



ADVANCING
ORPHAN
ONCOLOGY

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Nasdaq Stockholm
www.ascelia.com

ASCELIA PHARMA

COMPANY PRESENTATION

December 2021

ASCELIA
PHARMA

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INVESTMENT HIGHLIGHTS



ADVANCING ORPHAN ONCOLOGY

- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
 - **ORVIGLANCE** (MANGORAL) – in global Phase 3; FDA Orphan Drug Designation; U.S. launch expected H2 2023
 - **ONCORAL** – starting Phase 2 in Q4 2021*

BUILDING GLOBAL CAPABILITIES

- Financed well into 2023
- Based in Malmö (Sweden) & Woodbridge, NJ (US)
- Listed on NASDAQ Stockholm (Ticker: ACE)

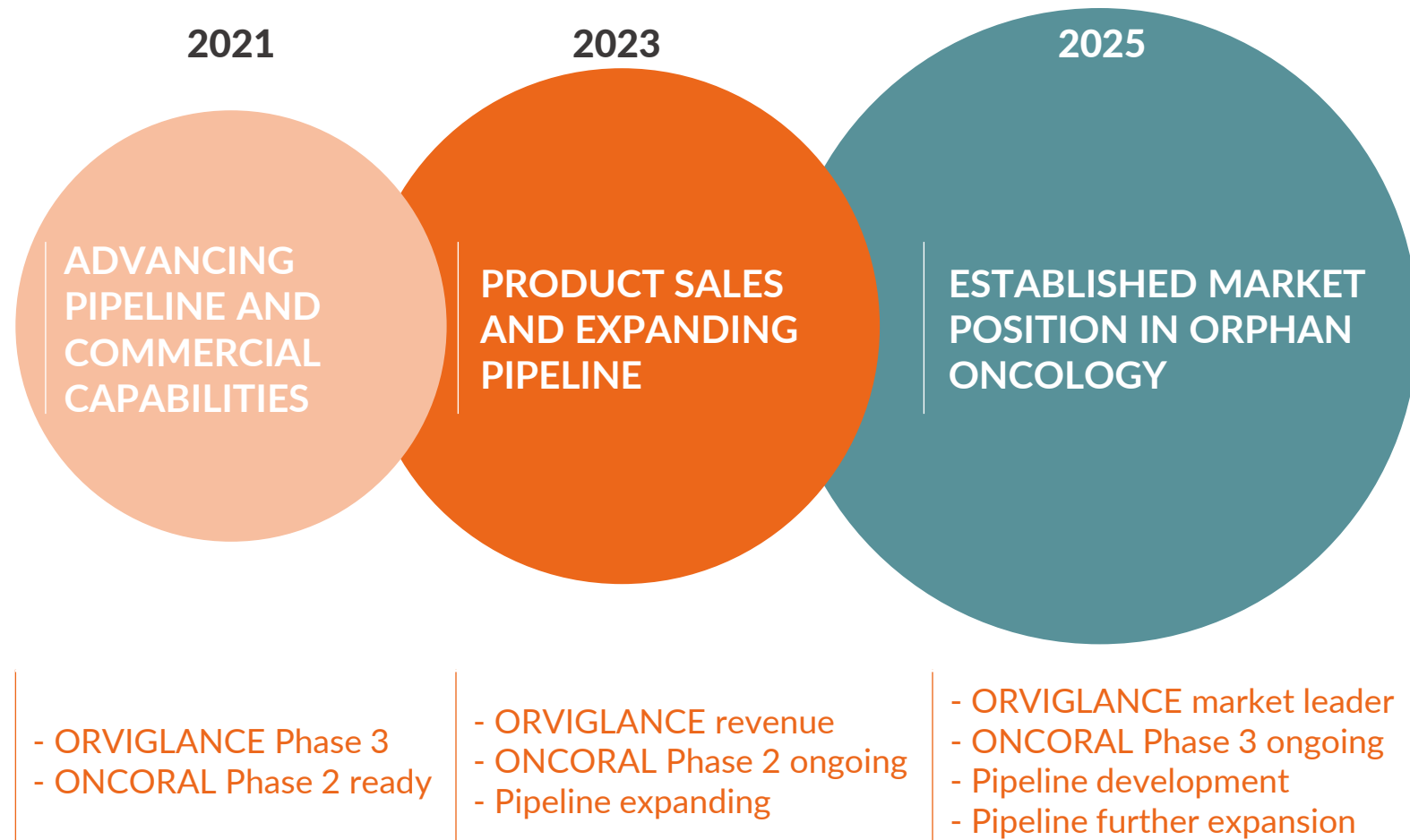
*Expected timing for study start approval (IND approval)

CURRENT CLINICAL STAGE PIPELINE

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Market launch
ORVIGLANCE	Detection and visualization of focal liver lesions	completed		Ongoing 2020 – H1 2022	H2 2023
ONCORAL	Gastric cancer	completed	Q4 2021* – 2024		
	Other solid tumors	completed			

Note: Timelines incorporate the currently assessed impact from Covid-19. An extended Covid-19 situation may further affect timelines.
 *Expected timing for study start approval (IND approval)

BUILDING VALUE





PORTFOLIO

ORVIGLANCE (Mangoral)

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

EARLY DETECTION OF LIVER METASTASES IS CRITICAL

LIVER METASTASES CRITICAL IN CANCER CARE

Liver metastases are common and often

- First site of metastases
- The cause of mortality

Incidence liver metastases per primary cancer ¹⁻³



* Metastatic breast cancer

CONTRAST ENHANCED MRI IS GOLD STANDARD

Contrast drug enhanced MRI enables

- Accurate detection and visualization
- Planning of surgery or drug treatment
- Post-treatment surveillance

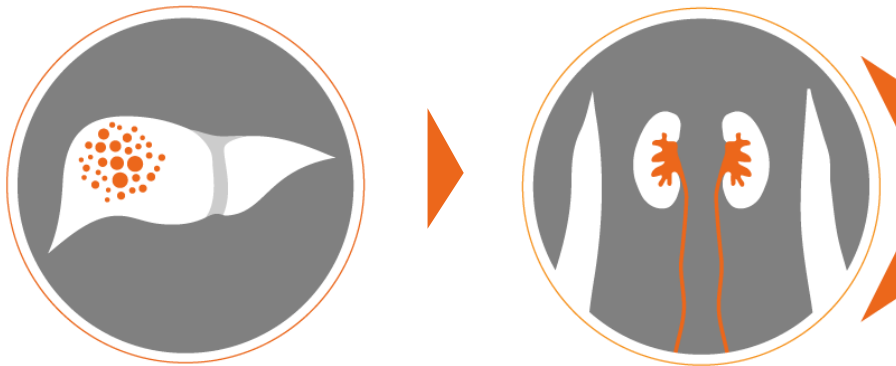
1) Riihimäki, M. et al. Patterns of metastasis in colon and rectal cancer. *Sci. Rep.* 6, 29765; doi: 10.1038/srep29765 (2016); *Journal of Pathology*, 2014, 232:23-31
2) Guy diSibio and Samuel W. French (2008) Metastatic Patterns of Cancers: Results From a Large Autopsy Study. *Archives of Pathology & 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

ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Suspected liver metastases
or primary liver cancer

Check kidney
status before MRI

Liver
MRI scan



A) Healthy kidneys

MRI with gadolinium contrast agent



B) Poor kidneys

- All gadolinium contrast agents have regulatory Black Box warnings
- Risk of severe and potentially fatal side-effect (Nephrogenic Systemic Fibrosis)

Solution:

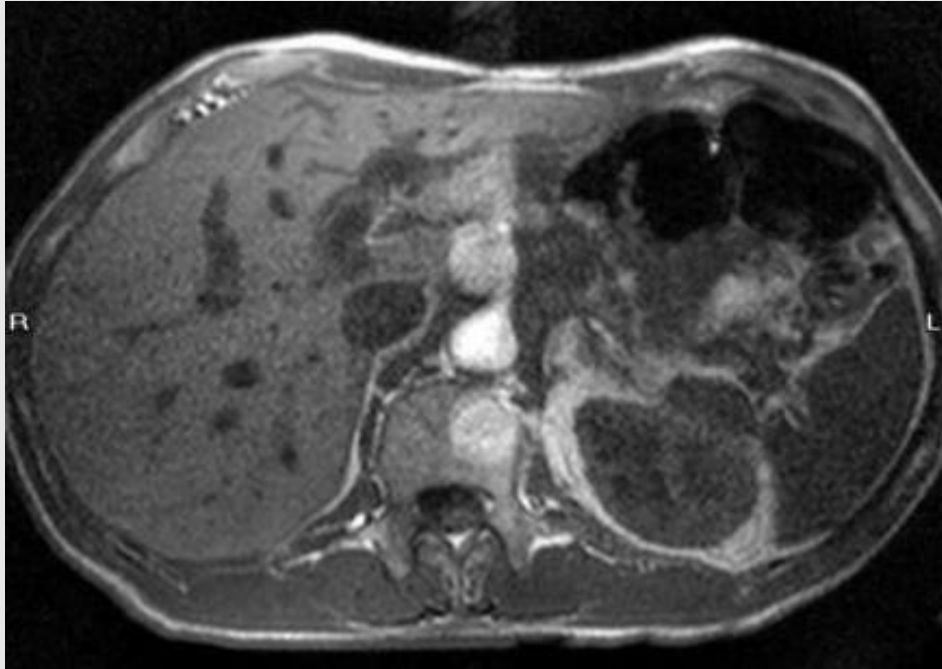
MRI with **ORVIGLANCE** (manganese based)



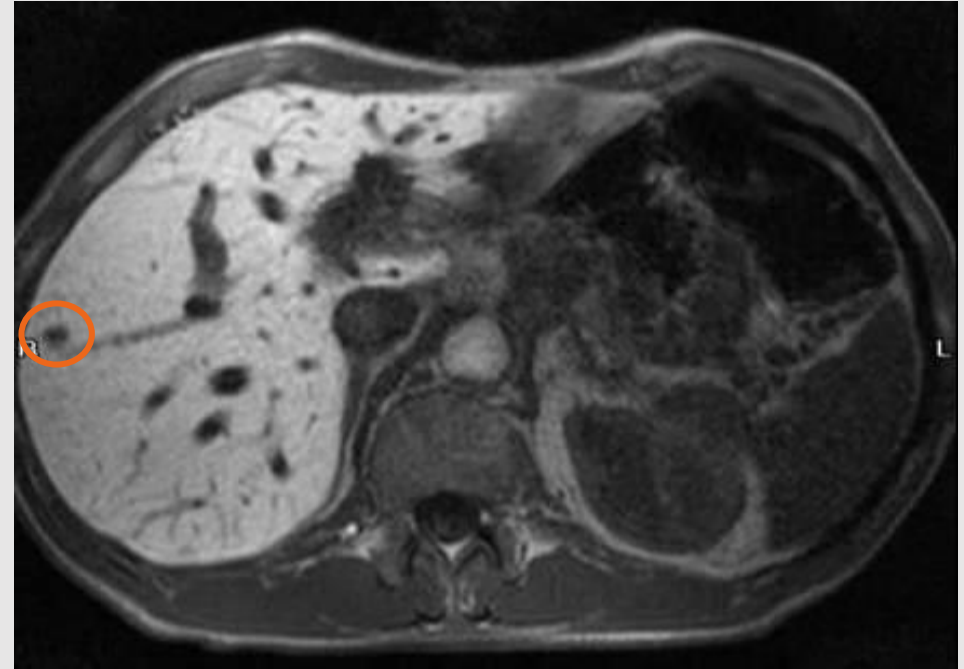
ORVIGLANCE aims to be the standard of care liver MRI contrast agent for target patients

STRONG LIVER ENHANCEMENT WITH ORVIGLANCE

PATIENT EXAMPLE FROM PHASE 2 STUDY



UNENHANCED liver MRI (without contrast agent)



ORVIGLANCE contrast enhanced liver MRI

Liver metastasis appear with Orviglance

ORVIGLANCE PHASE 1 & 2 RESULTS (6 STUDIES)

Consistent strong efficacy readout and safety profile

Blind read study of all images vs. unenhanced MRI

(178 persons)

- Significantly improved MRI
- 33% more lesions
- **Lesion visualization**
Delineation (border sharpness): **p-value <0.0001**
Conspicuity (contrast vs. background): **p-value <0.0001**









Re-read study vs. gadolinium contrast agent (GBCA)

(20 patients)

- ORVIGLANCE lesion visualization as effective as GBCA
(2 out of 3 readers favoured Orviglance)

