

MEDIVIR

A laboratory setting with two blue microplates in the foreground, each containing several small vials. The background is dark and out of focus, showing laboratory equipment. The overall lighting is blue and dim.

Improving life for cancer patients
through transformative drugs

July 2018

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Medivir in Brief

Improving life for cancer patients through transformative drugs

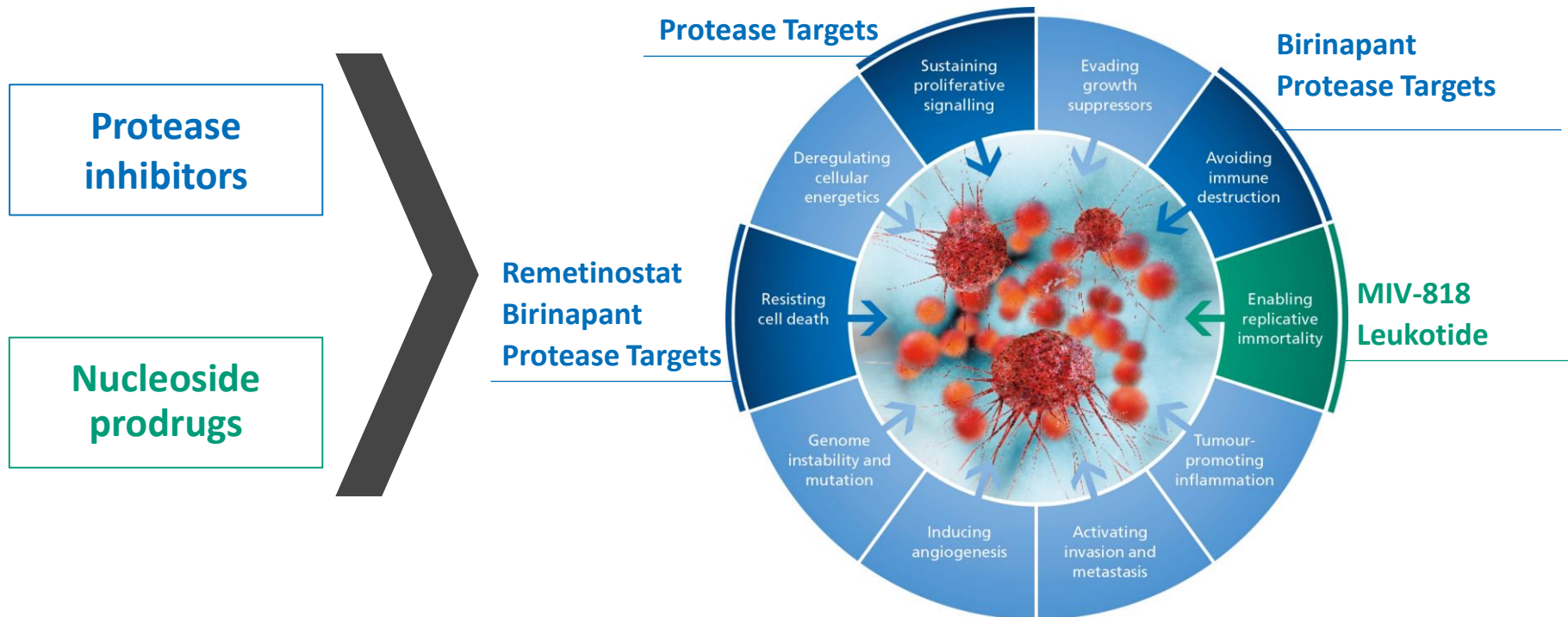
- Using **world-class scientific expertise** to bring new therapies to cancer patients
- **Clinical pipeline** composed of projects with **multi-billion dollar sales** potential as well as **orphan cancer drug candidates**
- Strong commercial focus – delivered more than **20 global partnerships** and **2 products from idea to market**

Basic facts

- Headquarters in Huddinge, Sweden
- 77 employees, 43 with PhDs
- Listed on the Nasdaq Stockholm, ticker: MVIR
- Current market capitalization: SEK 800m (~USD 90m)¹
- Website: www.medivir.com



Leveraging scientific expertise to build pipeline in oncology



Adapted from: The Hallmarks of Cancer: The Next Generation.
Hanahan and Weinberg, Cell (2011), 144, 646-674

Oncology drug development in areas of high unmet need

Strong and balanced development pipeline based around areas of scientific expertise and focused on cancer

	Project, Mechanism	Disease area	Clinical phase				Market
			Preclinical	Phase I	Phase II	Phase III	
Cancer	Remetinostat Topical HDAC inhibitor	Early-stage cutaneous T-cell lymphoma	[Blue bar spanning Preclinical, Phase I, and Phase II]				~\$1b US only
	Birinapant SMAC mimetic	Solid tumors (combo with Keytruda®)	[Blue bar spanning Preclinical and Phase I]				Blockbuster
	MIV-818 , Nucleotide DNA polymerase inhibitor	Hepatocellular carcinoma	[Green bar spanning Preclinical]				Orphan US/EU Significant Asia
	MIV-711 Cathepsin K inhibitor	Osteoarthritis	[Blue bar spanning Preclinical, Phase I, and Phase II]				Blockbuster

