Second Quarter 2018 Results

July 25, 2018

First quarter and after period close highlights and significant events

MIV-711

- Positive top-line results from the osteoarthritis phase IIa extension study

MIV-818

- Preclinical data presented at the AACR Annual Meeting

Birinapant

- Design of the ongoing phase I/II study of birinapant in combination with Keytruda® presented at the ASCO annual meeting

Remetinostat

- Additional data from the phase II study in patients with early stage CTCL were presented during the International Investigative Dermatology meeting
- Discussions continue with FDA to agree on the design of the planned pivotal phase III clinical study; study start not be possible by end of 2018 as previously expected

Financial

- Total royalties revenues of 2.8 MSEK in April – June 2018
- One class of shares outstanding, as all series A shares have been converted to series B shares

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Financial Summary

Financial Summary

Summary of the Group's figures (SEK m)	Q2		Q1 - Q2	
	2018	2017	2018	2017
Net turnover	2,8	9,5	7,3	27,3
EBITDA	-89,9	-90,9	-163,0	-171,8
Basic earnings per share, SEK	-3,88	-3,91	-6,96	-7,50
Net worth per share, SEK	20,33	34,41	20,33	34,41
Cash flow from operating activities	-82,7	-82,1	-169,7	-206,0
Cash and cash equivalents at period end	438,6	624,2	438,6	624,2

- Net turnover from royalty revenue
- Cost and cash spend is driven by our clinical projects and research portfolio
- Improved cost base post full realization of the reorganization announced in fall 2016

Program Highlights

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: Preclinical / Phase I / Phase II / Phase III	Market
Cancer	**Remetinostat** Topical HDAC inhibitor	**Early-stage cutaneous T-cell lymphoma**		~$1b US only
	Birinapant SMAC mimetic	**Solid tumors** (combo with Keytruda®)		Blockbuster
	MIV-818, Nucleotide DNA polymerase inhibitor	**Hepatocellular carcinoma**		Orphan US/EU Significant Asia
	MIV-711 Cathepsin K inhibitor	**Osteoarthritis**		Blockbuster

Protease related
Nucleot(s)ide related

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No existing disease-modifying drug for osteoarthritis

Blockbuster revenue opportunity for a disease-modifying osteoarthritis drug

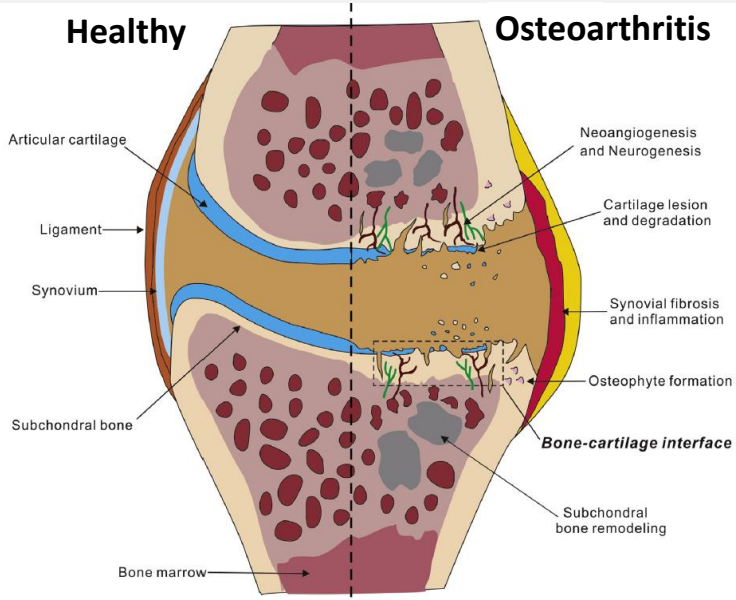
- Affects >30m adults in the US, and ~240m worldwide
- Prevalence increasing due to aging population and obesity epidemic
- Current treatments are insufficient focusing only on symptom relief

Annual US market potential[1]

>$6bn

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

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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Extension Study: Positive outcomes and primary endpoint met

Extension study recruited patients from placebo-controlled initial Phase IIa study (MIV-711-201)

