

A laboratory setting with a pipette and microplates. The scene is dimly lit with a blue glow from the microplates. The pipette is positioned above the microplates, and the background is blurred.

MEDIVIR

4th Quarter and Year-End 2017

February 14, 2018

Fourth Quarter and Full Year Highlights

Strong development across the portfolio

- Medivir received FDA Fast Track Designation for MIV-711 for the treatment of osteoarthritis (OA)
- Remetinostat phase II data demonstrated efficacy on skin lesions, reduction of itching and high tolerability in patients with early-stage cutaneous T-cell lymphoma (CTCL)
- A new cancer project entered lead optimization. The new project Leukotide, is aimed at an improved treatment for acute myeloid leukemia (AML) and other hematological malignancies, and is derived from Medivir's in-house nucleotide platform

Total royalties revenues of 4.2 MSEK in Q4

Janssen decided to terminate its simeprevir license effective June 2018.

Erik Björk appointed as Chief Financial Officer and Christina Herder appointed as Executive Vice President Strategic Business Development.



Significant Events After Year End

- Successful completion of pre-clinical safety studies with MIV-818, enabling start of phase I clinical studies in 2018
- Medivir has completed a directed share issue of approximately SEK 155 million before transaction related expenses
- The holders of series A shares have notified the Company that they will convert all their series A shares to series B shares





Program Highlights

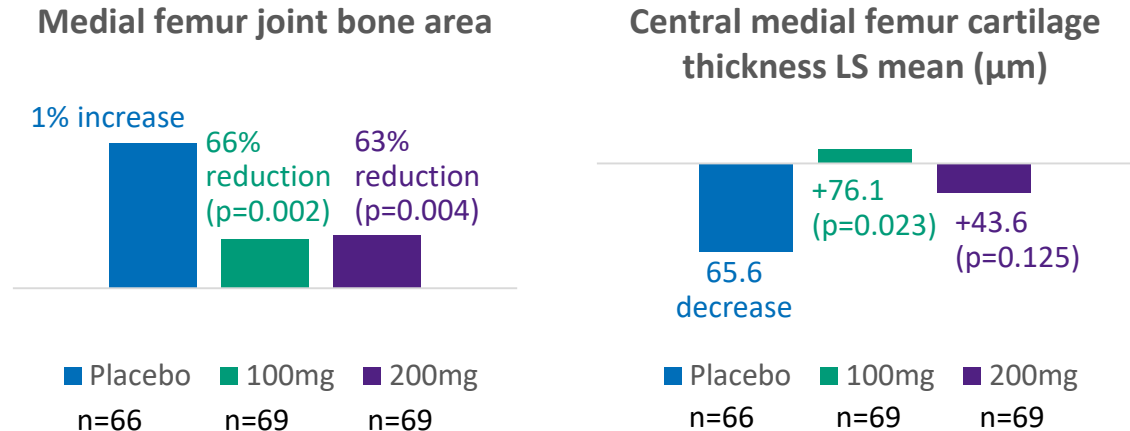
Phase IIa data show unprecedented OA disease modification after 6 months

No existing disease modifying drug for Osteoarthritis

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



Benefit on both bone and cartilage in Phase IIa study



- Positive trends across all pain and other patient reported outcomes
- Acceptable safety and tolerability profile