■ Protease related
■ Nucleot(s)ide related

Collaborations enhance the value of programs

Academic



Industrial

Product/Project

Zoviduo®/Xerclear
(labial herpes)
acyclovir + hydrocortisone

MIV-802 (HCV)
*Nucleotide NS5B
polymerase inhibitor*

Platform Link

Nucleoside
analogue

Nucleotide

Partners



Status

Marketed

Phase I ready

Medivir Interests

- Royalties from sales
- Approval milestones for additional OTC switches
- Development milestones
- Royalties from sales

Competences from discovery through regulatory approvals

Management team with extensive experience and proven track record of successful development



CHRISTINE LIND, President and CEO

- EVP, Business Development at Medivir
- VP, Business Development, LifeCell Corporation
- Biotech and pharma strategic advisory and capital raising at Merrill Lynch & Co. and GKM & Co.
- B. Sc. Finance and Info Systems, NYU and MBA, Columbia Business School



RICHARD BETHELL, Chief Scientific Officer

- 28 years drug discovery and development in oncology and infectious disease
- VP, Biology/DMPK (Boehringer Ingelheim (Canada))
- VP, Therapeutic Research (Shire)
- Pfizer and GlaxoSmithKline R&D
- Doctor of Philosophy (D. Phil.) in chemistry from Oxford University



ÅSA HOLMGREN, EVP Strategic Regulatory Affairs

- Head of Regulatory Affairs at Orexo AB
- Various large pharmaceutical companies, including 12 years as Senior Global Regulatory Affairs Director at AstraZeneca, and at AstraZeneca in Canada and Japan
- M. Sc. in Pharmacy, trained Uppsala University



ERIK BJÖRK, Chief Financial Officer

- CFO for AstraZeneca Sweden Operations
- 11 years with Procter & Gamble, in global finance leadership positions in Switzerland, UK and Sweden
- MSc in Finance and LLM from Lund University



CHRISTINA HERDER, EVP Strategic Business Development

- CEO of Modus Therapeutics
- Director, Corporate Development at Sobi
- Project & Portfolio Management at Biovitrum
- Current member of the boards of PCI Biotech and Idogen
- Ph. D. in physical chemistry from Royal Institute of Technology and MBA from Stockholm University



DANIEL ERIKSSON, Chief Information Officer

- Various IT roles relating to security, decision support, innovation, and digitalization
- Most recently, Technical Director for G4S Risk Management
- PhD Coventry University and BSc in Systems Science, Linköping University

Cancer biology, chemistry, intellectual property, DMPK, CMC, toxicology, clinical development, regulatory strategy, business development

77 employees, 43 with PhDs,
18 nationalities, balanced gender split



MIV-711 for Osteoarthritis

MIV-711: ORAL ONCE DAILY CATHEPSIN K INHIBITOR WITH FDA FAST TRACK STATUS FOR OA DISEASE MODIFICATION

No existing disease-modifying drug for osteoarthritis

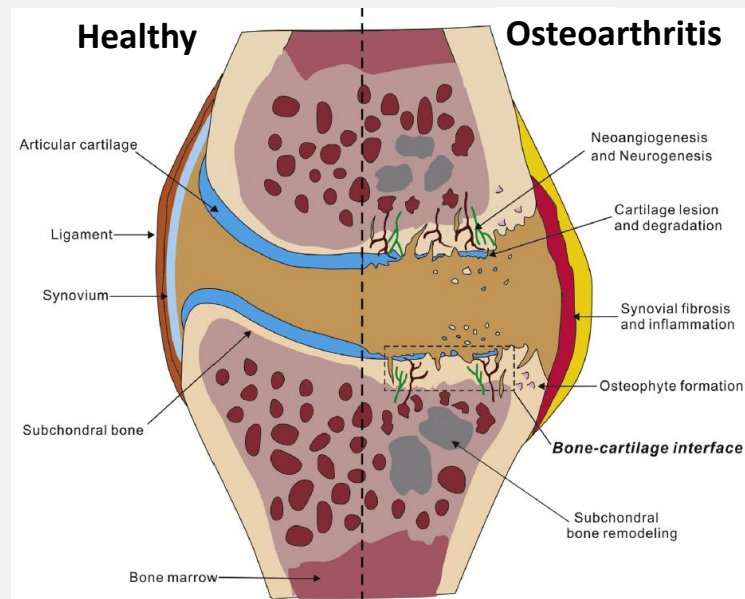
Blockbuster revenue opportunity for a disease-modifying osteoarthritis drug

- Affects >30m adults in the US, and ~240m worldwide
- Prevalence increasing due to aging population and obesity epidemic
- Current treatments are insufficient focusing only on symptom relief



Disease involves both bone and cartilage

- Cathepsin K protease involved in the breakdown of collagen in both bone and cartilage