- In the initial study, both doses of MIV-711 showed unprecedented activity on joint bone area growth and cartilage degradation after only six months' dosing, and an acceptable safety and tolerability profile compared to placebo
- Consistent tendency to improve outcomes across all pain measures & other patient reported symptoms vs. placebo

Extension study primary endpoint met: Safety & tolerability profile supports late-stage development

- Primary endpoint: acceptable safety and tolerability profile with 6 months of additional treatment with 200 mg MIV-711, following the initial phase IIa study 6-month treatment period
- Safety and tolerability after 6 months' treatment in patients with prior placebo treatment were comparable to the profile seen in the initial study
- The overall safety and tolerability profile and the accumulated safety data support the advancement of MIV-711 into further studies as a disease-modifying osteoarthritis drug

Positive signals on clinical symptoms continue

- Positive signals on patient reported pain and other clinical symptoms seen during the initial phase IIa study were sustained with the additional 6 months of treatment
- Effect on clinical symptoms in patients who had previously received placebo in the initial study and received six months of treatment in the extension study were consistent with what had previously been seen after 6 months' treatment with MIV-711 200mg in the initial study

MIV-711: Building towards partnership

MIV-711: Current activities

- Joint structure data from extension study expected 3rd quarter 2018
- Partnering discussions ongoing

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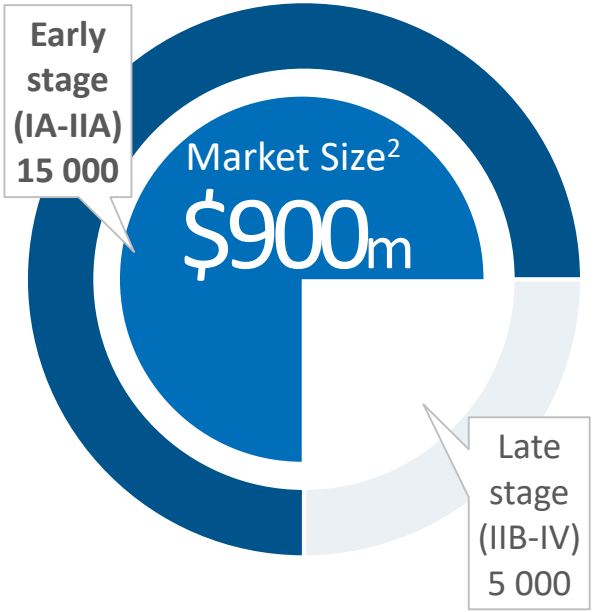
CTCL: orphan blood cancer with significant market opportunity

US CTCL patients[1]: 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:
Efficacy on lesions and pruritus; long-term tolerability

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

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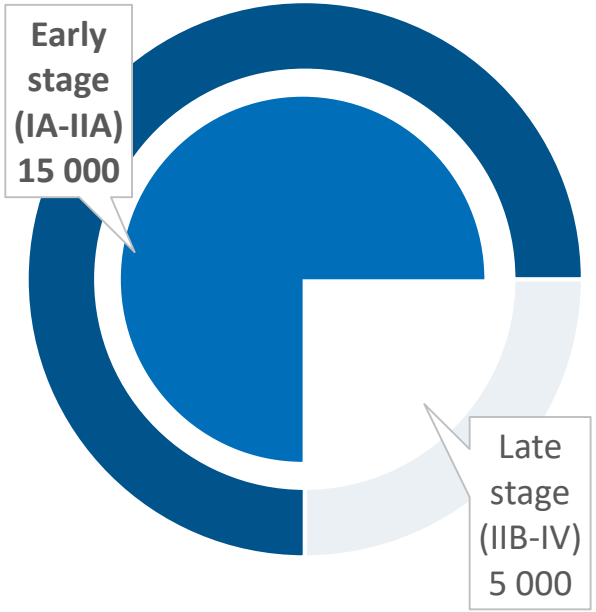
Remetinostat: rapid and durable effects on pruritus (itching)

Key unmet need of early-stage CTCL patients:

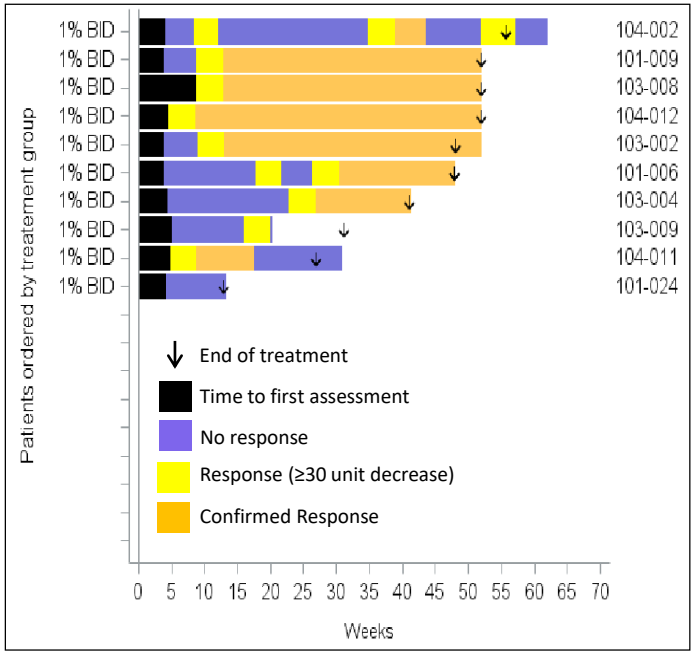
- Efficacy on lesions and pruritus
- Long-term tolerability



Remetinostat: Clinically effective against pruritus

Responses on pruritis seen before responses on lesions and good duration of effect

Pruritus status and responses over time (using VAS) in patients with clinically significant pruritus at baseline treated with remetinostat 1% gel twice daily[1]



1) M. Duvic *et al.*, International Investigative Dermatology 2018, Abstract 607.

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Planned Phase III clinical development for early-stage CTCL

Q2 2017 | Q3 2017 | 2018 | 2019 →

April 2017

☑ Positive data announced from the phase II study in patients with early-stage CTCL

October 2017

EORTC CLTF MEETING LONDON 2017

London, England

May 2018

IID 2018
International Investigative Dermatology

Orlando, USA

Continued discussions with FDA to agree on the design of the planned pivotal phase III clinical study

- Study start not possible by the end of 2018

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)

"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

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Despite immuno-oncology breakthroughs patients have unmet needs

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

Revenues of PD-1/PD-L1 inhibitors [1)]