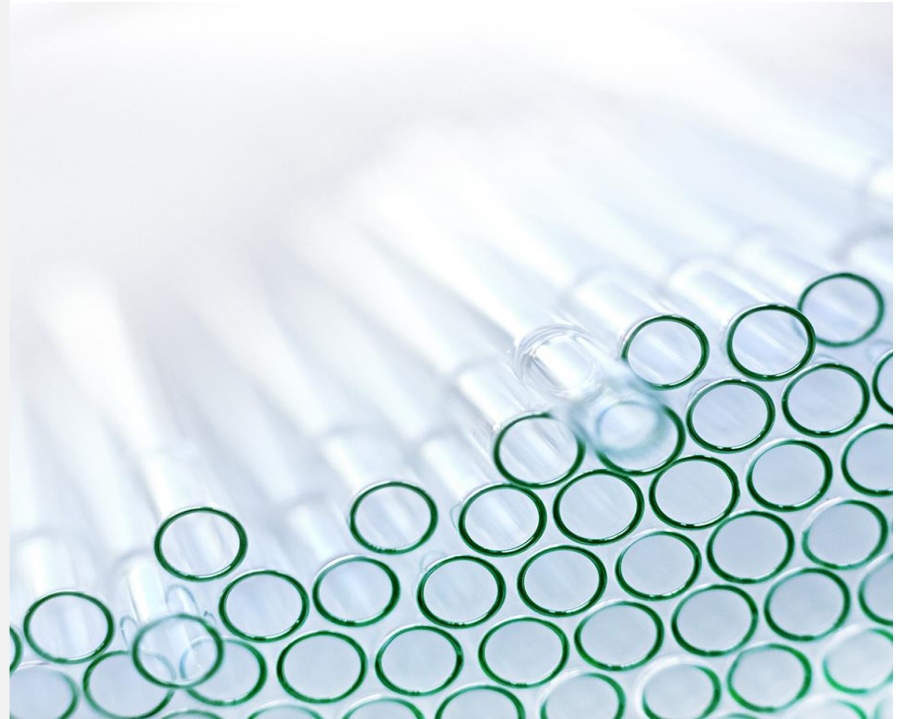
<http://acrabstracts.org/> Abstract 14L

MIV-711: Ongoing development and future plans

- Fast track designation granted by FDA (October 2017)
- Phase IIa data presented in the late-breaker session at the 2017 Annual Meeting of American College of Rheumatology (November 2017)
- Partnering discussions ongoing
- Additional 12 and 6 month efficacy data from extension study expected 1H'18

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

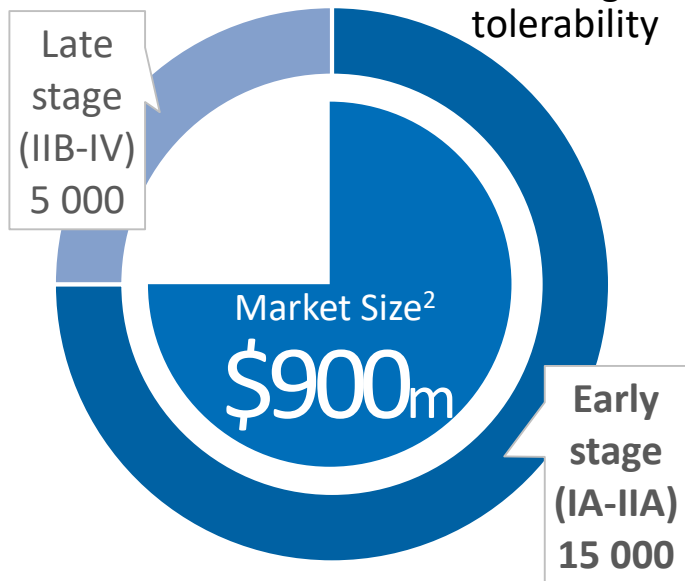
Professor Philip Conaghan, Professor of Musculoskeletal Medicine at the University of Leeds, UK, and lead investigator on the MIV-711-201 study



Addresses key unmet need with positive Phase II data

**US CTCL patients¹:
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%

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

Design

Phase II data supporting highest dose twice daily for Phase III

- Dose response: CAILS ORR & pruritus VAS responses
- A balanced safety profile across all three doses
- Minimal systemic exposure, even at the top dose

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

Program Timing

- Phase II final data reported (EORTC CLTF Meeting, 2017)
- Ongoing discussions with the FDA (End of Phase II) to enable Phase III