Proceed into Phase 3

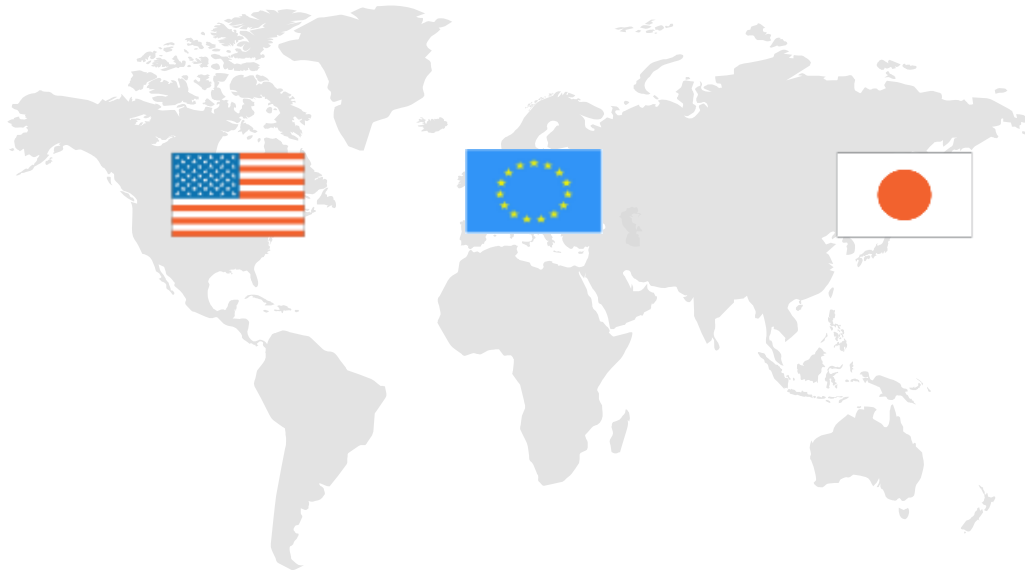
ORVIGLANCE ONGOING PHASE 3 STUDY – SPARKLE

Patients 	<ul style="list-style-type: none">• Global study, 200 patients• Known or suspected focal liver lesions and severe renal impairment		Status update: US, Europe, Latin America 40+ sites increasing to over 50 sites
Comparator 	Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI		No randomization – each patient as own control
Endpoint 	Lesion visualization <ul style="list-style-type: none">• Lesion border delineation• Conspicuity		<ul style="list-style-type: none">• Same endpoints as in Phase 2• Same endpoints as for approved gadolinium agents
Follow-up 	Less than a week		Expected pivotal study patient enrollment: H1 2022

ORVIGLANCE MARKET \$500-600 MILLION ANNUALLY

\$500-600M ADDRESSABLE MARKET IN US, EU AND JAPAN

- Ascelia Pharma to commercialize in the U.S
- RoW commercialization with partners



DRIVERS

- Patients with suspected primary liver cancer or liver metastases and severe kidney impairment (~4%)
- Actual imaging procedures (real-world data)¹
- Payer and expert input (+75 stakeholders)²

UPSIDES

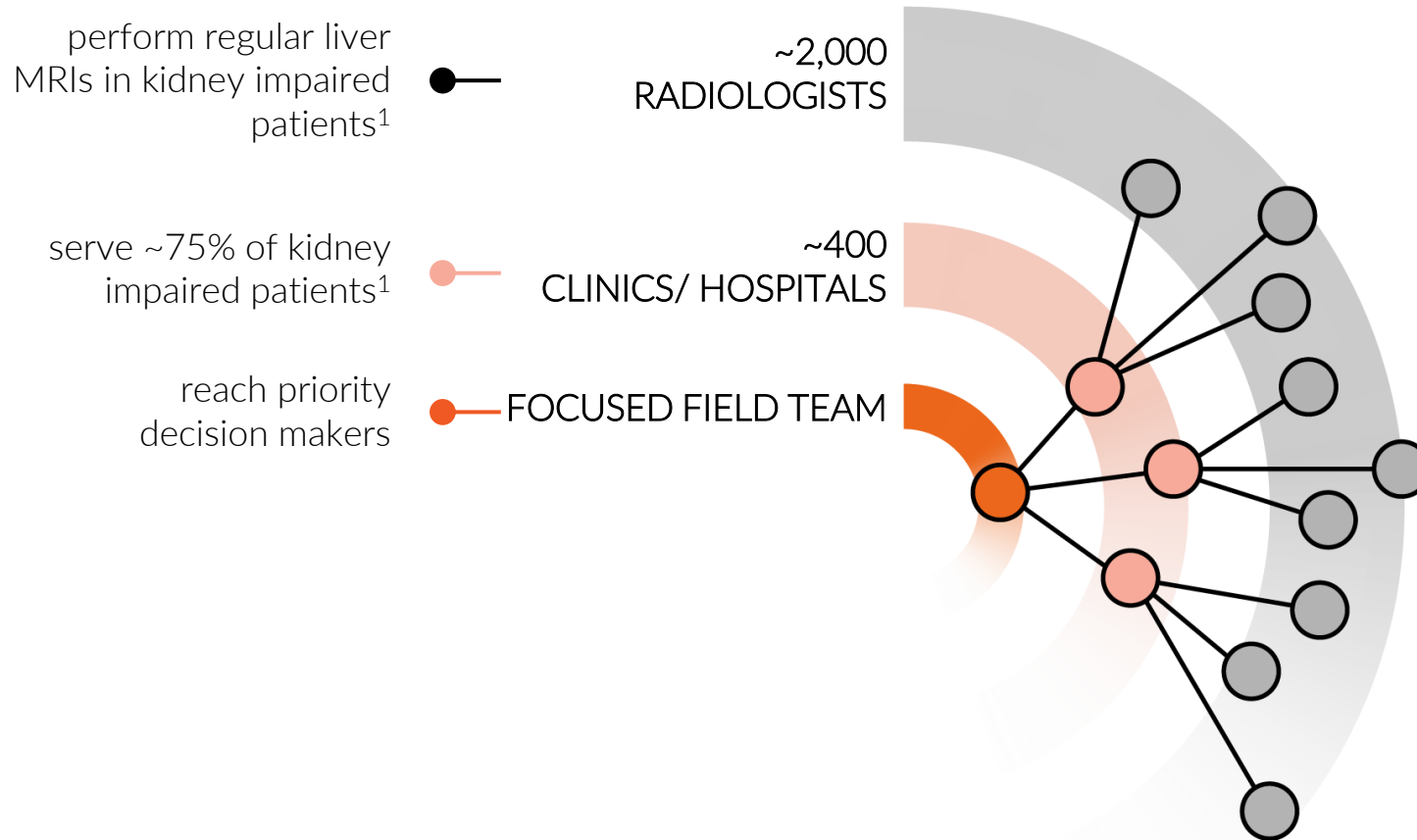
- Other markets, e.g., China
- Annual growth of 4-5%

Sources:

1) Market research with Decision Resources Group, 2020

2) Market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

CAPTURING US MARKET VALUE WITH ASCELIA'S TEAM



BUILDING ASCELIA U.S. TEAM

New Jersey office (up to 40 FTEs at launch)

Cambrex manufacturing partner in New Jersey

BUILDING OUT U.S. FOOTPRINT

SPARKLE Phase 3 study 13+ US Sites including Yale, Stanford, Mass. General, UCLA Medical Center