Yuan *et al.* Osteoarthritis and Cartilage (2014), 22, 1077

MIV-711: ORAL ONCE DAILY CATHEPSIN K INHIBITOR WITH FDA FAST TRACK STATUS FOR OA DISEASE MODIFICATION

Phase IIa data show unprecedented OA disease modification after 6 months

Potential disease-modifying convenient osteoarthritis drug

- Only cathepsin K-inhibitor in development for osteoarthritis
- Once daily oral administration

Strong patent position

- Expected patent life to ~2034, including extensions

US FDA Fast Track designation

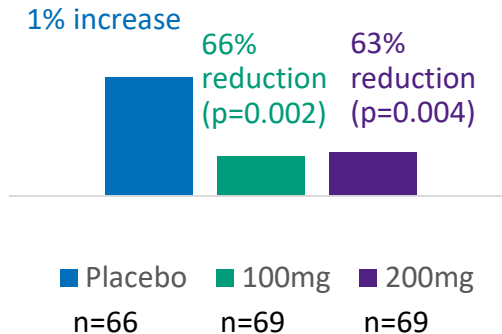
- Granted by FDA October 2017

“The finding that MIV-711 slows the degenerative changes on both bone and cartilage in knees affected by OA is an enormously exciting finding”

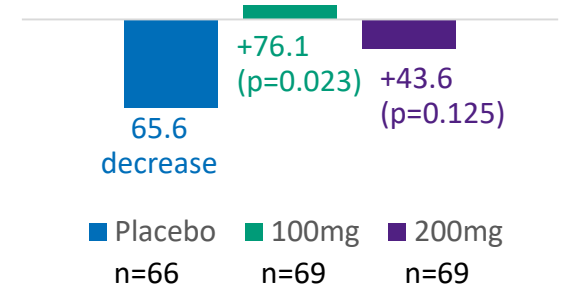
Professor Philip Conaghan, Professor of Musculoskeletal Medicine at the University of Leeds, UK, and MIV-711 lead investigator

Benefit on both bone and cartilage in Phase IIa study

Change in medial femur joint bone area (%)



Change in central medial femur cartilage thickness (µm)

