



MEDIVIR BIO INTERNATIONAL

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SCIENCE WORKING WONDERS

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Brief intro to Medivir

- Founded in 1988
- Now focused on clinical development in oncology
- Located in Stockholm, Sweden
- Listed on Nasdaq Stockholm's Small Cap list
- More info on www.medivir.com

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

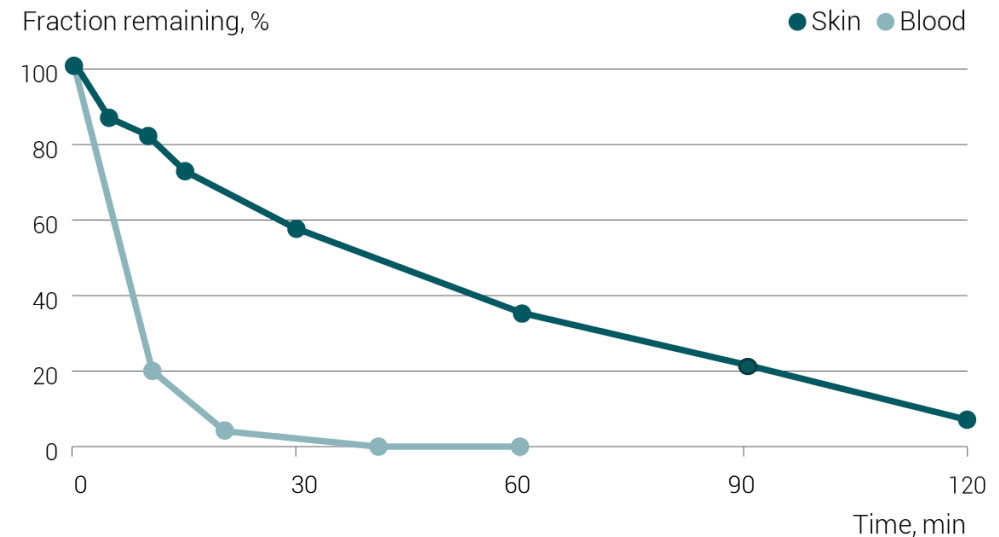
MF-CTCL: orphan blood cancer indication

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



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)

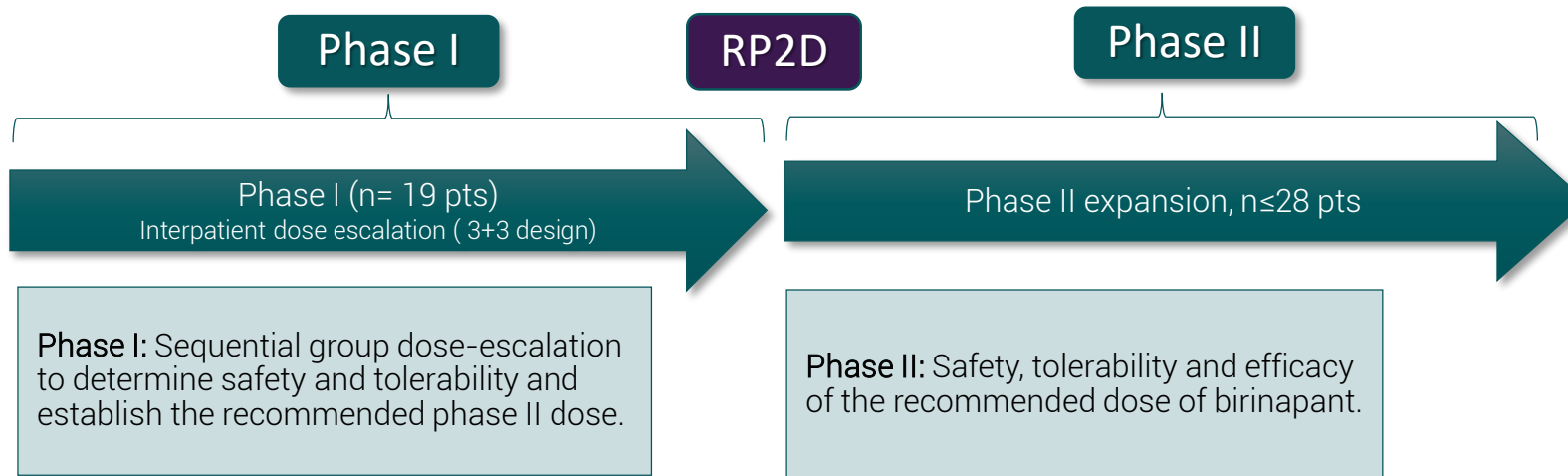
- The second most common cancer in women and the third in men
- Estimated new cases 2018: US: ~ 140,000; EU: ~ 490,000; Sweden: ~ 6,200
- Five-year survival when metastatic: 14%

