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ASCELIA PHARMA

ADVANCING ORPHAN ONCOLOGY

Capital Markets Day

Carl Bjartmar, Chief Medical Officer

21 October 2020

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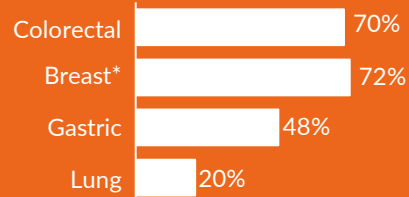
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CLEAR UNMET MEDICAL NEED

Liver metastases

- ... are the most common malignant liver lesions
- Develops in many cancer types and often the cause of mortality

Incidence rate of liver metastasis in various primary cancers ¹⁻⁴



■ % of patients developing liver metastasis per primary cancer type

* Metastatic breast cancer

Contrast-enhanced MRI

- ...is the gold standard for early and accurate detection of liver metastases
- Guideline recommended method for:
 - Detection and visualization of liver metastases
 - Planning of surgery or treatment (localised therapies or drugs)
 - Monitoring and surveillance post-treatment

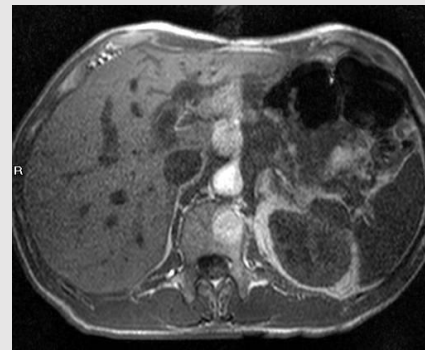
Patients with impaired kidneys

- ...are recommended not to receive the standard gadolinium-based MRI contrast agents
- Risk of serious side-effects
- Gadolinium-based contrast agents carry regulatory black box warnings (FDA, EMA, PMDA etc)
- These patients lack an MRI contrast agent – a clear unmet medical need

MANGORAL – ADVANCING LIVER IMAGING

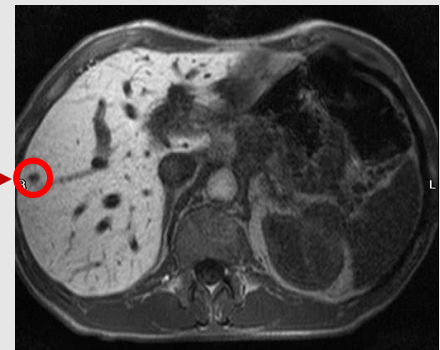
MANGORAL

- Oral manganese-based diagnostic drug for liver MRI
- Targeting patients with severe renal insufficiency
- These patients are at risk of potentially fatal side effects from the products on the market based on gadolinium
- Orphan Drug Designation from FDA
- Ongoing Phase 3 study SPARKLE



Unenhanced liver MRI

(standard of care today in target patient population)



Mangoral enhanced liver MRI

Liver metastasis visualized with Mangoral

MANGORAL – ADDRESSING THE UNMET MEDICAL NEED

TODAY

→ NORMAL KIDNEY FUNCTION
Gadolinium imaging drug

→ POOR KIDNEY FUNCTION
NO imaging drug due to
potentially fatal side-effects
(black-box warning)

TOMORROW

→ NORMAL KIDNEY FUNCTION
Gadolinium imaging drug

→ POOR KIDNEY FUNCTION
~4% of patients
MANGORAL imaging drug
(based on manganese)

Mangoral aims to be the standard of care
liver MRI imaging drug for patients where
gadolinium-based contrast agents may be
medically inadvisable or cannot be
administered

ONGOING PHASE 3 STUDY – SPARKLE

Strong data package for Mangoral

Six phase 1 and 2 clinical studies completed

Consistent strong efficacy readout and safety profile

Blind read study of all imaging data presented at major conferences

- The study with 178 persons further underlined that Mangoral significantly improves MRI performance
- 33% more lesions were detected after Mangoral enhanced MRI
- **Mangoral significantly improved lesion visualisation**
Delineation: p-value <0.0001
Conspicuity: p-value <0.0001

Phase 3 registration-enabling study (study ongoing)

Number of patients

Global study in up to 200 patients

Endpoint



Lesion visualisation

- Lesion border delineation (border sharpness of lesions)
- Conspicuity (lesion contrast compared to liver background)

Comparator



Unenhanced MRI + Mangoral MRI
vs.
Unenhanced MRI

Follow-up



72 hours

Randomisation



No – each patient at his/her own control

Validation



Phase 3 program has been discussed with FDA and EMA

WORLD-CLASS CLINICS PARTICIPATING IN SPARKLE

Global Phase 3 study (SPARKLE)

- 40–50 clinical sites including:
 - Yale University School of Medicine, USA
 - Harvard Medical School, USA
 - Stanford School of Medicine, USA
 - Charité Universitätsmedizin, Germany
 - Karolinska University Hospital, Sweden

Leading expert radiologists participating

- Strong relationship and support
- Awareness of Mangoral
- Validates the unmet medical need

MANGORAL PHASE 3 DEVELOPMENT PROGRESSING

Mangoral indication	Phase 1	Phase 2	Phase 3	Filing	Market
Visualization of focal liver lesions: <ul style="list-style-type: none">• Liver metastases• Primary liver tumors• Malignant or benign	Completed	Completed	Ongoing 2020 – 2H 2021	1H 2022	Q4 2022- 1H 2023