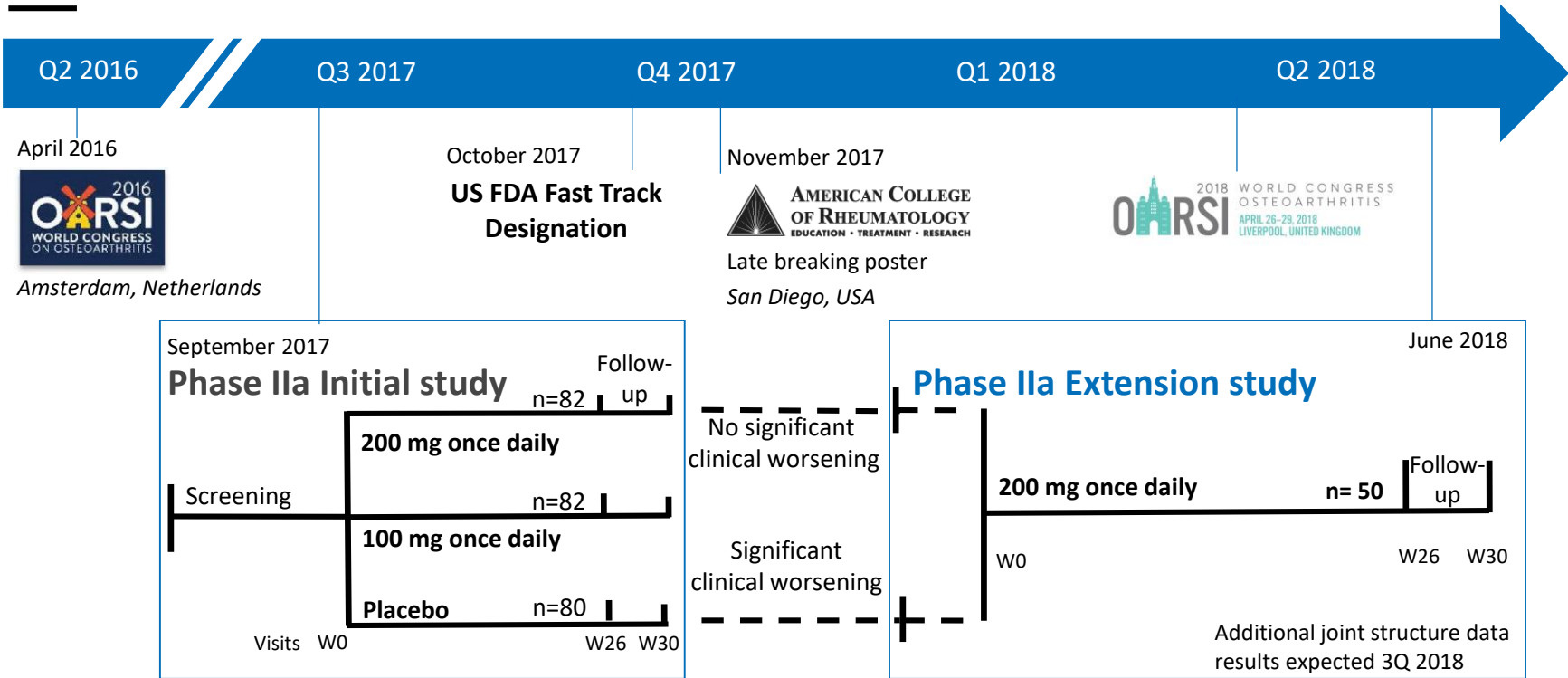


- MIV-711 consistent tendency to improve outcomes across all pain and other patient reported symptoms vs. placebo and sustained with additional 6 months treatment
- Acceptable safety and tolerability profile

<http://acrabstracts.org/> Abstract 14L

MIV-711: ORAL ONCE DAILY CATHEPSIN K INHIBITOR WITH FDA FAST TRACK STATUS FOR OA DISEASE MODIFICATION

MIV-711: Building towards partnership

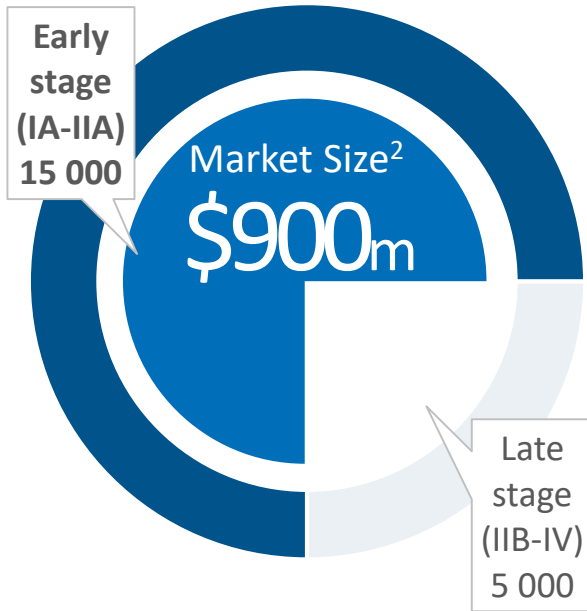


- Partnering discussions ongoing

Remetinostat for early-stage CTCL

CTCL: orphan blood cancer with significant market opportunity

US CTCL patients¹: orphan disease



Early Stage CTCL: Disease background

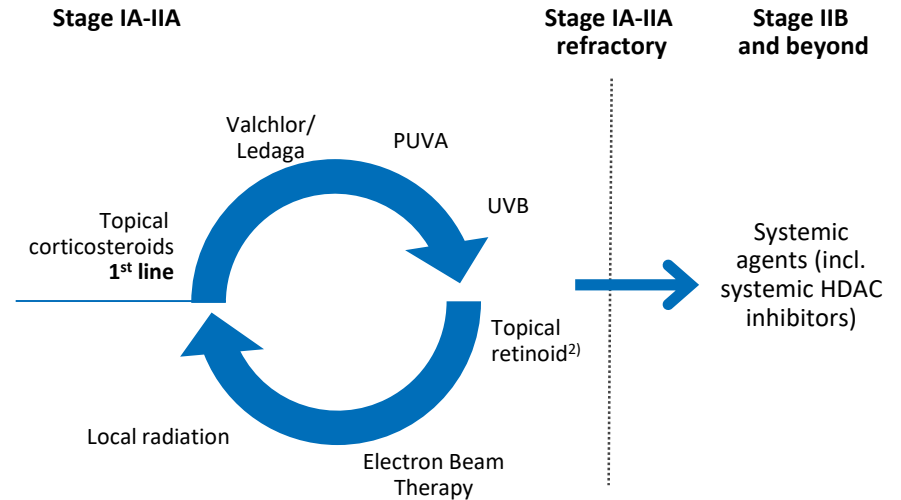
- Confined to the skin
- High 5-year survival rates (~85%)
- Patients remain at this stage for extended periods and require long-term treatment
- Significant quality of life issues, especially pruritus (itch)

Key unmet need:
balance of efficacy and long-term tolerability

Patients & physicians need new treatments for early-stage CTCL

- Currently approved early-stage CTCL drugs lack sustained efficacy and/or tolerability and are highly irritating
- Valchlor/Ledaga is a topical alkylating agent (the active agent in mustard gas)
- No single treatment for long-term use
- At this early stage, physicians avoid using systemic drugs, including other HDAC inhibitors, due to the side effect profile

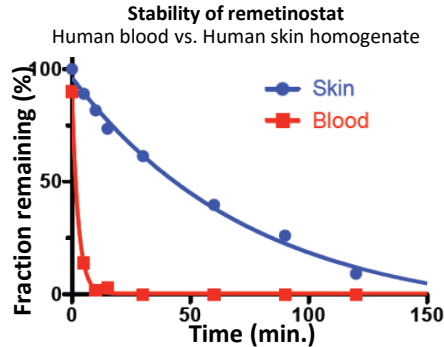
Currently approved therapies by disease stage



Remetinostat potential to meet patients' key unmet need

Designed to act only where needed

- HDAC inhibitors¹ approved in late-stage CTCL patients but not in early-stage patients due to systemic toxicities
- Reteminostat's unique design and topical application provides activity in skin, but rapid degradation in blood



- Expected patent life to ~2034 (including extensions)
- US orphan drug designation

“As a topical, skin-specific HDAC inhibitor, reteminostat has the potential to be efficacious and have an improved safety profile compared to other available treatments.”