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

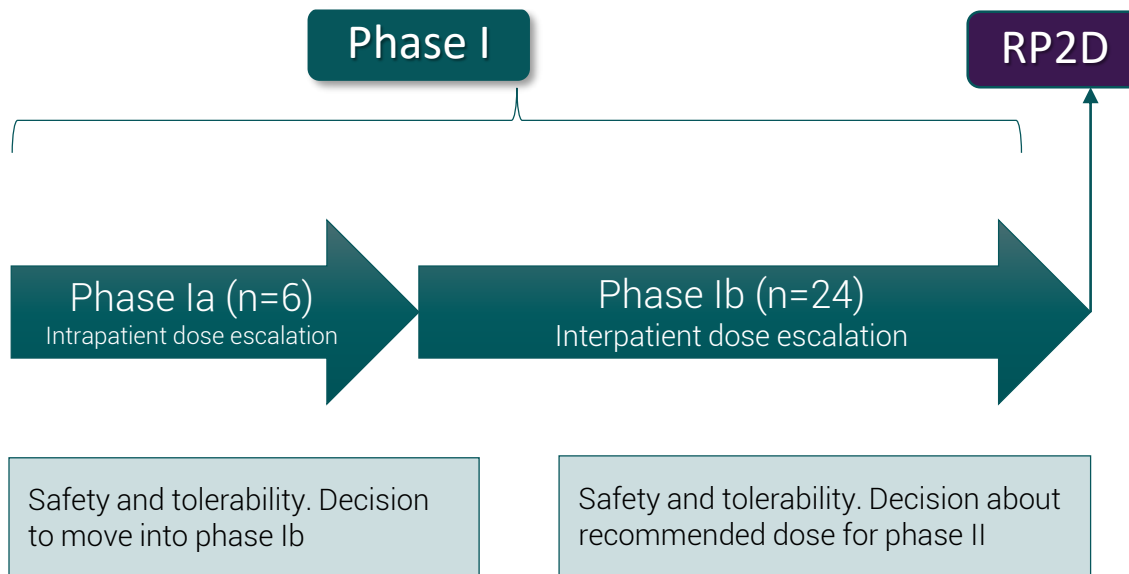
Troxacitabine

- 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



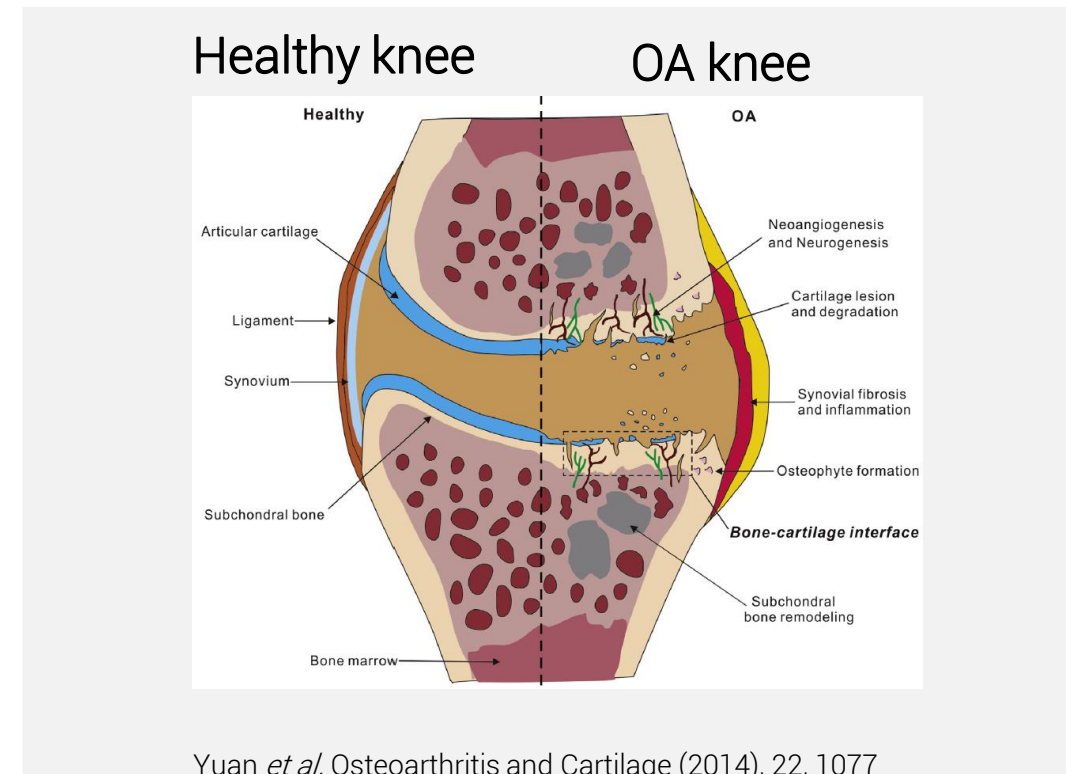


MIV-711: Cathepsin K inhibitor with FDA fast track status

Osteoarthritis (OA): the most common form of joint disease

- Affects ~240m adults worldwide
- Prevalence increasing due to aging population and obesity epidemic
- Current treatments focus only on pain relief
- Large unmet medical need for a disease-modifying drug (DMOAD) with potential to slow, halt or reverse the progression of OA
- New US FDA guidelines in OA may enable pathway for accelerated regulatory approval
- New draft FDA Guidance published August 2018, focused on structural endpoints in OA development

Cathepsin K protease is involved in the breakdown of collagen I in both bone and collagen II in cartilage



MIV-711: positive effects on joint structure and signals of benefit on clinical symptoms

- Study design (MIV-711-201): 3 arms, 26 weeks treatment
- Study design (MIV-711-202): 200 mg MIV-711, 26 additional weeks

MIV-711-201: Change from baseline vs week 26

	Placebo n=80	MIV-711 100 mg QD n=80	MIV-711 200 mg QD n=80
Femur bone area (mm ²)	23.2	8.1	8.2
Cartilage thickness (mm)	-0.066	0.008	-0.017

- A trend consistently favoring MIV-711 arms in all predefined analyses of clinical outcomes, e.g. knee pain and knee function
- Safety and tolerability profile supporting advancement of MIV-711 as a disease-modifying OA drug candidate

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