MEDIVIR

Improving life for cancer patients
through transformative drugs

# Trout Hamptons CEO Roundtable

August 2018

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# 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
→ 79 employees, 43 with PhDs
→ Listed on the Nasdaq Stockholm, ticker: MVIR
→ Current market capitalization: >SEK 900m (>USD 100m)[1]
→ Website: www.medivir.com



1) As of Aug 1, 2018. Stock price 37,35 SEK

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# Leveraging scientific expertise to build pipeline in oncology

**Protease inhibitors**

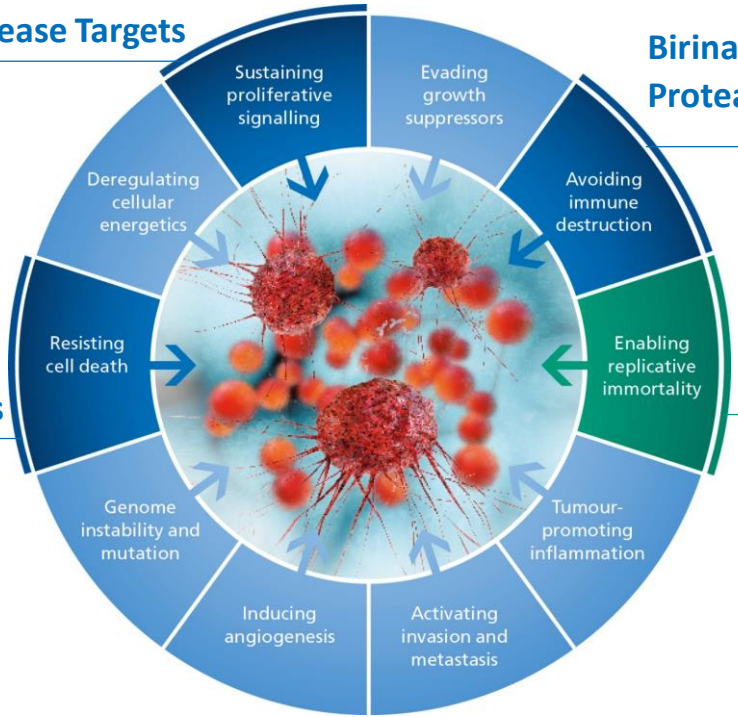
**Nucleoside prodrugs**

**Protease Targets**

**Remetinostat**
**Birinapant**
**Protease Targets**

**Birinapant**
**Protease Targets**

**MIV-818**
**Leukotide**




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



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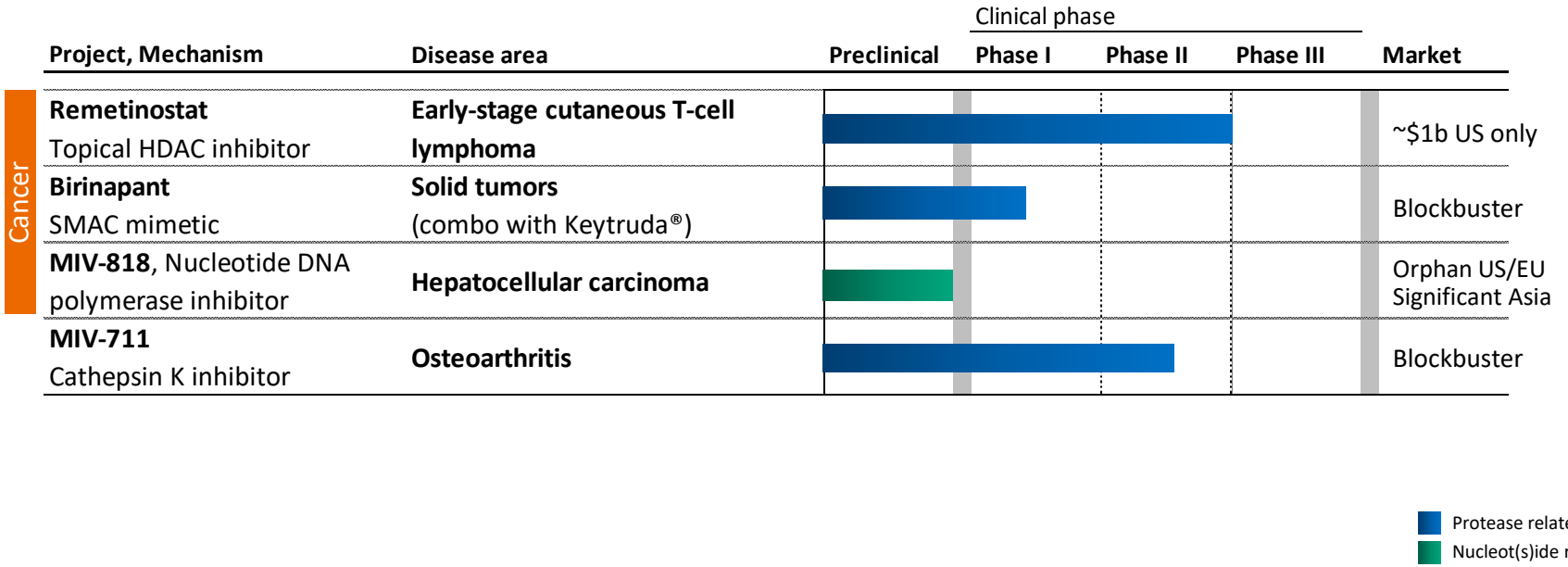
# Oncology drug development in areas of high unmet need