Youn Kim M.D.
Stanford University Medical Center, USA

Addresses key unmet need with positive Phase II data

Effect on lesions & reduction of pruritus (itch)

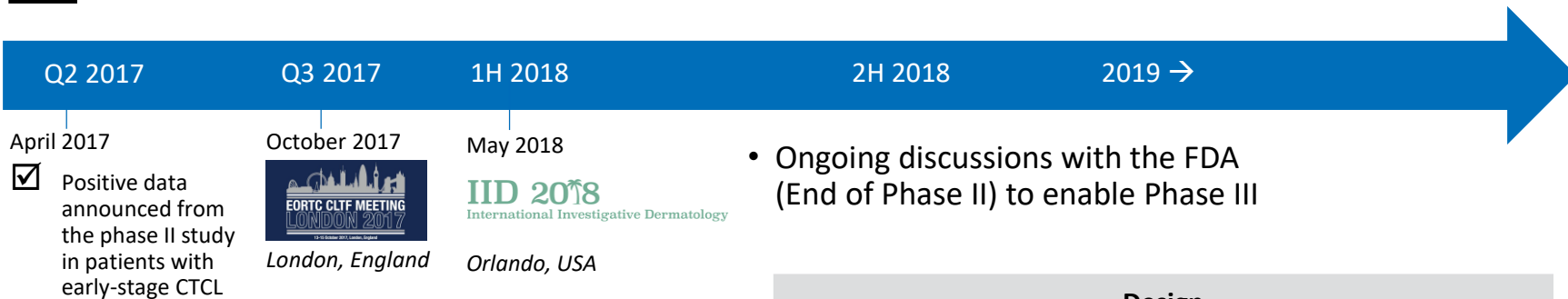
Dose	1% 1x/day n=20	0.5% 2x/day n=20	1% 2x/day n=20
Lesion responses ¹	20%	25%	40%
Patients with clinically significant pruritus ²	8/20 (40%)	6/20 (30%)	10/20 (50%)
Pruritus responses	37.5%	50%	80%

Highly tolerable with no systemic side effects

- Even dose distribution of AEs, mostly grade 1 or 2
- No HDAC inhibitor-associated systemic adverse events
- Median time on treatment: 332 days (1% 2x/day dose)

M Duvic *et al.*, EORTC Cutaneous Lymphoma Task Force Meeting (2017), Abstract O55

Planned Phase III clinical development for early-stage CTCL



“The introduction of remetinostat to the market as a novel topical agent for the treatment of CTCL is likely to find broad application and lead to novel combinatorial approaches in CTCL.”

*Pierluigi Porcu, M.D.
Jefferson University Hospital, USA*

- Ongoing discussions with the FDA (End of Phase II) to enable Phase III

Design

One Phase III study expected to be sufficient for NDA

- Past approvals in CTCL were based on pivotal clinical studies involving ≤ 260 patients
- Focus on treatment-experienced patients where the medical need is high

Costs

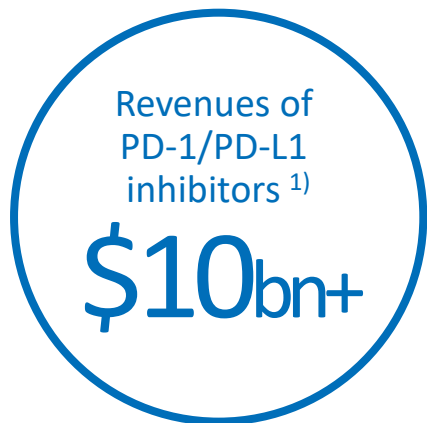
- ~\$50m (SEK 400m) expected clinical costs to NDA submission over a ~3 year period (incl. Phase III study and third party milestones)



