ADVANCING
ORPHAN
ONCOLOGY

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ADVANCING ORPHAN ONCOLOGY

August 2023

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Ascelia Pharma is identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancer conditions

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ASCELIA PHARMA - HIGHLIGHTS

Two drugs in advanced clinical development

ORVIGLANCE® – Nearing completion of Phase 3

- 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 patient recruitment completed; readout pending

ONCORAL – Phase 2-ready

- Daily, oral irinotecan chemotherapy
- Clinical collaboration with Taiho Oncology
- Opportunity in gastric cancer and other solid tumors

Building global capabilities

Focused ORVIGLANCE launch in the US lead by Ascelia; partnering in other geographies

Based in Malmö (Sweden), US office in New Jersey (US)

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RECENT KEY EVENTS

Key events in Q2-2023

- Hepatic impairment study accepted for presentation at major radiology and liver conferences
- Ascelia Pharma presented Orviglance hepatic impairment data and hosted a Q&A with liver imaging experts at the 2023 ESGAR annual meeting

Key events after Q2-2023

- **Re**-evaluation required after intra-reader inconsistency in scoring of images from phase 3 study SPARKLE
- Clarification that images were not read and scored properly

ORVIGLANCE®

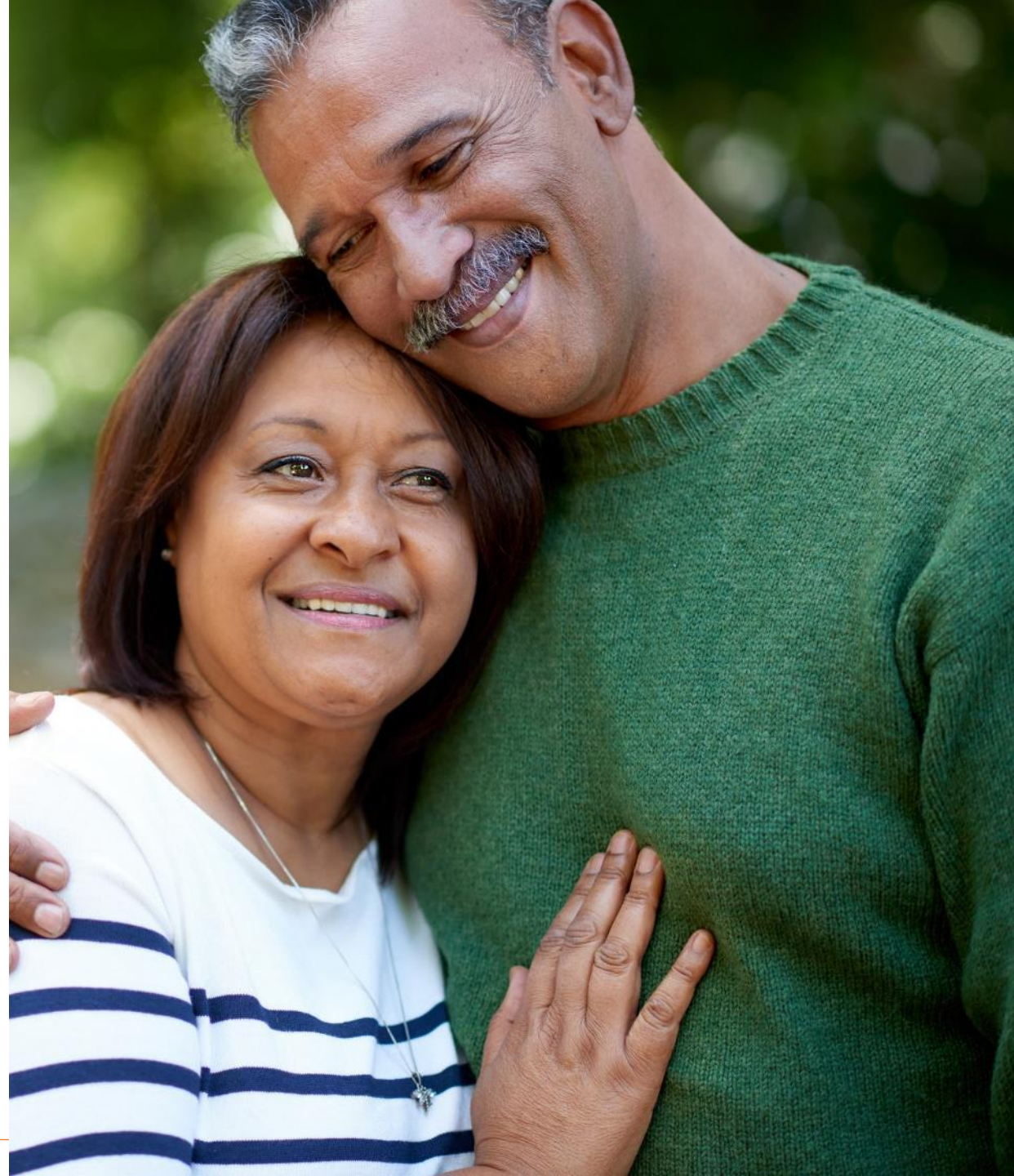
Liver diagnostic imaging drug with positive Phase 3 results