Sources:

1) Market research with Decision Resources Group, 2020



PORTFOLIO

ORVIGLANCE (Mangoral)

Liver contrast agent in ongoing Phase 3

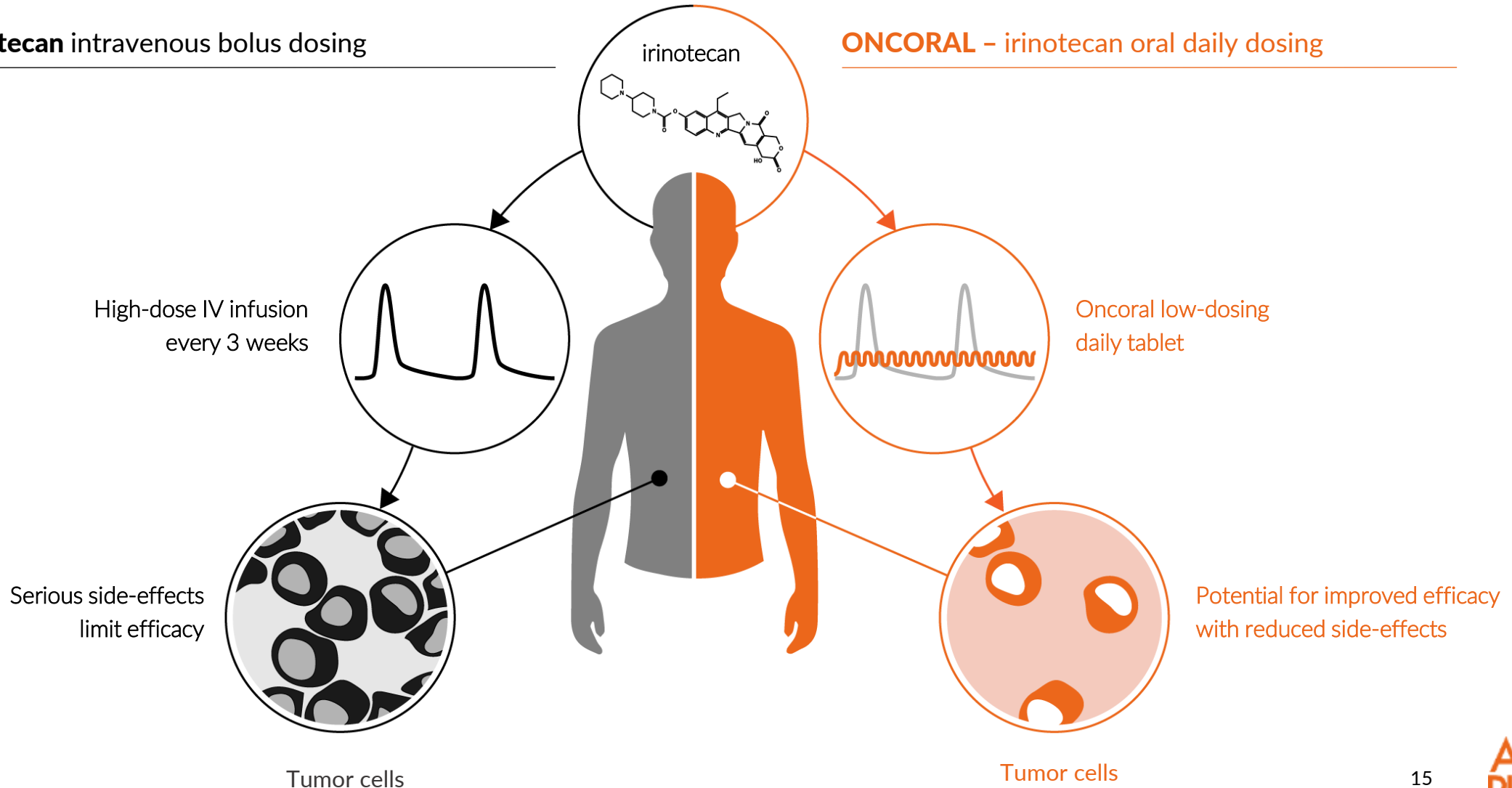
ONCORAL

Daily oral chemotherapy ready for Phase 2

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

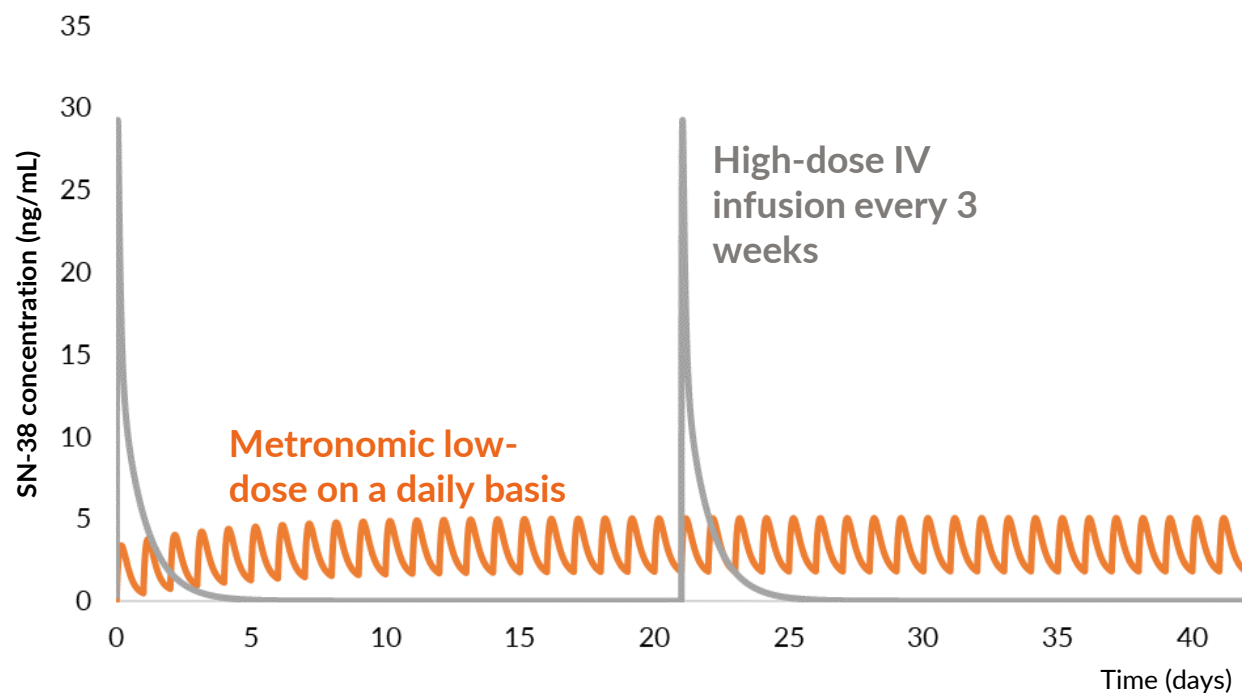
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar performed by Pkxpert AB