Birinapant for solid tumors

Despite immuno-oncology breakthroughs patients have unmet needs

Multi-billion dollar market,
and growing for immuno-
oncology agents



< 1/2
of patients derive
meaningful clinical
benefit in approved
indications

0-5%
ORR in other indications
such as MSS colorectal
cancer

Combination
regimens to
enhance benefit
in underserved
patients

Linking targeted therapy with immuno-oncology

Uniquely potent molecule against a novel target

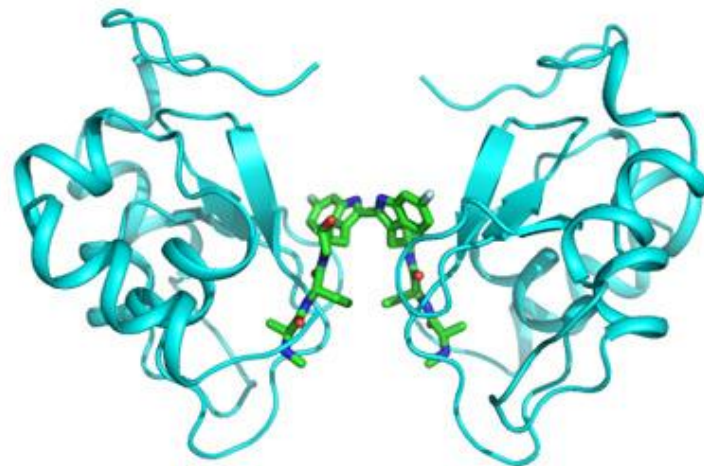
- Bivalent SMAC (second mitochondrial-derived activator of caspases) mimetic
- Targeting of cIAPs results in dual action on T-cells and tumor cells

Strong rationale for use in combinations

- Synergistic with anti-PD1 and likely other IO pathways
- Efficacy observed in both hematological and solid tumor models
- Phase I/II study in combination with Merck's Keytruda® underway

Blockbuster potential and strong patent position

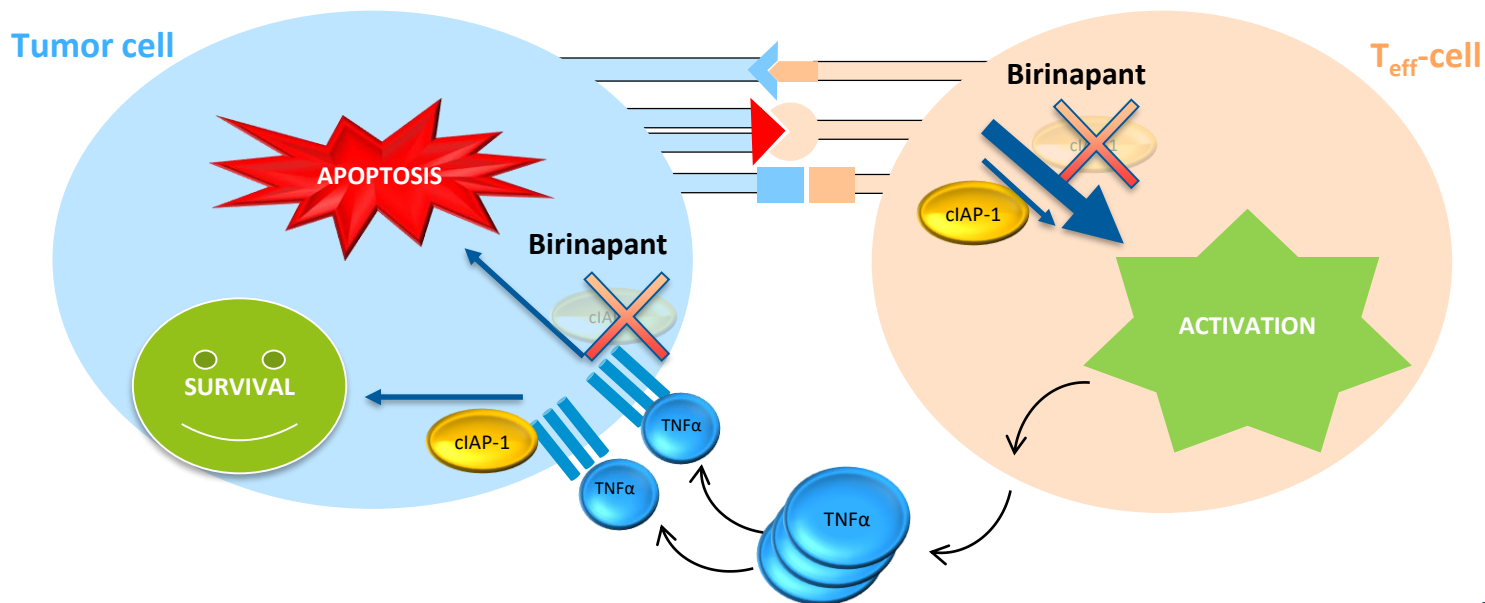
- Expected patent life to ~2034, including extensions



Dual action enhances cancer cell death

Targeting of cIAPs results in dual action on T-cells and tumor cells

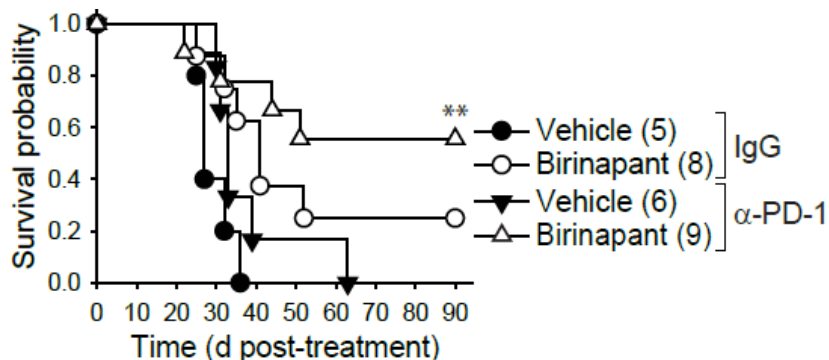
- Enhances pro-apoptotic, and suppresses pro-survival, signaling downstream of TNF- α
- Augments human T cell responses to physiologically relevant stimuli¹