ONCORAL

Phase 2-ready, daily, oral chemotherapy

CLEAR UNMET NEED AND CONSISTENT POSITIVE DATA

- A well-defined unmet need for liver imaging in cancer patients with poor kidney function
- A global addressable market opportunity of USD 800 million
- Consistent positive efficacy and safety in eight completed Phase 1 and 2 studies
- Patient recruitment and MR image collection for SPARKLE Phase 3 study completed
  - Common adverse events were in line with previous studies
  - Efficacy conclusions from pending re-evaluation



RE-EVALUATION REQUIRED TO REACH RESULTS

High Intra-Reader Variability

- As per FDA guidance, a pre-defined number of patients were evaluated twice, which showed a high level of variability in the evaluation of images by some readers
- A re-evaluation of all images by a new group of independent radiology readers is required

Plan Ahead

- All activities and resources will now be focused on the re-evaluation
- Ascelia sees no need for enrollment of more patients or an additional clinical study
- Cost-saving initiatives are taken
- A timeline and financial implications for the re-evaluation will be presented by mid-September

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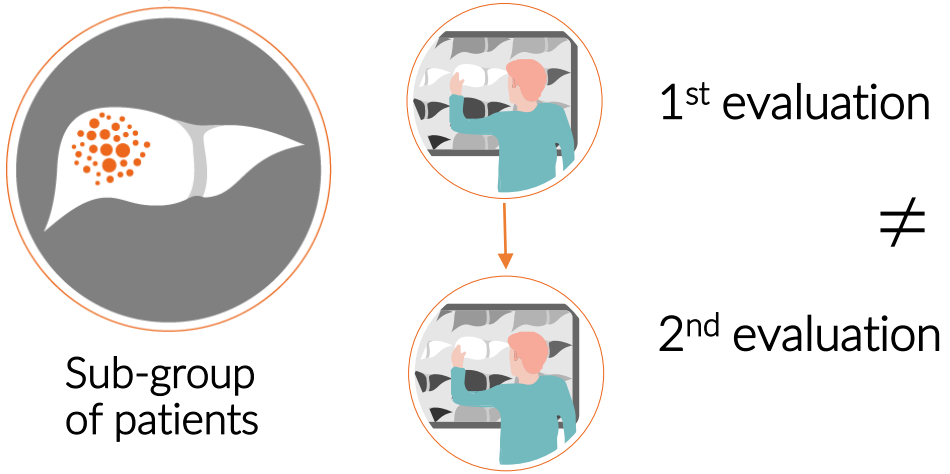
UNRELIABLE MEASUREMENTS - EFFICACY NOT EVALUABLE

- Two readers with high level of intra-reader variability
- High intra-reader variability means the scorings are unreliable
- Unreliable scoring cannot be used to evaluate the effect
- All clinical data has been collected and no further patient enrollment is needed