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

Infrequent high-dose IV irinotecan

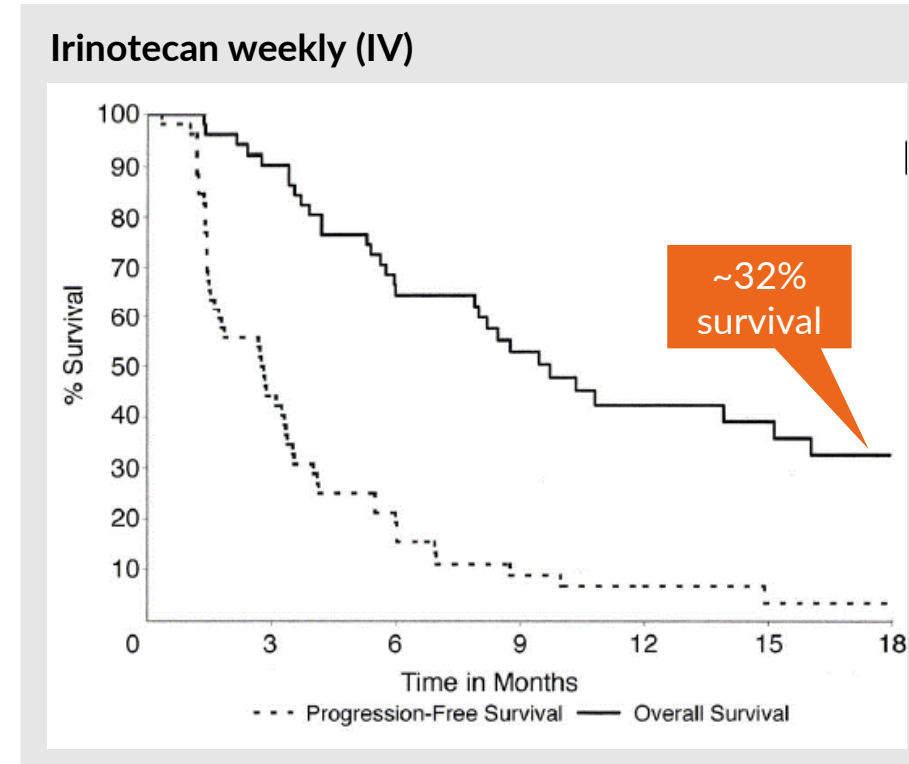
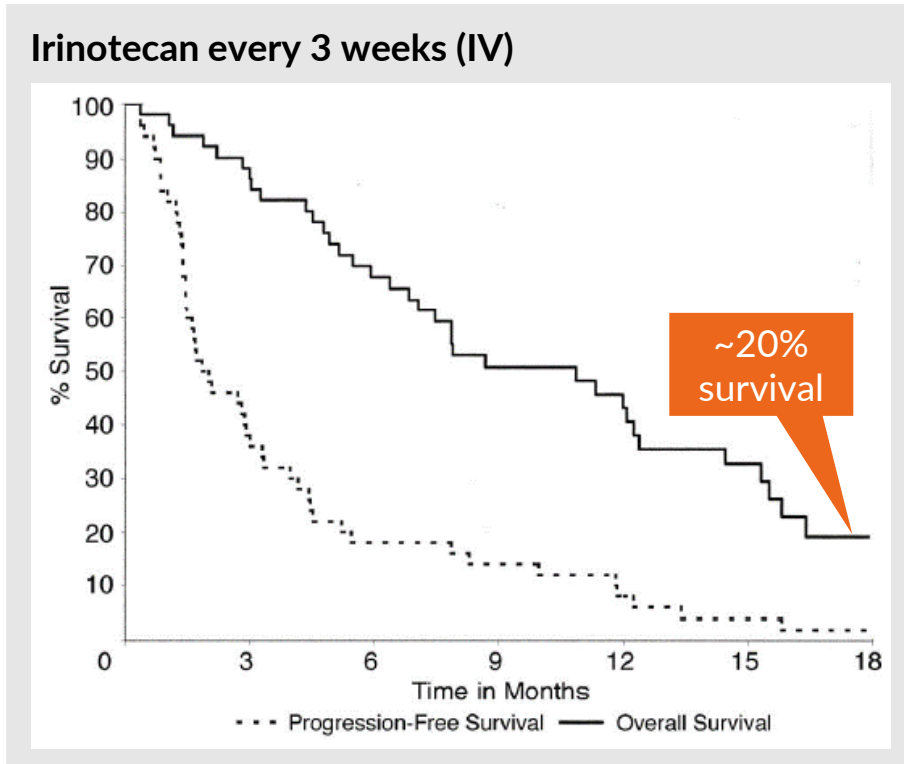
Gastrointestinal and hematological side effects, ~30% severe or life-threatening (grade 3 or 4)¹

Frequent (metronomic) low-dose irinotecan

- Several studies show improved tolerability^{2,3}
- Daily dosing – adjust quickly if acute toxicity

IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

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



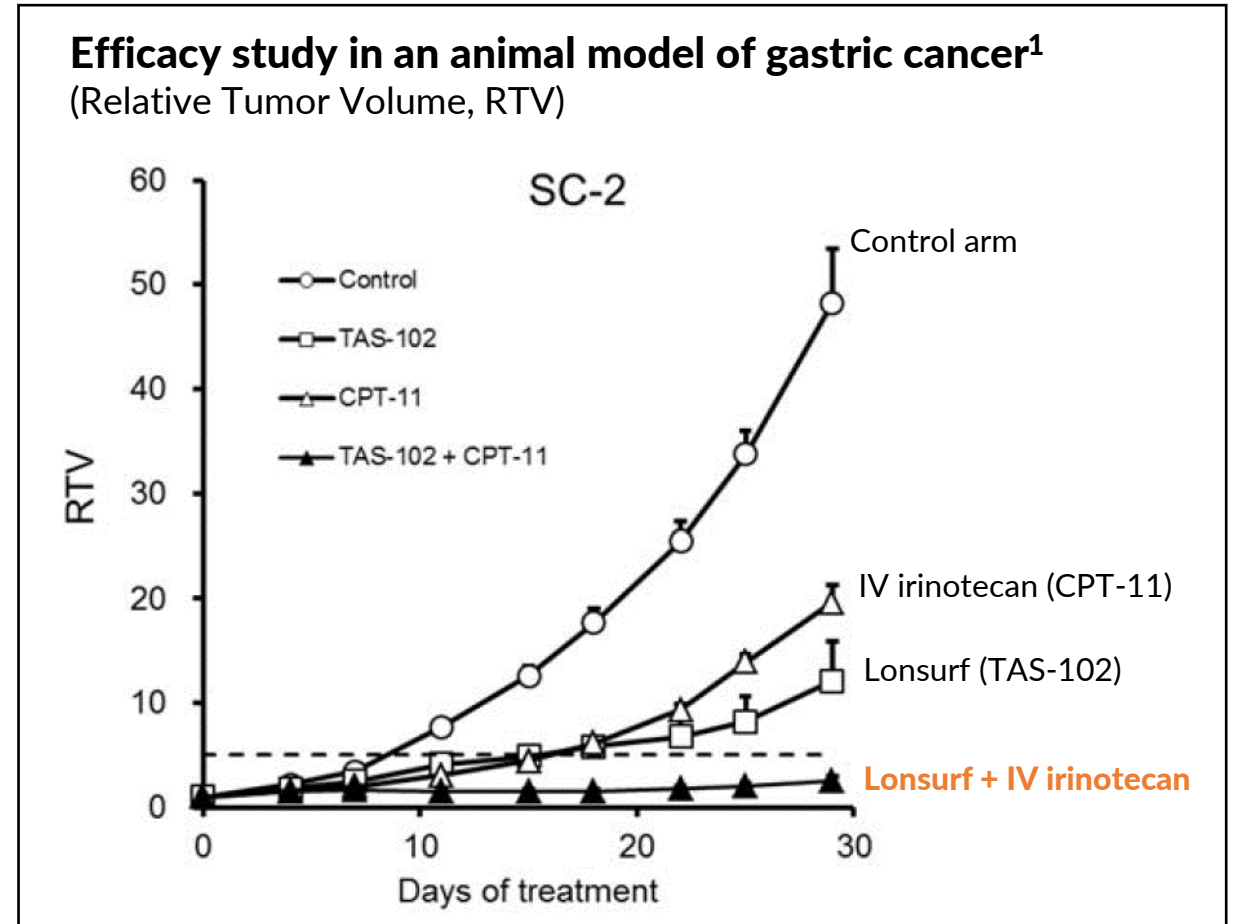
Study in patients with metastatic refractory breast cancer, N=103

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

ONCORAL PHASE 2 IN GASTRIC CANCER





STRONG RATIONALE FOR GASTRIC CANCER

- Clinical guidelines support efficacy of irinotecan
- Potential for Orphan Drug Designation
- Potential for synergistic effect between Lonsurf and irinotecan



STUDY DESIGN AND CLINICAL COLLABORATION

STUDY DESIGN (ALL-ORAL COMBINATION STUDY)

Patients 	<ul style="list-style-type: none">• Around 100 patients• Metastatic gastric cancer• Randomized controlled, multicenter/multinational
Comparator 	Oncoral + Lonsurf vs. Lonsurf
Endpoints 	Primary: Progression Free Survival Secondary: Response rate, PK, Safety and Overall Survival data in a follow up analysis
Study period 	Q4 2021* – 2024

*Expected timing for study start approval (IND approval)

CLINICAL COLLABORATION WITH TAIHO ONCOLOGY

- Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of Otsuka Group)
- Taiho Oncology Inc. will supply Lonsurf as well as provide scientific expertise for the study
- Depending on the results, the collaboration may be extended for further development
- Ascelia Pharma retains full development and commercialization rights to Oncoral

Clinical collaboration with



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

ONCORAL SCIENTIFIC ADVISORY BOARD

Prof Josep Tabernero, MD, PhD

Head of the Medical Oncology Department at the Vall d'Hebron Barcelona Hospital Campus, Director of the Vall d'Hebron Institute of Oncology (VHIO), and Professor of Medicine

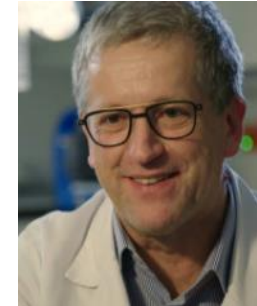
President (2018 – 2019) of ESMO and an Executive Board and Council Member



Prof Eric Van Cutsem, MD, PhD

Professor and Division Head of Digestive Oncology at University of Leuven (KUL) and University Hospitals Gasthuisberg, Leuven, Belgium

Co-founded ESMO GI/World Congress on GI Cancer. Serves/served on the board/ committee of ESMO, ASCO, ENET, EORTC, ECCO, ESDO



Prof Jaffer A Ajani, MD

Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, USA

Chairs the NCCN committee for gastroesophageal cancers



Prof Jeff Evans, MD

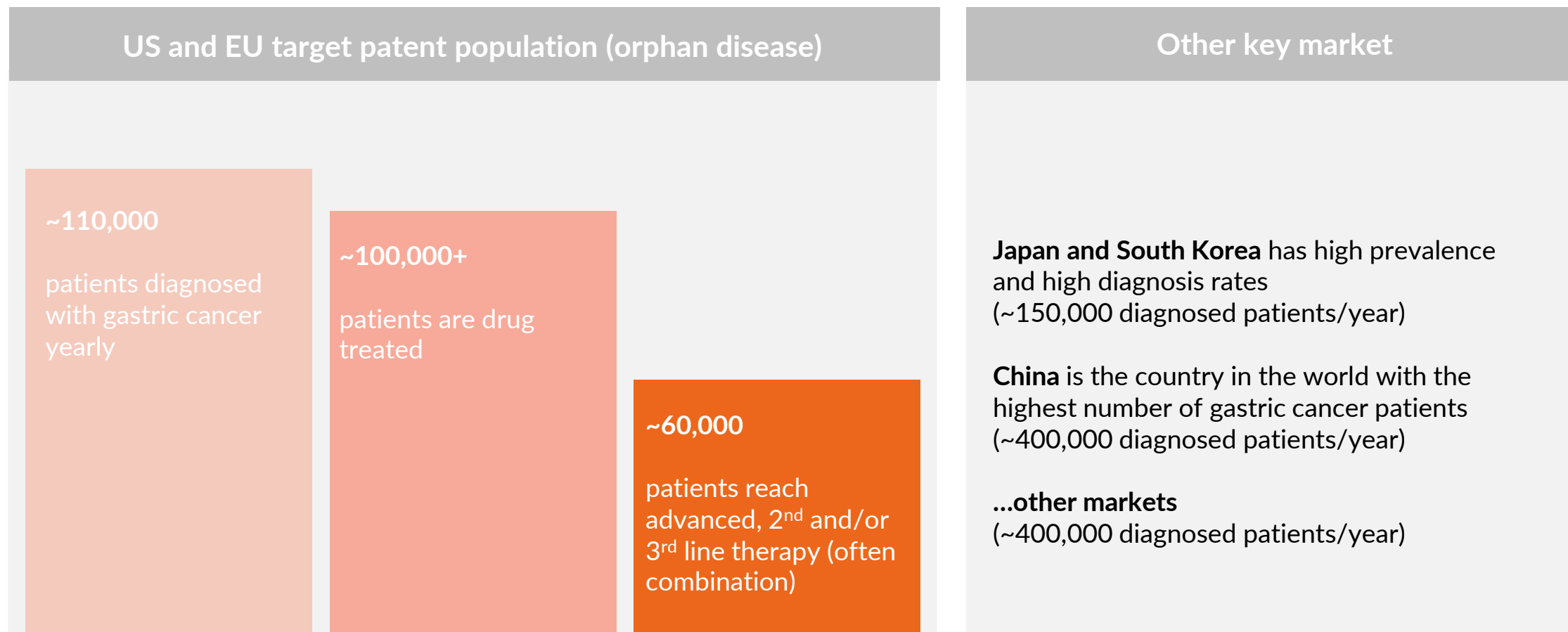
Professor of Translational Cancer Research and Clinical Lead of the Institute of Cancer Sciences, University of Glasgow

