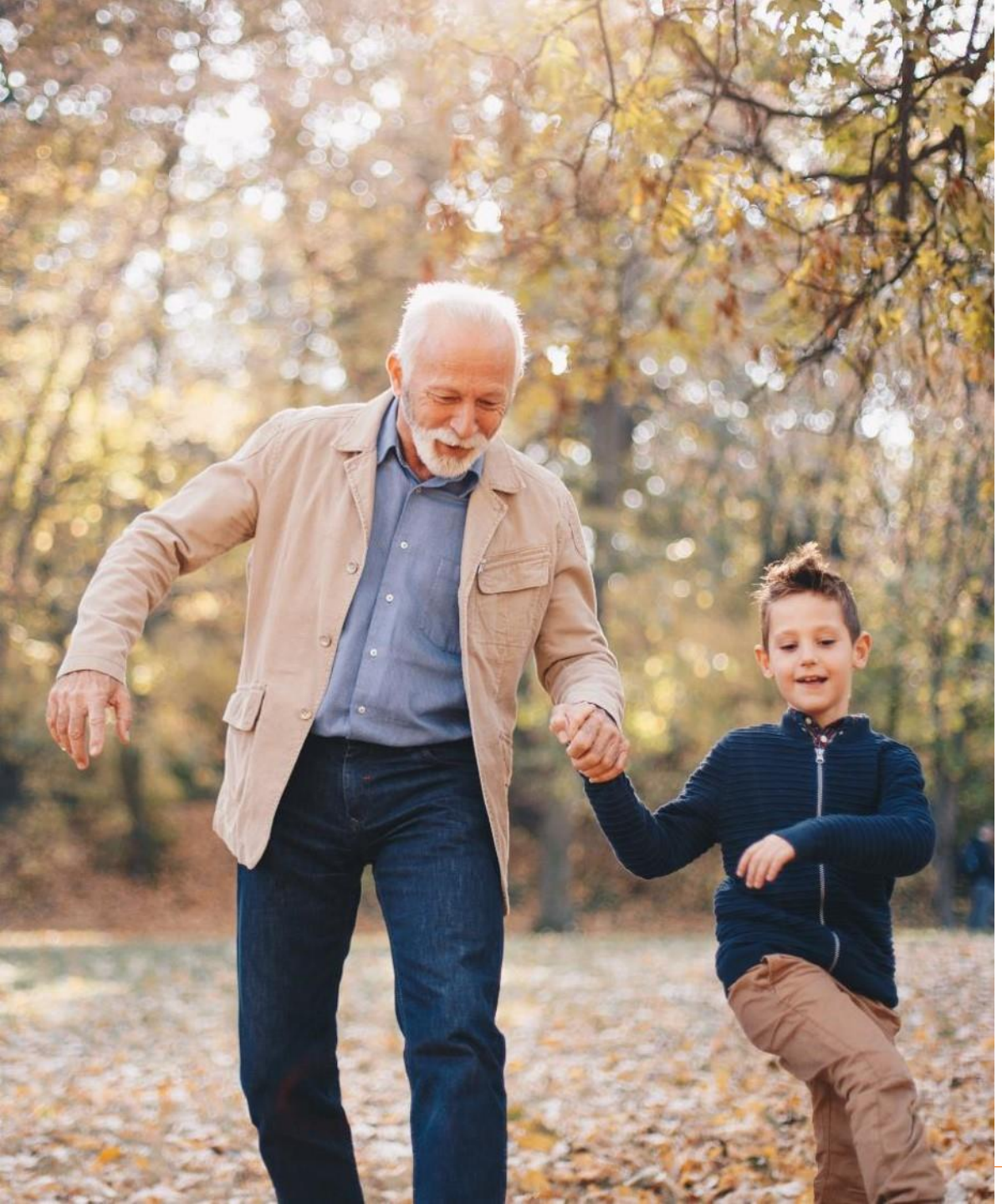

MAKING PROGRESS ON OUR MISSION

PRIORITIES 2023

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

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SUBSTANTIAL VALUE CREATION OPPORTUNITIES AHEAD

Orviglance – a first-in-class orphan diagnostic drug targeting $800m market

Orviglance phase 3 readout mid 2023; significantly improved visualization (same endpoint) in a 20-patient phase 2 study (p=0.009)

Attractive potential for Oncoral in gastric cancer and other solid tumors

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