



CORPORATE PRESENTATION
OCTOBER 2019

MEDIVIR

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About Medivir

- Founded in 1988
- Listed on Nasdaq Stockholm
- Market cap around 590 million SEK, cash position at Q2-19: 192 million SEK
- Has developed two drugs from idea to market: Xerclear and Olysio
- Has established over 20 partnerships that generated over 400 million USD
- Current focus: oncology drug development and business development
- Highly competent and effective organization; 14 FTEs

Experienced leadership team



Uli Hacksell, PhD; CEO
Uppsala U, Astra, ACADIA



Christina Herder, PhD; COO
Pharmacia, Biovitrum



Magnus Christensen, MBA; CFO
O'Learys Trademark, ICA Sverige, HKScan



Linda Basse, MD; PhD; CMO
Abbott, Topo Target, Genmab, Zealand



Rikard Höse, MD; Med Dir.
Karolinska U Hospital, Novartis



Fredrik Öberg, PhD; CSO
Uppsala U



Linda Palmér, Sr Dir Clin Ops
Pfizer

Medivir – Oncology focused biotech with major upside

CLINICAL DEVELOPMENT

- Birinapant/Keytruda® combination: Ongoing phase II MSS CRC
 - Interim data in Q4-19
- MIV-818: Ongoing phase I study in liver cancer
 - Early proof of concept in phase Ia (Q2-19)
 - Phase Ib to start in Q4-19
- Remetinostat: Ongoing phase II ISS study for BCC
 - Positive interim data in Q2-19

BUSINESS DEVELOPMENT

- Out-licensing of phase III-ready MIV-711 for OA
- Partnering of phase III-ready remetinostat for CTCL
- Finding new homes for our preclinical research programs

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)	MSS colorectal cancer (combo with Keytruda®)	Completed				Ongoing		IP: 2034	
	Head & Neck cancer (with radiation) ²⁾	Completed			Ongoing				
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.
- 2) Investigator sponsored study at US NCI.

Completed Ongoing

Remetinostat for early-stage MF cutaneous T-cell lymphoma

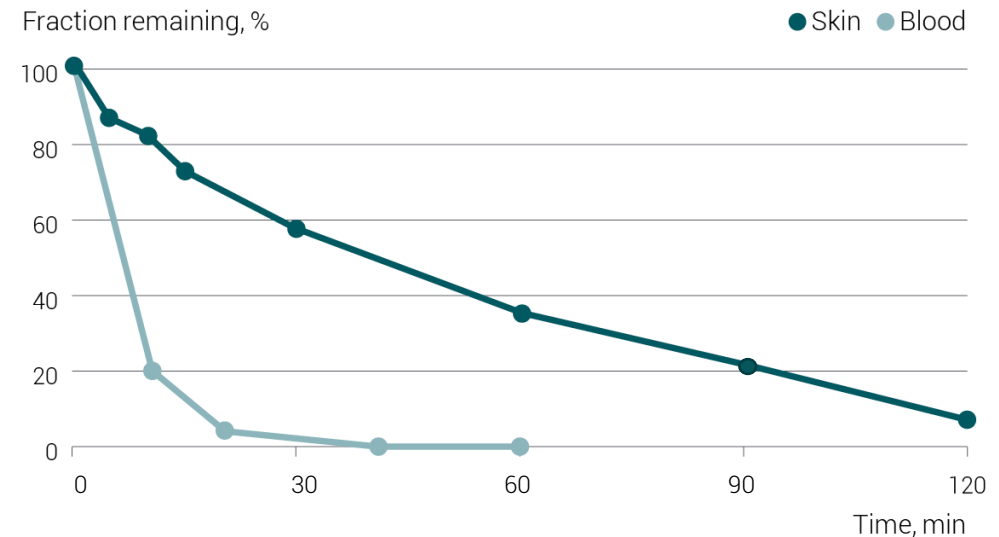
MF-CTCL: orphan blood cancer indication

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, such as Vorinostat and other systemic HDAC inhibitors, bexarotene, and Valchlor, 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 has defined a 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 seeks to identify a business partner for the further development of remetinostat

Remetinostat for basal cell carcinoma

Remetinostat: interim phase II BCC data presented at SID 2019*

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

Interim phase II data

- Fifteen patients recruited in open-label study
- Treatment: retinostat gel 1% (with occlusion) 3 times/day for six weeks
- ORR ($\geq 30\%$ in longest diameter): 64%
- 43% of tumors fully cleared
- No systemic toxicities
- Grade 2 reversible eczematous reaction in 71% of patients