Potential to enhance patient response with immune-oncology therapies

Strong rationale for combination with Keytruda®

- Birinapant/anti-PD1 mAb combo showed enhanced activity in preclinical models¹ compared to either agent alone



¹) Solid tumor model: Beug et al., Nature Communications (2017) 8:14278

Multiple myeloma model: Chesi et al., Nature Med. (2016) 22, 1411–1420

Cooperation of IAPs and PD-L1 to protect tumor cells: Kearney et al., Cell Death and Diff. (2017), 24, 1705–1716

Phase I/II study underway in collaboration with MERCK

- Development collaboration for the Phase I/II study in solid tumors
- Keytruda® provided at no cost
- Joint Development Committee to oversee the study, bringing Merck's immuno-oncology expertise
- Medivir retains full global rights to birinapant and data

Birinapant/Keytruda® combination: Phase I/II Study underway



June 2018
ASCO American Society of Clinical Oncology
Chicago, USA



Phase I: Sequential group dose-escalation to determine the dose-limiting toxicity and recommended Phase II dose, in combination with Keytruda®

Phase II: Safety and tolerability of the recommended dose of birinapant, in combination with Keytruda® in defined disease cohorts:

- MSS Colorectal cancer
- Ovarian cancer
- Cervical cancer
- Other cancer types exploratory cohort



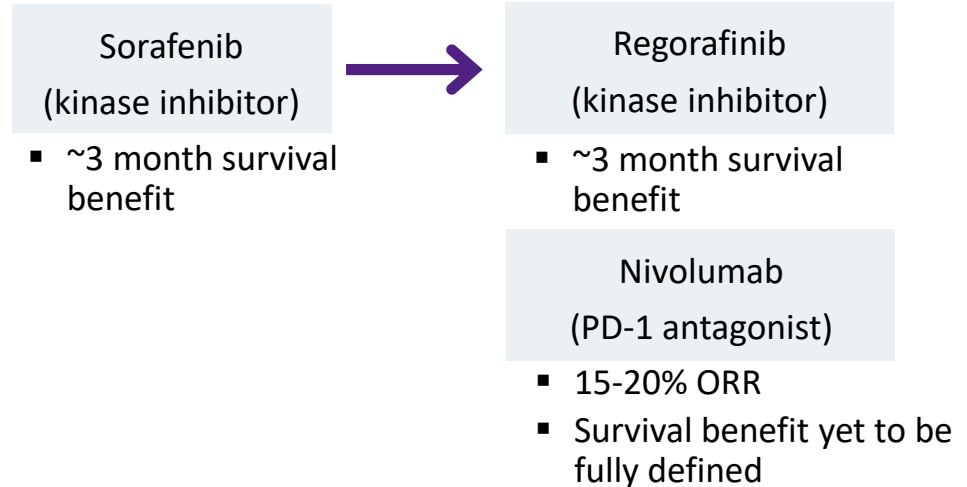
MIV-818 for liver cancers

Liver cancer is 2nd leading cause of cancer related death worldwide

Liver cancer¹

- Orphan disease in Western markets, but much more common in Asia
- One of fastest growing and most deadly cancers in US
- Genetically heterogeneous leading to limited effect of molecularly targeted therapies

Patients with advanced liver cancer in need of new treatments



1) Howlader et al. (eds). SEER Cancer Statistics Review, 1975-2011, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2011/

Potential to improve efficacy and safety for patients with liver cancers

Improve a nucleoside with Medivir prodrug technology

Troxacitabine

(nucleoside)

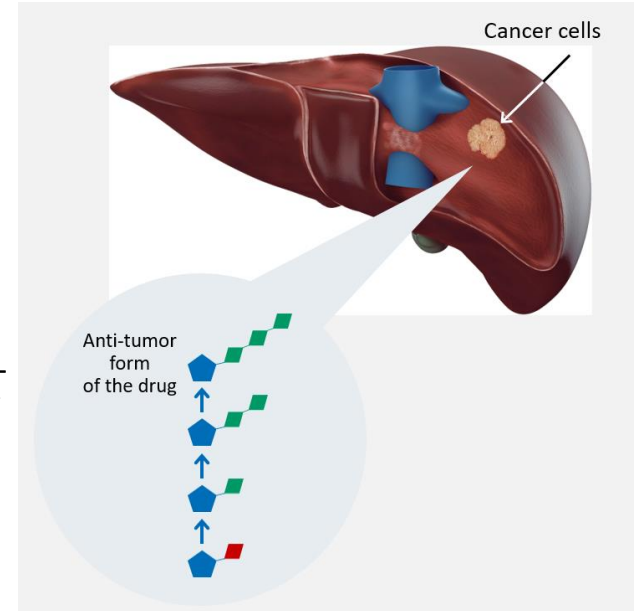
- **Active** in preclinical cancer models and in clinic
- Failed in clinic due to systemic dose-limiting **toxicities**