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



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Partner

# Collaborations enhance the value of programs

## Academic

The University of Nottingham
UHN Princess Margaret Cancer Centre
Stanford Health Care
University of Leeds
Karolinska Institutet
UT Southwestern Medical Center
Uppsala Universitet
Stockholm University
Newcastle University
University of Leicester

## Industrial

| Product/Project | Platform Link | Partners | Status | Medivir Interests |
|---|---|---|---|---|
| Zoviduo®/Xerclear (labial herpes) *acyclovir + hydrocortisone* | Nucleoside analogue | gsk | Marketed | ▪ Royalties from sales<br>▪ Approval milestones for additional OTC switches |
| MIV-802 (HCV) *Nucleotide NS5B polymerase inhibitor* | Nucleotide | TREK Therapeutics<br>歌礼中国 Ascletis | Phase I ready<br>Ascletis intends to file IND in China during Q3 2018[1] | ▪ Development milestones<br>▪ Royalties from sales |



1) http://www.hkexnews.hk/APP/SEHK/2018/2018050401/Documents/SEHK201805070011.pdf

# 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**

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



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# Phase IIa data show unprecedented osteoarthritis disease modification

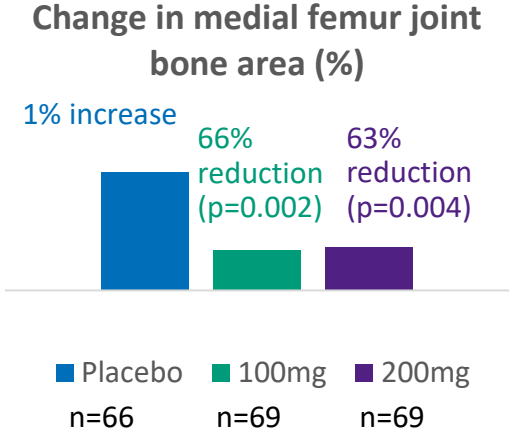
## No existing disease modifying drug for Osteoarthritis

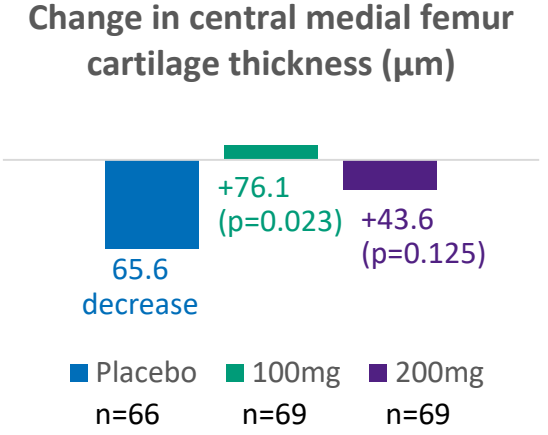
- Affects >30m adults in the US, and ~240m worldwide
- Disease involves both bone and cartilage