* Urman et al., An open label phase 2 clinical trial of topical retinostat for basal cell carcinoma



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/Keytruda[®] studied in cancer patients with solid tumors

- Birinapant, a bivalent 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 combination study of birinapant/Keytruda[®] 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
- Phase I
 - 19 patients with solid tumors were evaluated. Highest dose tested recommended for phase II
 - 1 MSS colorectal cancer patient has partial response. Continued treatment after 80 weeks*
- Phase II
 - 15 patients with MSS colorectal cancer have been recruited
 - Interim/futility analysis in Q4 2019

* ASCO 2019 oral presentation: Schilder et al., Determination of the Recommended phase 2 dose of birinapant in combination with pembrolizumab: Results from the dose escalation phase of BPT-201.



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

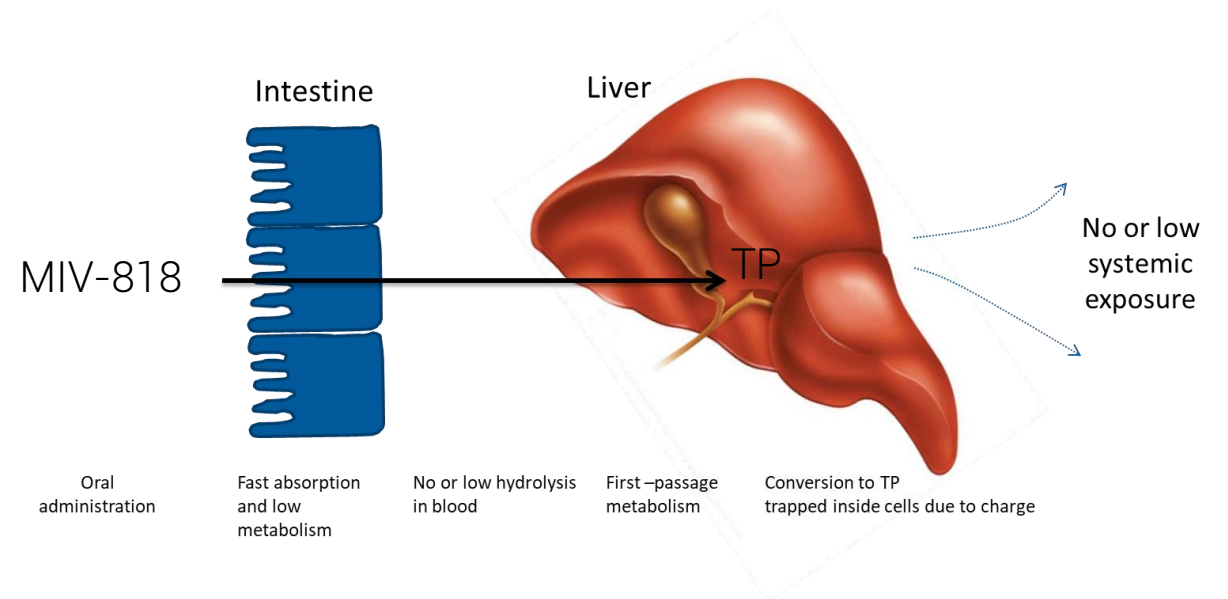
Primary liver cancer: hepatocellular carcinoma and intrahepatic cholangiocarcinoma

- Hepatocellular carcinoma (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: 11% for regional disease and 2% for distant disease
 - Genetically heterogeneous leading to limited effect of molecularly targeted therapies
- Intrahepatic cholangiocarcinoma (iCCA) is the second most common primary liver tumor
 - Median survival is only 12 months
- Existing treatment options provide very little survival benefit with no drugs approved for iCCA

MIV-818 for treatment of liver cancer

Liver targeting

- MIV-818 is a troxacitabine (TRX)-based prodrug, designed to increase generation of the active metabolite TRX triphosphate (TP) in the liver after oral dosing
- When incorporated into DNA, TP causes double strand DNA breaks and cell death



Prodrug approach

- Increase generation of TP in liver by first-pass uptake and rapid intracellular conversion to non-permeable charged metabolites
- Minimize systemic exposure to troxacitabine