SPARKLE CLINICAL STUDY

Unenhanced and Orviglance enhanced images from 85 patients

Intra-Reader Variability Assessment



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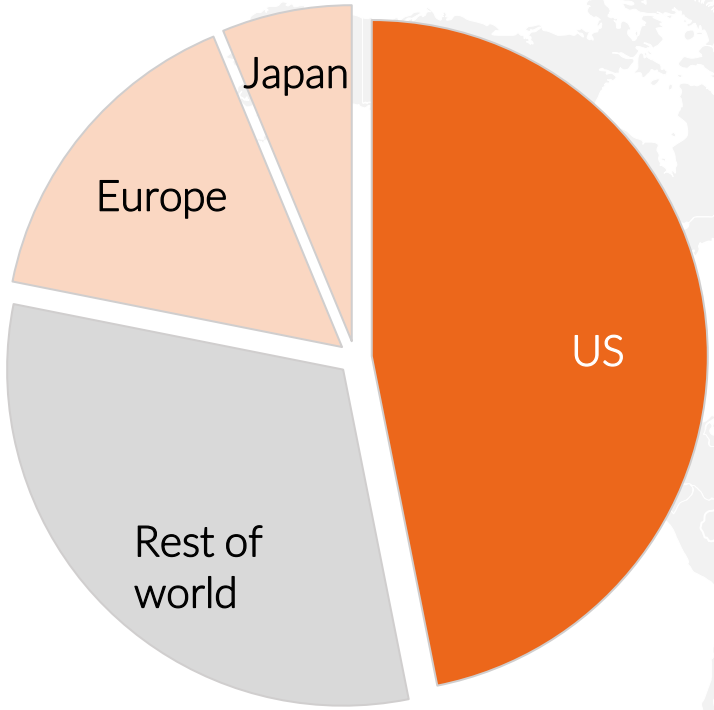
ATTRACTIVE ADDRESSABLE MARKET



Global addressable market of USD 800 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]

Focused US launch by Ascelia Pharma to maximize value creation and partnering in other geographies