Annual US market potential[1]

>$6bn

## Benefit on both bone and cartilage in Phase IIa study




## Positive signals on clinical symptoms

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

**Safety and tolerability profile supports late stage development**

http://acrabstracts.org/ Abstract 14L



**Sources**: Hunter et al, Nat Rev Rheumatol, 2014; Reginster et al, Ann Rheum Dis 2013

1) >2M adults in US with moderate osteoarthritis in weight bearing joints at annual treatment cost for a drug that impacts disease progression of 3,000 USD/Year (Losina et al 2014)

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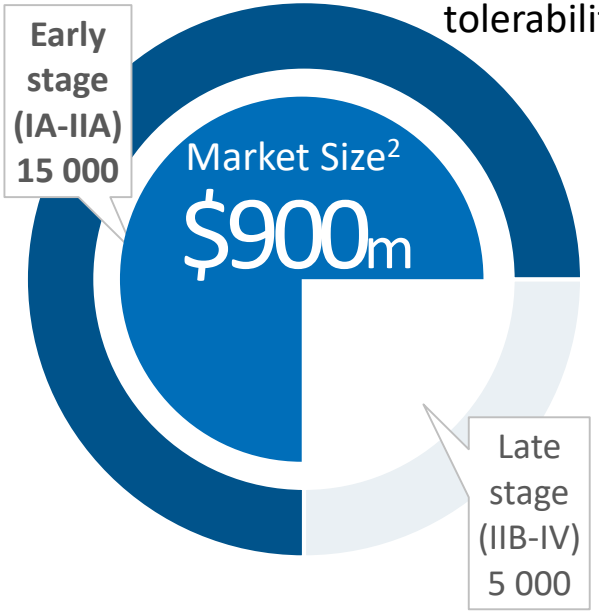
# Addresses key unmet need with positive Phase II data

## US CTCL patients[1]: orphan disease

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




## 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[3] | 20% | 25% | 40% |
| Patients with clinically significant pruritus[4] | *8/20 (40%)* | *6/20 (30%)* | *10/20 (50%)* |
| Pruritus responses | 37.5% | 50% | 80% |

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

## 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)



1. Leukemia & Lymphoma Society; 2. Early-stage patients at $60 000 per patient year price based on market research and competitive topical treatment pricing. The Medical Letter, Issue 1467, April 27, 2015 and Actelion public information; 3. Confirmed responses based on CAILS, the Composite Assessment of Index Lesion Severity; 4. Clinically significant pruritus defined at baseline as VAS ≥30 mm

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# Potential to enhance patient response with immune-oncology therapies

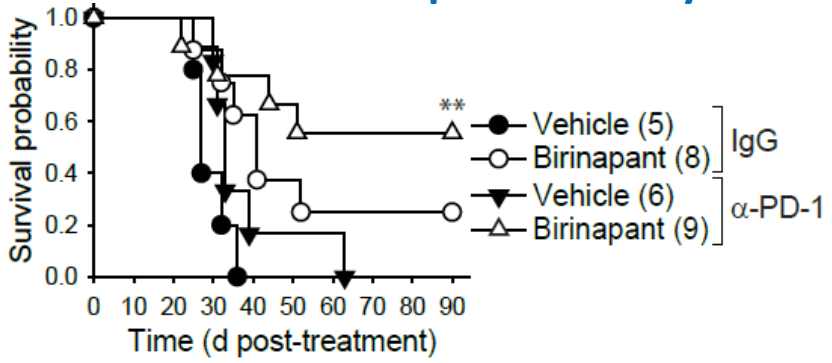
**Despite immuno-oncology breakthroughs patients have unmet needs**

