



REDEYE PRE-ASCO SEMINAR STOCKHOLM

2019-05-28

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SCIENCE WORKING WONDERS

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Broad and robust pipeline

PROJECT & MECHANISM	DISEASE AREA	RESEARCH	PRECLINICAL	PHASE I	PHASE II	PHASE III	EXCLUSIVITY	
Remetinostat HDAC INHIBITOR (TOPICAL)	Cutaneous T-cell lymphoma (MF)	Completed					IP: 2034	
	Basal cell carcinoma ¹⁾	Completed		Ongoing			IP: 2034	
Birinapant SMAC MIMETIC (INTRAVENOUS)	Solid tumors (combo with Keytruda®)	Completed			Ongoing		IP: 2034	
MIV-818 NUCLEOTIDE DNA POLYMERASE INHIBITOR (ORAL)	Hepatocellular carcinoma	Completed		Ongoing			IP: 2035	
MIV-828 NUCLEOTIDE BASED DNA POLYMERASE INHIBITOR (INTRAVENOUS)	Blood cancer (acute myeloid leukemia)	Completed	Ongoing					IP: Est 2039
MIV-711 CATHEPSIN K INHIBITOR (ORAL)	Osteoarthritis	Completed					IP: 2034	

¹⁾ Investigator sponsored study at Stanford U.

Completed
 Ongoing

Remetinostat for early-stage MF cutaneous T-cell lymphoma

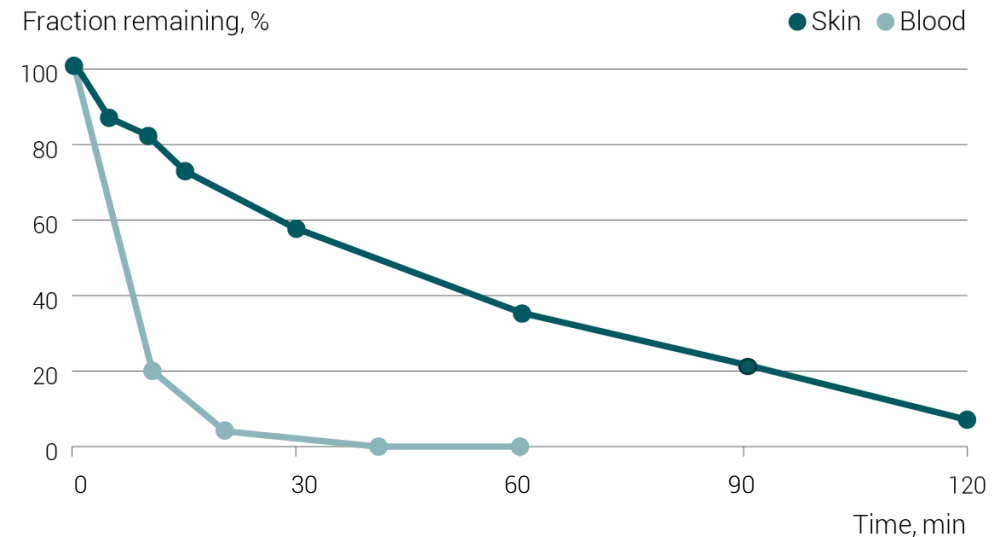
MF-CTCL: orphan blood cancer indication

Cutaneous T-cell lymphoma (CTCL) affects lymphocytes (cells belonging to the immune defense system) located in the skin and typically has a chronic course.

- CTCL is a rare form of non-Hodgkin lymphoma primarily present in the skin. Mycosis fungoides (MF) is the most common form of CTCL
- Annual new cases; US ~ 2,000; EU ~ 3,000; Sweden ~ 25
- Five-year survival: ~ 85%; more than 16,000 US patients live with MF-CTCL
- Skin lesions and severe itching are common and affect patients quality of life
- Early stage disease lasts for long periods and requires well tolerated therapy
- Available treatments, including systemic HDAC inhibitors, have severe side effects

Remetinostat: for treatment of early stage MF-CTCL

- Remetinostat is a histone deacetylase (HDAC) inhibitor
- Remetinostat's unique chemistry and topical formulation provides for activity in skin and rapid degradation in blood
- Approved HDAC inhibitors not used in early-stage MF-CTCL patients
- US orphan drug designation



Remetinostat: clinical proof-of-concept phase II MF-CTCL study

Twelve months phase II data shows reduction in both lesions and severe itch

Dose	1% 1x/day n=20	0.5% 2x/day n=20	1% 2x/day n=20
Lesion responses ¹	20%	25%	40%
Patients with clinically significant pruritus	(40%) n=8/20	(30%) n=6/20	(50%) n=10/20
Pruritus responses	38%	50%	80%

Well tolerated:

- No HDAC inhibitor-associated systemic adverse events
- Median time on treatment: 336 days (1% 2x/day dose)

1) Confirmed responses based on CAILS, the Composite Assessment of Index Lesion Severity