$10bn+

< 1/2

of patients derive meaningful clinical benefit in approved indications

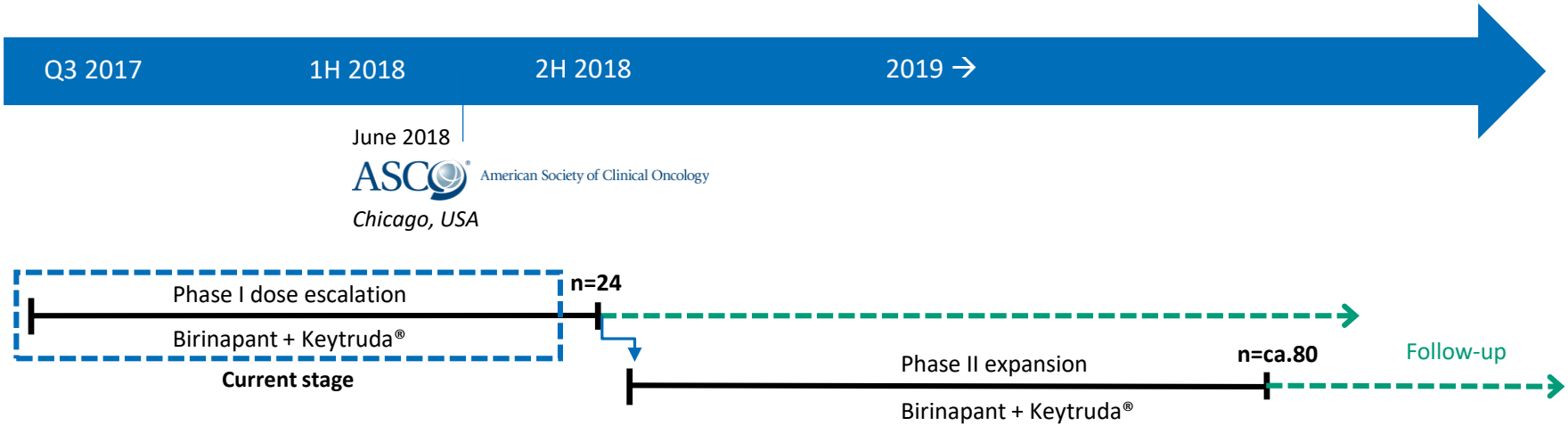
0-5%

ORR in other indications such as MSS colorectal cancer

Combination regimens to enhance benefit in underserved patients

1) Merck (Keytruda), Bristol-Myers Squibb (Opdivo), AstraZeneca (Imfinzi) and Roche (Tecentriq) financial reports, twelve months ended March 31, 2018

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



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

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

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

Patients with advanced liver cancer in need of new treatments

Multikinase Inhibitors
- Sorafenib
- *Lenvatinib*

- ~3 month survival benefit

→

(Multi)kinase Inhibitors
- Regorafinib
- *Cabozantanib*
- *Ramucirumab (AFP^{hi} patients only)*

- Incremental survival benefit

PD-1 antagonists
- Nivolumab

- 15-20% ORR; Survival benefit yet to be fully defined

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

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MIV-818: Delivering a new treatment option for liver cancer patients

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

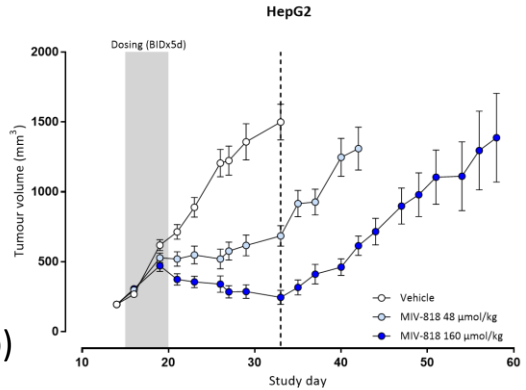
Troxacitabine: nucleoside

Clinically active but development halted due to narrow therapeutic window

↓ **Medivir prodrug technology**

MIV-818: liver-targeted prodrug

- **Exhanced activity** 10x more potent against HCC cell lines than parent troxacitabine
- **Selectivity for cancer** for HCC cells relative to non-cancerous human hepatocytes
- **Delivery to the liver improved** >100-fold relative to systemic exposure of troxacitabine
- **Synergy with multikinase inhibitors** (e.g. sorafenib)



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

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MIV-818: Gearing up for Phase I study start

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Collaborations enhance the value of programs

Industrial

Product/Project	Platform Link	Partners	Status	Medivir Interests
Zoviduo®/Xerclear (labial herpes) *acyclovir + hydrocortisone*	Nucleoside analogue	gsk	Marketed	▪ Royalties from sales ▪ Approval milestones for additional OTC switches
MIV-802 (HCV) *Nucleotide NS5B polymerase inhibitor*	Nucleotide	TREK THERAPEUTICS 歌礼中国 ASCLETIS	Phase I ready	▪ Development milestones ▪ Royalties from sales

Ascletis intends to file IND in China during Q3 2018[1]

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

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

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Outlook

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

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

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Recent and upcoming events and financial reports

Recent events

Date	Event
19 Apr 2018	Kempen Life Sciences Conference, Amsterdam, Netherlands
5-8 Jun 2018	Jefferies Global Healthcare Conference, New York, US
19-20 Jun 2018	Citi European Healthcare Conference, London, UK
19 Jul 2018	European Biotech Investor Day, New York, US
25 Jul 2018	Interim Report January - June 2018

Upcoming events

Date	Event
16 Aug 2018	Solebury Trout Hamptons CEO Roundtable, Bridgehampton, US
29-30 Aug 2018	LSX Nordic Congress, Stockholm, Sweden
10-12 Sep 2018	Nordic Life Science Days, Stockholm, Sweden
26 Oct 2018	Interim Report January - September 2018

Q&A

Improving life for cancer patients through transformative drugs

www.medivir.com

Ticker: MVIR
Exchange: Nasdaq Stockholm

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