**0-5% ORR**

**Currently in indications such as MSS colorectal cancer**

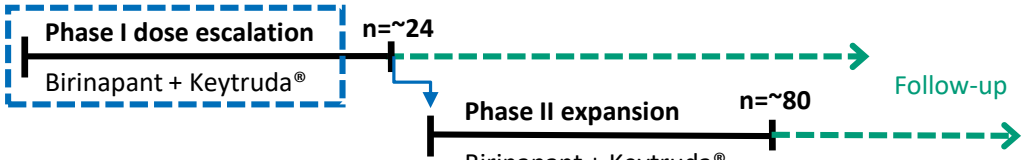
## Strong rationale for combination of birinapant with Keytruda®

Enhanced activity in preclinical models[1] compared to either agent alone




## Phase I/II study underway in collaboration with MERCK

- Keytruda® provided at no cost
- Joint Development Committee, bringing Merck's immuno-oncology expertise
- Medivir retains full global rights to birinapant and data






[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

MIV-818: LIVER TARGETED NUCLEOTIDE PRODRUG SPECIFICALLY DEVELOPED FOR LIVER CANCERS

# Potential to improve efficacy and safety for patients with liver cancers

## Liver cancer[1]

- 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

## 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)

- **Exhanced 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
- **Synergy with multikinase inhibitors** (e.g. sorafenib)
- **Market exclusivity** with full new chemical entity patent protection

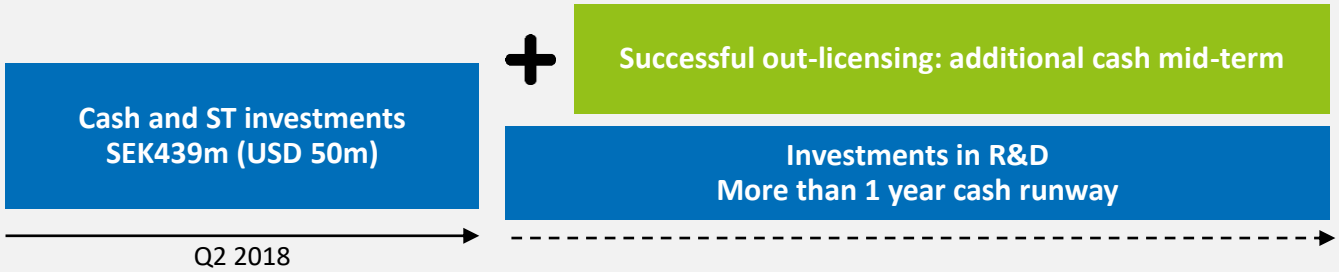


1) Howlader et al. (eds). SEER Cancer Statistics Review, 1975-2011, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2011/

# Outlook

# Cash position and shareholder base

## Cash Position




## The Share

- Market Cap[1)] >900m SEK (>USD 100m)
- International Ownership ~30%
- Top 20 shareholders ~51%



1) As of Aug 1, 2018. Stock price 37.35 SEK. 24,287,818 total Class B shares.

# Key milestones throughout the year

## Track record of delivery

☑ **Completed**
MIV-818 (liver cancer) IND-enabling preclinical studies

MIV-818
EASL | HCC SUMMIT
*Geneva, Switzerland*
March 2018

MIV-818
AACR American Association for Cancer Research
*Chicago, USA*
April 2018

MIV-711
2018 WORLD CONGRESS OSTEOARTHRITIS OARSI
APRIL 26–28, 2018 LIVERPOOL, UNITED KINGDOM

Remetinostat
IID 2018 International Investigative Dermatology
*Orlando, USA*
May 2018

Birinapant
ASCO American Society of Clinical Oncology
*Chicago, USA*
June 2018

☑ **Completed**
MIV-711 Phase IIa osteoarthritis extension study

## Coming events

- ☐ Start of MIV-818 (HCC nuc) Phase I study (2H 2018)
- ☐ Completion of the dose escalation portion of the birinapant Phase I/II study in combination with Keytruda® (2H 2018)
- ☐ Start of Phase III CTCL study remetinostat (2019)



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# 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