Remetinostat: next steps

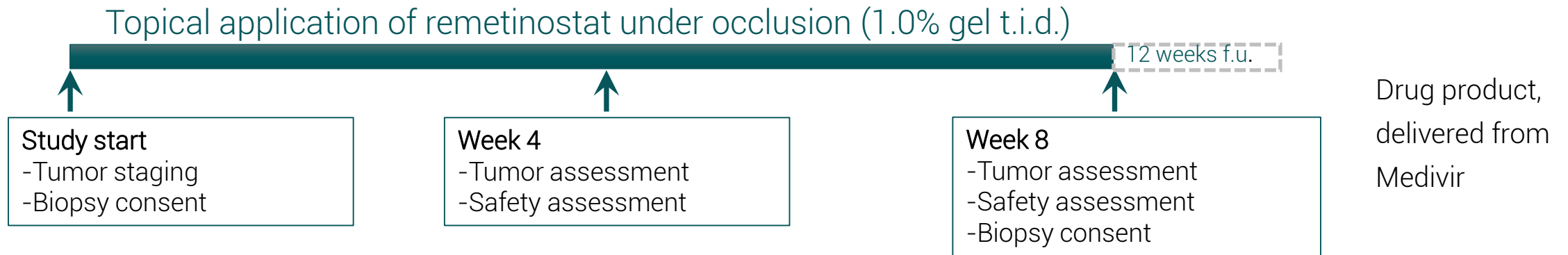
- Medivir will further define a planned phase III design based on the requirements clarified by the FDA
- One phase III study expected to be sufficient for FDA
- Phase III study will enroll treatment-experienced patients
- Medivir aims to identify a business partner for the further development of remetinostat

Retinostat opportunity in other skin cancers

Investigator-initiated phase II study in BCC ongoing

Basal cell carcinoma

- The most common form of cancer in humans occurring in the skin
- Surgery is standard of care, but there is a need for efficacious and safe treatments when surgery is impractical, e.g. multiple lesions and/or difficult treatment sites



Study design

- 8-week open-label phase II clinical study to assess efficacy of remetinostat in patients with BCC
- Primary objective: Determination of suppression of BCC growth & ORR (overall response rate) using RECIST v1.1 criteria

Investigator: Kavita Sarin, Stanford University School of Medicine in California, USA

Interim results presented at SID Annual meeting May 2019

- The ORR, at least a 30% decrease in longest diameter, was 64% (9/14).
- The average decrease in tumor area is 70% (n=14), while the average decrease in longest diameter is 62% (n=14). 43% (6/14) of tumors were fully cleared.
- No systemic toxicities have been observed.
- Grade 2 eczematous local site reactions occurred in 71% (10/14) tumors treated with topical remetinostat under bandage occlusion.

More information can be found at www.medivir.com



Birinapant: Uniquely potent against selected solid tumors

Solid tumors: large unmet medical needs

Many patients with solid tumors have few or no options and are in need of effective medicines to extend life. The immuno-oncology medicine Keytruda[®] on its own is not sufficiently effective in treatment of certain solid tumors.

Colorectal cancer indication (CRC)

- The second most common cancer in women and the third in men
- Estimated new cases 2018: US: ~ 140,000; EU: ~ 490,000; Sweden: ~ 6,200
- Five-year survival when metastatic: 14%

Other cancer indications

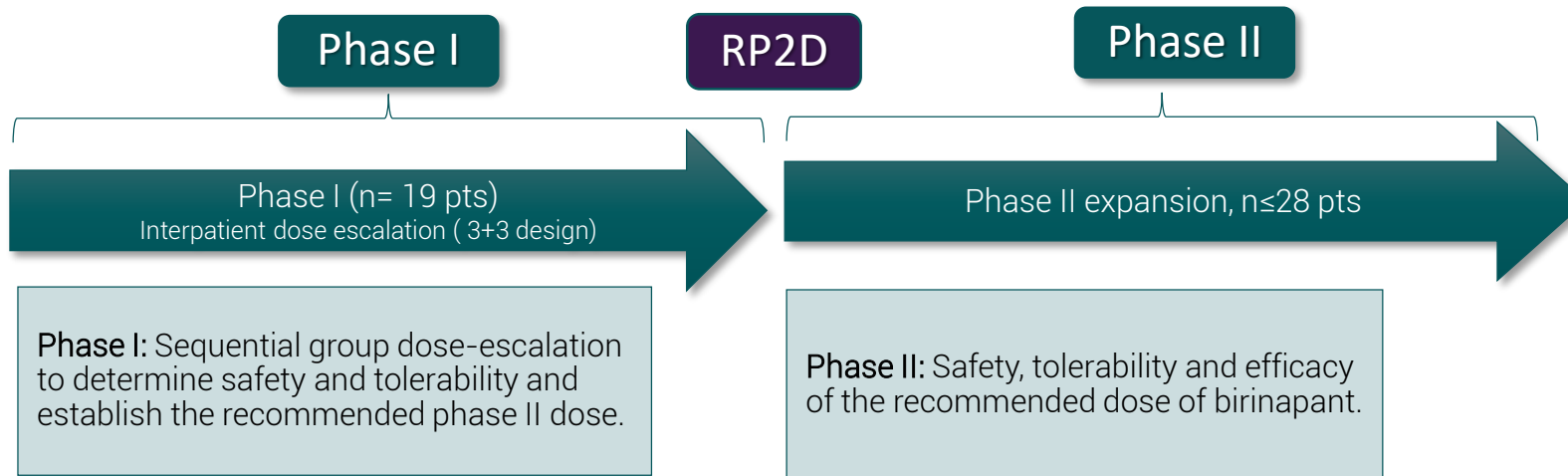
- Ovarian cancer, the leading cause of mortality due a gynecologic tumor
 - Estimated new cases 2018: US: ~ 22,000; EU: ~ 23,000 Sweden: ~ 700
 - Five-year survival: 47%
- Cervical cancer, the third most common cancer in women world-wide
 - Estimated new cases 2018: US: ~ 13,000; EU: ~ 60,000; Sweden: ~ 450
 - Five-year survival: 62.5%