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

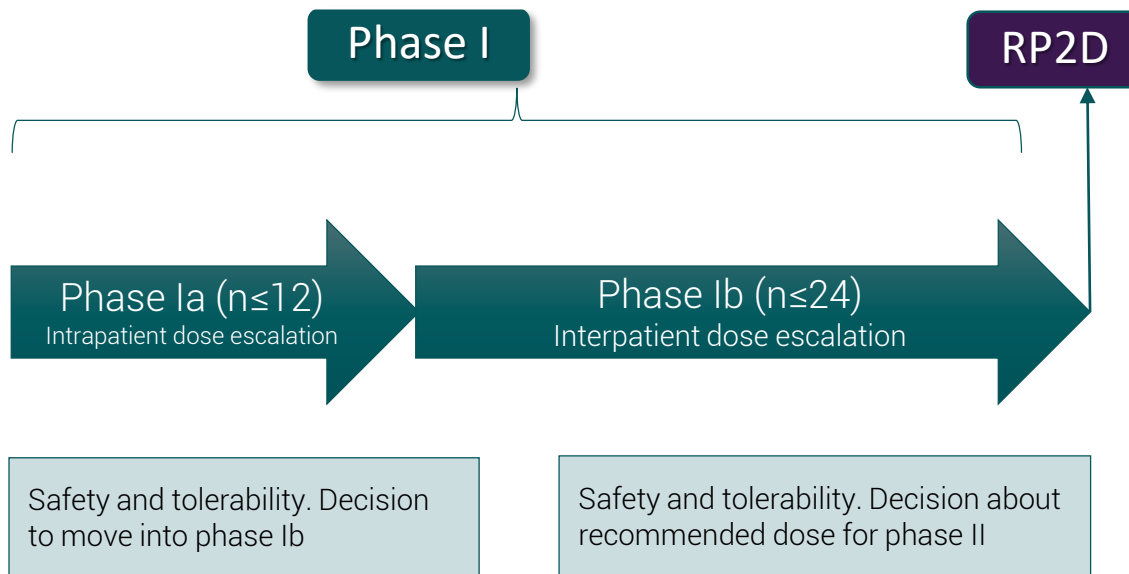
Troxacitabine (iv)

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



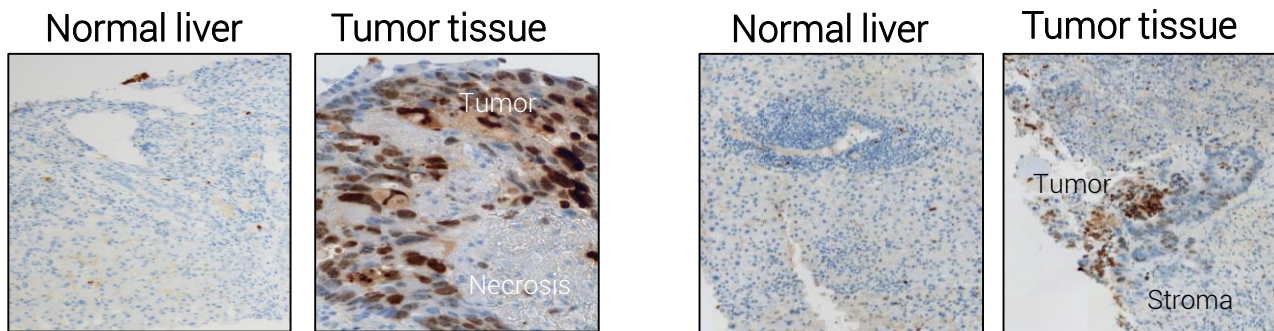
MIV-818 (oral)

- Enhanced activity
- Selectivity for cancer cells
- Improved delivery to the liver
- Limited systemic side effects



MIV-818: Proof-of-concept phase Ia data

- Data analyzed from six patients with advanced liver cancer treated with escalated doses of MIV-818
- MIV-818 was well tolerated. Lowering of blood counts in the patient at the highest dose suggests that we are close to the maximal tolerated dose
- Clear signs of effect, measured as DNA damage, in biopsies from liver cancer tissue. No DNA damage seen in normal liver tissue
- DNA damage also observed in hypoxic liver cancer regions
- Signs of effect on the size of the liver tumors in several patients
- Tumor selective effect observed at low MIV-818 levels in plasma



Data from Patient 2

Data from Patient 4

Clear evidence of pH2AX induction (brown nuclear stain) resulting from DNA-damage in tumor but not in normal liver tissue

MIV-828: For acute myeloid leukemia

MIV-828: Summary

Acute myeloid leukemia (AML) leads to an overproduction of abnormal immature cells in the bone marrow and prevents development of normal blood cells, which could lead to anemia, bleeding episodes and a high susceptibility for severe infections.