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

ORVIGLANCE®

Liver diagnostic drug in ongoing Phase 3

ONCORAL

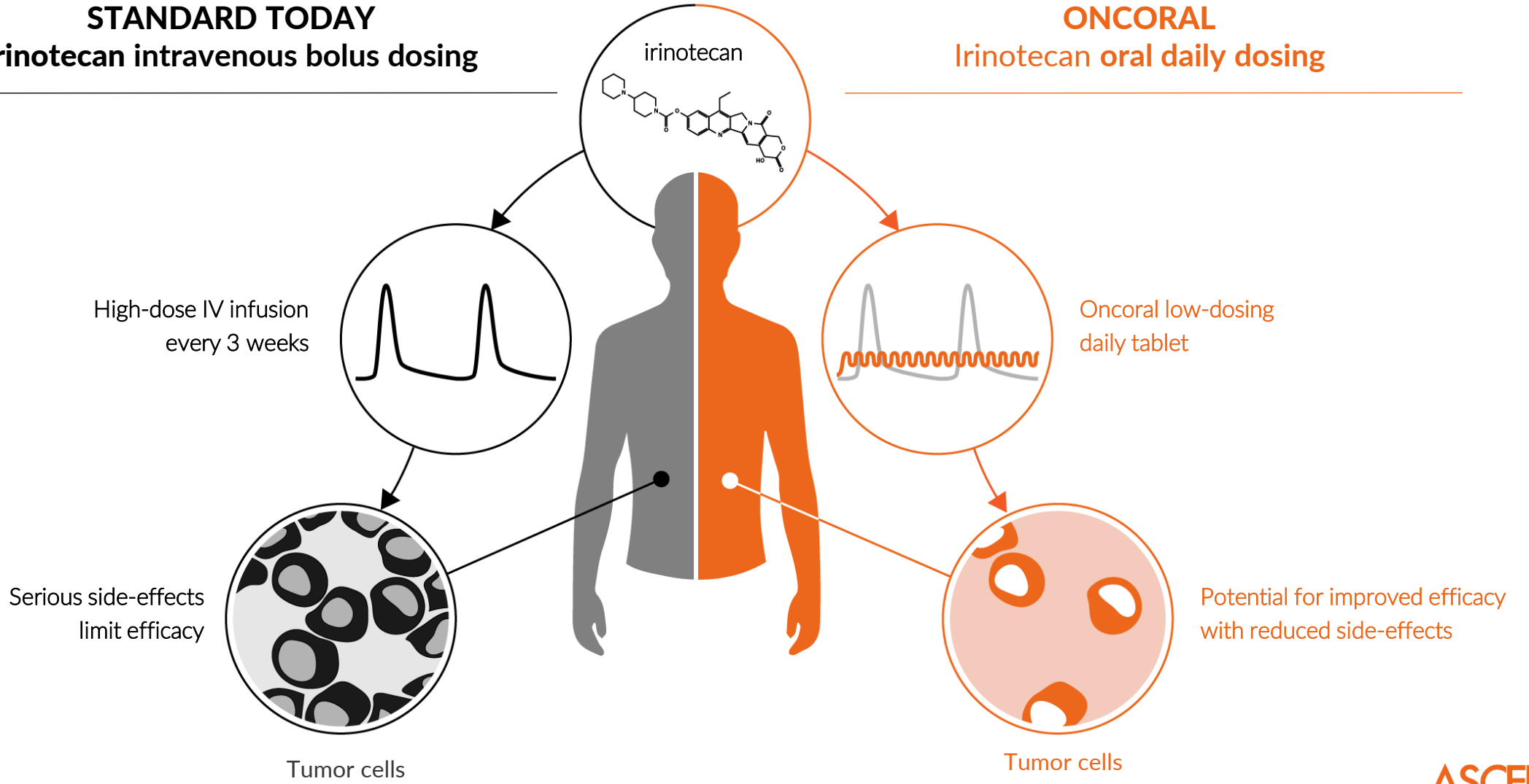
Phase 2-ready, daily, oral chemotherapy

OUR PORTFOLIO

IMPROVING **EFFICACY** AND **TOLERABILITY** IN SOLID TUMORS

STANDARD TODAY
Irinotecan intravenous bolus dosing

ONCORAL
Irinotecan **oral daily dosing**

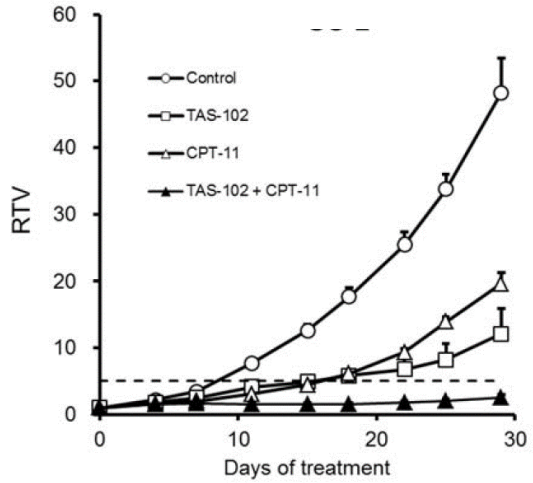


ONCORAL PHASE 2 IN GASTRIC CANCER

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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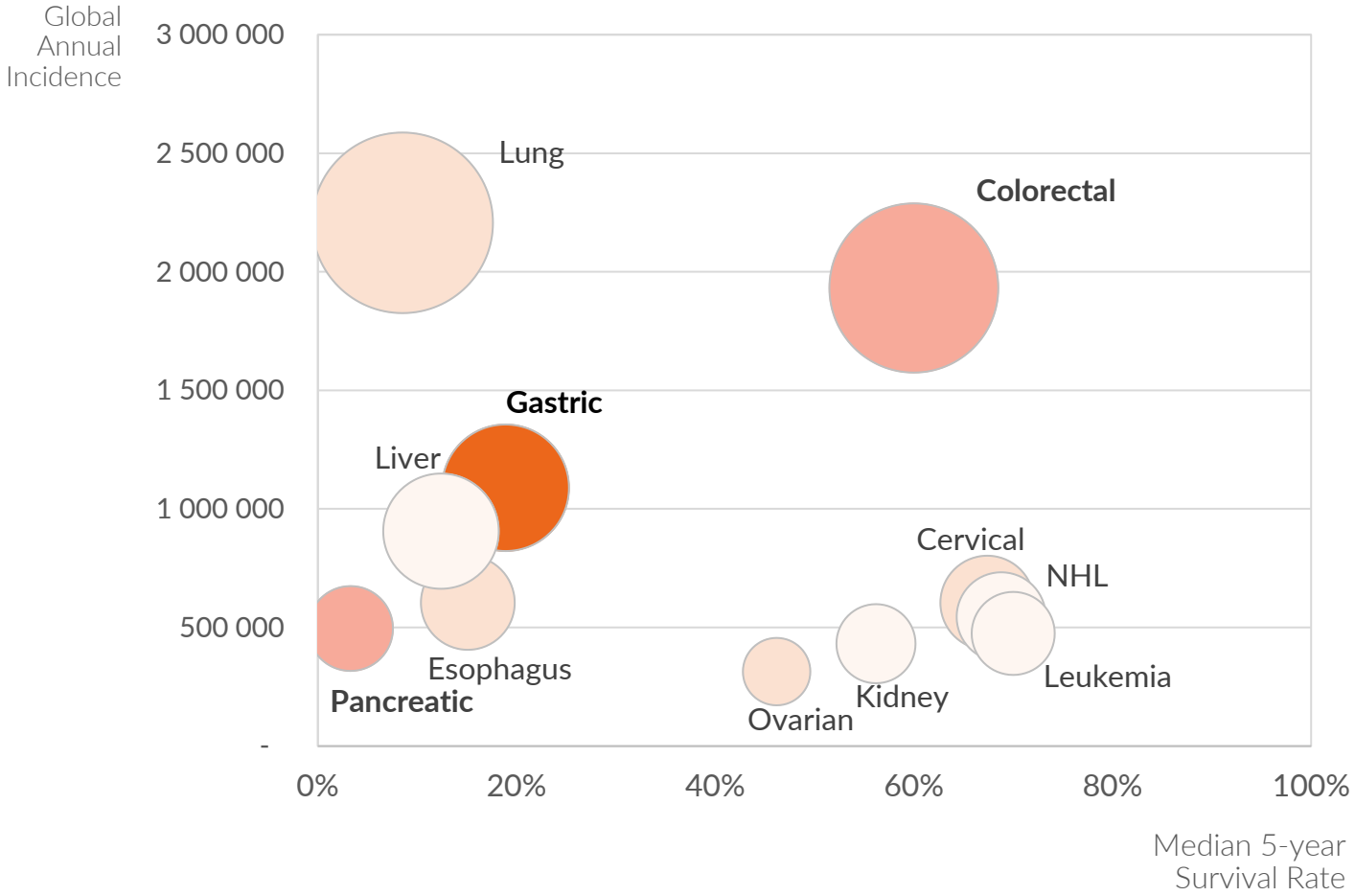
HIGH VALUE GASTRIC CANCER OPPORTUNITIES WITH EXPANSIONS