Medivir
prodrug
technology

MIV-818

(liver-targeted nucleotide prodrug)

- **Enhanced activity** 10x more potent against HCC cell lines than parent troxacitabine
- **Selectivity for cancer** Active on HCC cells while sparing non-cancerous hepatocytes
- **Improved delivery to the liver** >100-fold relative to systemic exposure of troxacitabine
- **Market exclusivity** with full new chemical entity patent protection



MIV-818: Gearing up for Phase I study start

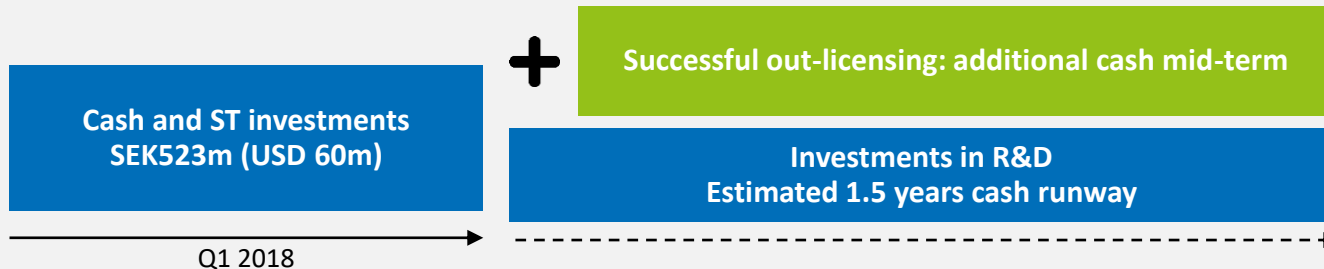




Outlook

Cash position and shareholder base

CASH POSITION



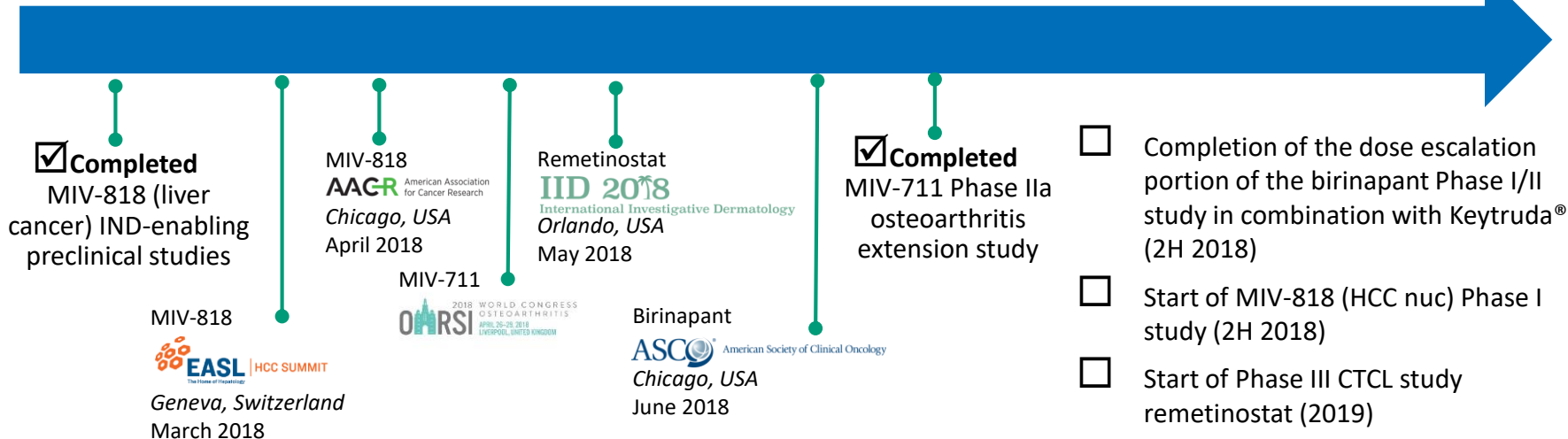
THE SHARE



Key milestones throughout the year

Track record of delivery

Coming events



Upcoming Financial Reports

- 2Q interim report (July 25, 2018)
- 3Q interim report (October 26, 2018)
- Year end report (February 14, 2019)

Why Medivir?

For more information:

- Nasdaq Stockholm, ticker: MVIR
- www.medivir.com

- Track record of delivery

3 new drugs from research
into development in 2 years

2 products from
idea to market

>20 global partnerships,
multiple repeat partners

- Strong pipeline from discovery through clinical stages with upcoming catalysts
- Competences from discovery through regulatory approvals
- Near-term opportunities for revenues from partnerships