- Expected new cases 2018: US: ~ 19,500; EU: ~ 43,000; Sweden: ~ 350
- Affects all ages, median age at diagnosis 68 years in the US
- Five-year survival: 50% in younger patients (<60y) and less than 10% in patients > 70y

Opportunity in hematological cancers

- Better tolerated and more effective agent in patients with AML and other hematological cancers
- Initial development in relapsed/refractory AML patients

Profile of MIV-828

- Nucleotide prodrug based on one of Medivir's proprietary areas of expertise
- Active metabolite shown to have potent anti-leukemic activity in preclinical in vivo models
- Increased activity and reduced susceptibility to pharmacologic resistance mechanisms of prodrugs
- Preclinical activity also demonstrated against T-cell lymphoma

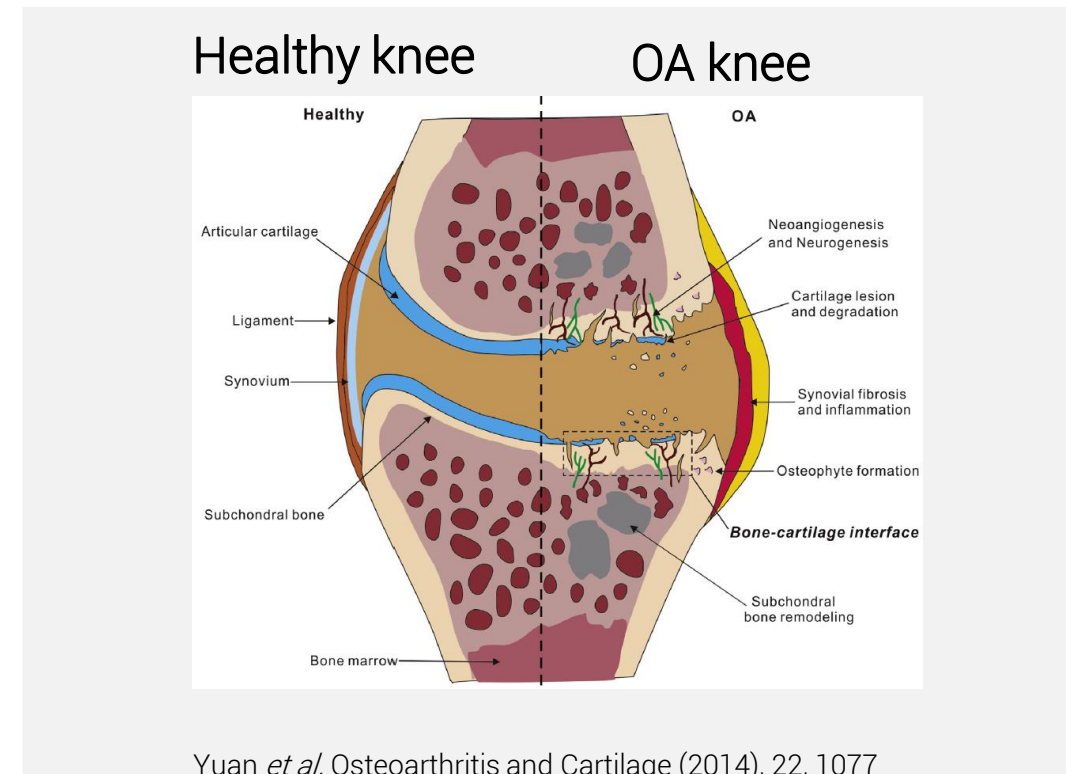


MIV-711: Cathepsin K inhibitor with FDA fast track status

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

Milestones

Medivir - recent and upcoming milestones

MIV-828: CD nomination	Q4 2018	✓
Birinapant/Keytruda®: completion of phase I	Q4 2018	✓
MIV-818: Start of phase Ia	Q4 2018	✓
Remetinostat: EoP2 meeting with FDA	Q4 2018	✓
Birinapant/Keytruda®: start of phase II	Q4 2018	✓
MIV-818: POC in phase Ia	Q2 2019	✓
New organization in place	Q3 2019	✓
Birinapant/Keytruda®: phase II futility analysis	Q4 2019	
MIV-818: Planned start of phase Ib	Q4 2019	