Member of the NCRN Upper GI Cancer Pancreatic Cancer and Gastro-Oesophageal Cancer sub-groups



Joint view that Oncoral would be an important treatment option for cancer patients, especially in later disease stages

GASTRIC CANCER – A \$3BN+ MARKET OPPORTUNITY

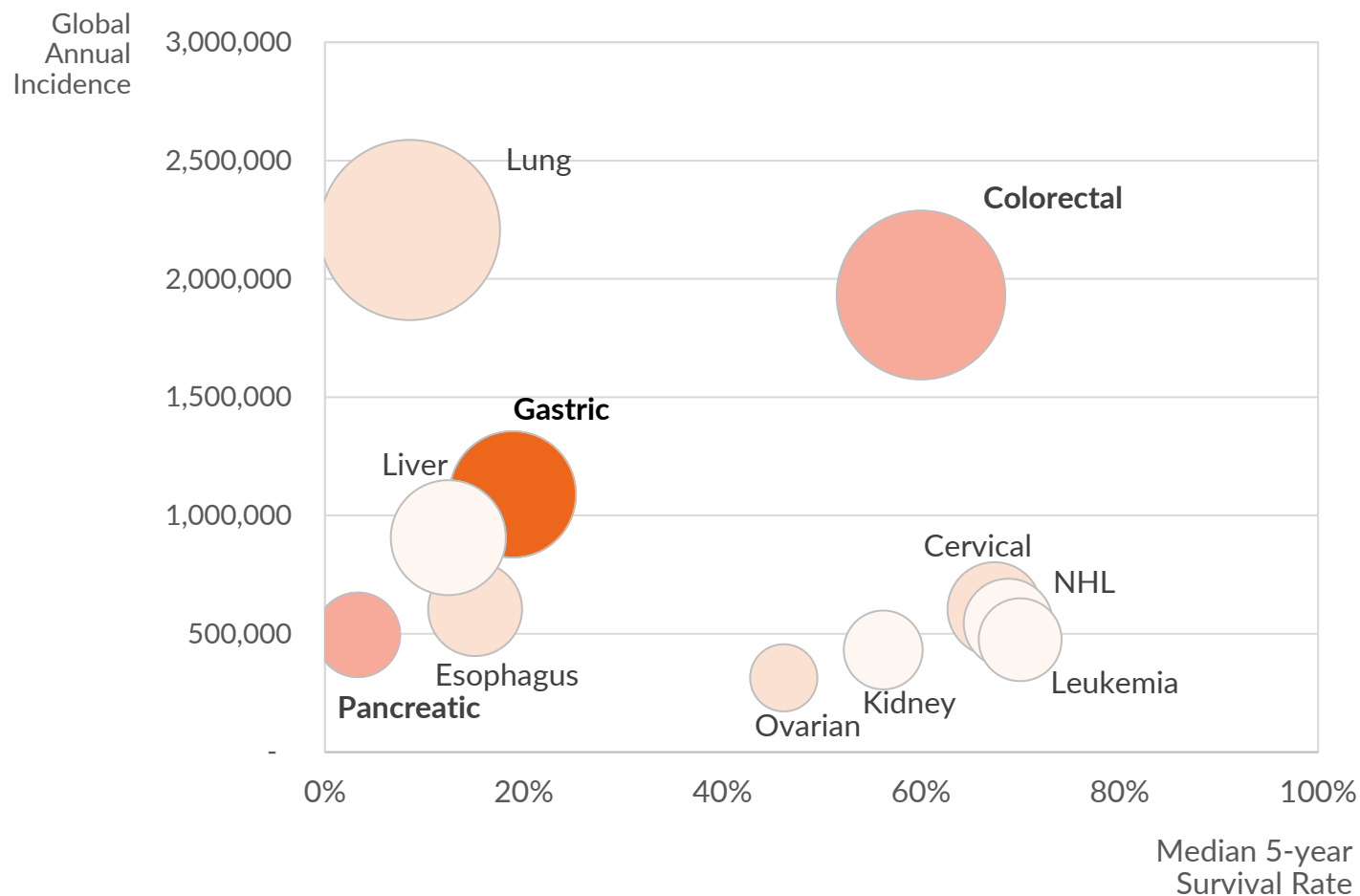


Sources:

International Agency for Research on Cancer (IARC, 2021, input from key opinion leaders and Ascelia analysis)
GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN³



- **Current focus: Gastric cancer**
 - 3rd highest cancer deaths¹
 - Orphan opportunity (U.S. and EU)
 - \$3-4bn market²
- Approved indications for IV irinotecan infusions
- Indications for which IV irinotecan infusions are clinically demonstrated & NCCN recognized
- Indications for which IV irinotecan infusions 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