Birinapant may benefit patients with inadequate response to immuno-oncology therapies

- Birinapant, a SMAC mimetic, enables tumor cell death and augments the immune system
- Great potential to improve treatment of cancers when combined with immuno-therapy
- Ongoing collaboration with Merck for a phase I/II study in solid tumors
 - Joint development committee oversees the study
 - Keytruda® provided at no cost by Merck
 - Medivir retains full global rights to birinapant and data

Birinapant/Keytruda[®] combination - phase I/II study ongoing

- Dose escalation completed; December 2018: n=19
 - One CRC patient has achieved partial response, which had been maintained for over 1 year
 - Two patients had stable disease for 18 weeks
 - Safety and tolerability: No concerns
 - Phase II dose selected at 22 mg/m²



- In late December 2018 the first patient was dosed in the phase II part of the study



MIV-818: Nucleotide prodrug for the treatment of liver cancer

Liver cancer focus: hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma

- HCC is the third leading cause of cancer-related deaths worldwide
 - Estimated new cases 2018: Asia: ~ 610,000; US: ~ 42,000; EU: ~ 82,000; Sweden: ~ 550
 - Orphan disease in Western markets, but one of fastest growing and most deadly cancers in US
 - High incidence in Asia including China - Hepatitis B & C very common
 - Five-year survival: 18%
 - Genetically heterogeneous leading to limited effect of molecularly targeted therapies
- Intrahepatic cholangiocarcinoma is the second most common primary liver tumor
 - Median survival is only twelve months
- Existing treatment options provide very little survival benefit

MIV-818: prodrug for enhanced efficacy and safety in liver cancer therapy

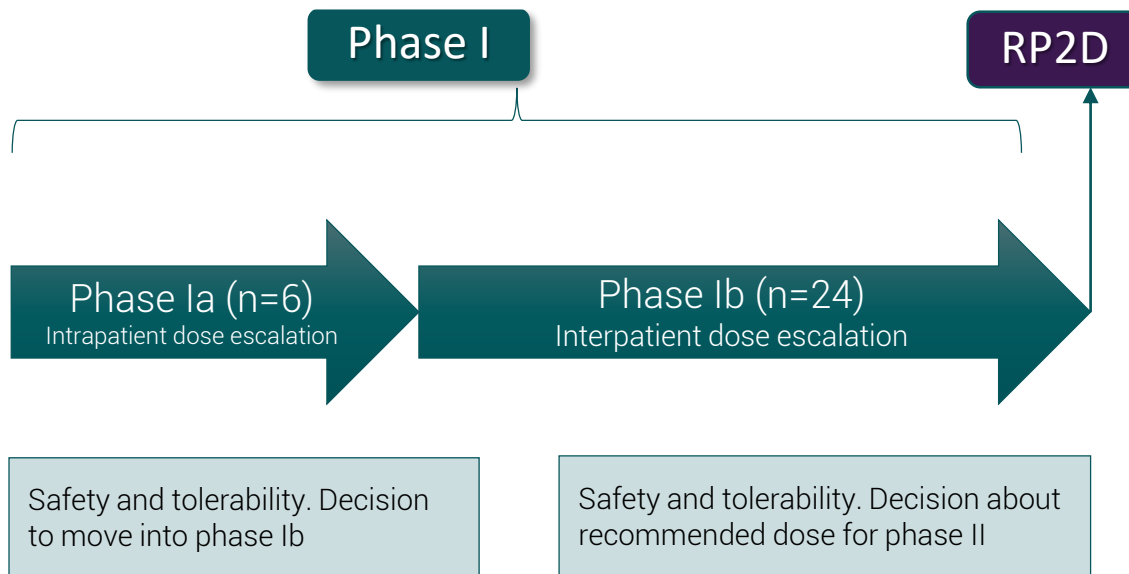
Troxacitabine

- Clinically active but failed due to systemic dose-limiting toxicities



MIV-818

- Enhanced activity
- Selectivity for cancer
- Improved delivery to the liver
- Oral administration
- Limited systemic side effect



Summary

Strategic focus on cancer indications with high unmet need

Near term value inflection points

- MIV-818: completion phase Ia study – Q2 2019
- Birinapant/Keytruda[®]: fertility analysis completed – Q4 2019