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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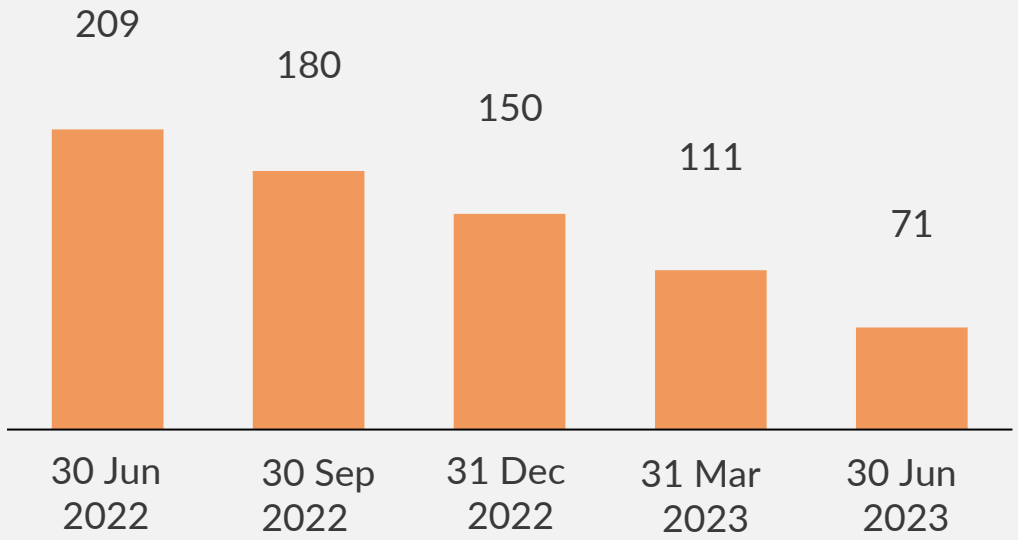
FINANCIAL HIGHLIGHTS Q2 2023 – LIQUIDITY POSITION

- **Liquid assets of 71 MSEK ($6.5 million) by 30 June 2023**
- **Ambition to complete the SPARKLE image re-evaluation with current cash**
  - **Activities not related to the re-evaluation are postponed and cost saving initiatives taken**
  - **We will communicate the timeline for the re-evaluation activity and the financial runway in mid September**

Liquid assets including marketable securities
(SEK million)



UNCHANGED CONFIDENCE IN ORVIGLANCE

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

✓	3 Mar 2023	Phase 3 LPLV
	Mid-Sept 2023	Focused Plan for Re-Evaluation

Oncoral – Phase 2 ready with attractive potential in gastric cancer and other solid tumors

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