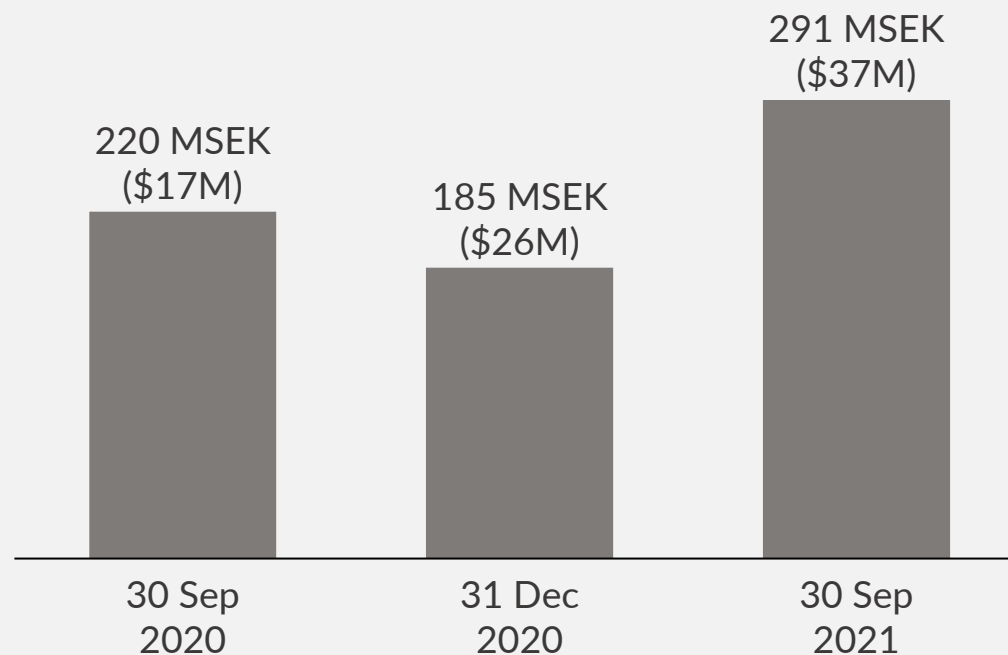
FINANCIALS, MILESTONES AND SUMMARY

FINANCIAL HIGHLIGHTS Q3 2021 – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets of 291 MSEK (\$34 million) by 30 Sep 2021
- Quarterly burn rate in 9M 2021 of ~30 MSEK (\$3-4 million)
- Current cash position provides financing well into 2023

Liquid assets including marketable securities (million)





PRIORITIES AND KEY MILESTONES

- Initiate Phase 2 study for Oncoral (study approval start, IND, expected Q4-2021)¹

- Complete Orvigance Phase 3 patient enrollment (expected H1-2022)¹

- Prepare Orvigance launch (planned for H2-2023)¹

1) Timelines incorporate the currently assessed impact from Covid-19. An extended Covid-19 situation may further affect timelines.

INVESTMENT HIGHLIGHTS



ASCELIA PHARMA (ticker: ACE) – Advancing Orphan Oncology

- Novel drugs with a clear development and market pathway
- Transforming to commercial stage
- Solid financial position

ORVIGLANCE – Phase 3 non-gadolinium liver diagnostic drug

- \$500-600M/year addressable market
- Orphan Drug Designation from FDA
- Ongoing Phase 3 – completion of patient enrollment expected H1-2022

ONCORAL – Phase 2 ready daily chemotherapy

- Oral daily dosing of irinotecan chemotherapy
- Potential for better efficacy and safety
- Phase 2 in gastric cancer

EXECUTIVE MANAGEMENT



Magnus Corfitzen
Chief Executive Officer

- 20+ years experience investing, building and growing Life Science companies
- Board experience 10+ life science companies

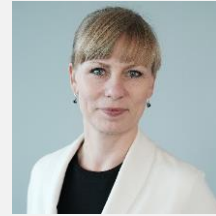
Sunstone

Mekinessy&Company

Danske

Capital

VÆKSTFONDEN



Julie Waras Brogren
Chief Commercial Officer

- 20+ years experience life science. Leadership positions at Novo Nordisk, COO of Bresotec, Canada
- Excellent track record in global product launches and launch preparations. e.g. multi-blockbuster Victoza®



Bresotec

accenture



Carl Bjartmar
Chief Medical Officer, MD, Ph.D.

- 20+ years experience senior positions in big pharma; CMO for Wilson Therapeutics
- Outstanding track record in orphan drug development



Kristian Borbos
Chief Financial Officer

- 20 years experience finance and IR in large caps and banking (sell-side, advisory)
- Completed and lead multiple capital market transactions



BOARD OF DIRECTORS



Peter Benson
Chairman

- Chairman and General Partner at Sunstone Capital Life Science Ventures
- Extensive experience from the Life Science sector from executive positions in Big Pharma and board member in listed companies as well as an investor
- Previous positions include: EVP and President Hospital Care at Pharmacia, VP Marketing & Sales at Kabi Pharmacia Parenterals and Head of Life Science Ventures at the Danish Growth Fund



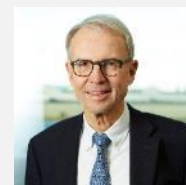
Prof. Hans Maier
Director

- Co-Founder and Managing Partner of BGM Associates GmbH
- Extensive big pharma experience from executive positions within Schering AG and Bayer AG
- Previous positions include: President of the Global Business Unit Diagnostic Imaging at both Schering AG and Bayer AG and part of the Executive Committee of Bayer-Schering AG



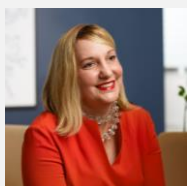
Dr. Bo Jesper Hansen
Director

- Chairman of Laborie and non-executive Director of a number of biotech and pharma companies incl. Orphazyme and Ablynx
- Extensive experience from orphan drug research and development, international marketing and business development
- Previous positions include: Executive Chairman of SOBI and Karolinska Development, CEO and President at Swedish Orphan, non-executive Director of Gambro and Executive Chairman of Topotarget



Niels Mengel
Director

- Founding Partner and CEO at Øresund-Healthcare Capital
- Extensive experience from the healthcare industry as an investor and Board member of Danish Shareholders Association
- Previous positions include: EVP at ISS World Services A/S and Director at PA Consulting Group



Lauren Barnes
Director

- SVP Market Access at Blueprint Medicines (listed on Nasdaq US)
- Extensive expertise and experience in pricing, market access, pre-commercialization and managed markets in particular for the US market. Involved in launch planning of more than 50 drugs
- Previous positions include: VP at Vertex Pharmaceuticals, SVP Avalere Health and led their Reimbursement & Commercialization practice. Various roles at Amgen and the agency that runs the United States Medicare Program, the Centers for Medicare and Medicaid Services



René Spogård
Director

- Chairman and investor in a number of companies including JEKA Fish A/S (fish) and Bollerup Jensen A/S (chemicals) and Flexfunding
- Extensive experience from investing in the healthcare sector and board positions in a public environment
- Previous positions include: Managing Director at TNS Gallup and Director at TNS plc (London Stock Exchange)



Helena Wennerström
Director

- Chief Financial Officer ViaCon Group
- Extensive finance executive experience from listed companies
- Previous position include: EVP and CFO of NASDAQ-listed Bulten AB