Costs

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

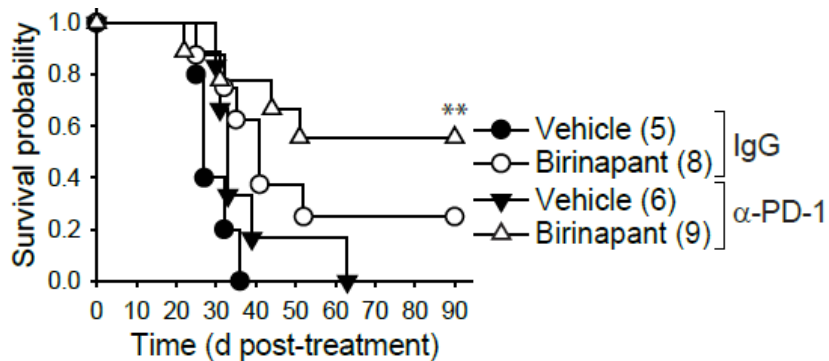
“As a topical, skin-specific HDAC inhibitor, remetinostat has the potential to be efficacious and have an improved safety profile compared to other available treatments.”

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

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



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

¹ Solid tumor model: Beug et al., Nature Communications (2017) 8:14278
Multiple myeloma model: Chesi et al., Nature Med. (2016) 22, 1411–1420

Potential to improve efficacy and safety for patients with liver cancers

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

Improve a nucleoside with Medivir prodrug technology

Troxacitabine
(nucleoside)



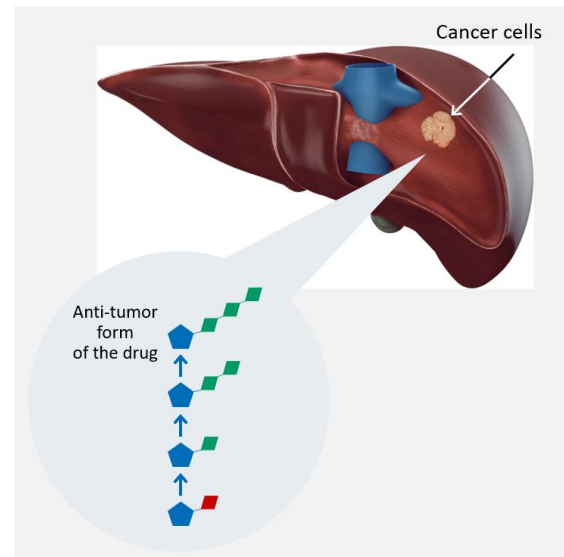
MIV-818

(liver-targeted nucleotide prodrug)

- **Active** in preclinical cancer models and in clinic
- Failed in clinic due to systemic dose-limiting **toxicities**
- **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** >10-fold increased delivery of the active drug to the liver, with a 10-fold reduction in exposure to troxacitabine elsewhere

MIV-818: Ongoing development and future plans

- GLP safety studies completed in January 2018
- Documentation being prepared for submission to regulatory authorities
- Phase I study planned to start in second half of 2018
- Abstracts on the preclinical profile of MIV-818 accepted for presentation at:
 - EASL HCC Summit (March 1-3, Geneva)
 - AACR Annual Meeting (April 14-18, Chicago)





Financial Summary

Financial Summary

Summary of the Group's figures

(SEK m)

	Q4		Q1 - Q4	
	2017	2016	2017	2016
Net turnover	4,2	9,9	36,6	93,0
EBITDA	-92,6	-125,8	-342,6	-300,6
Basic earnings per share, SEK	-5,08	-4,50	-16,40	-10,94
Net worth per share, SEK	25,31	64,38	25,31	64,38
Cash flow from operating activities	-88,9	-71,8	-358,5	-182,3
Cash and cash equivalents at period end	467,8	1 698,5	467,8	1 698,5

- Net turnover from royalty revenue
- Cost and cash spend is driven by the strong development in our clinical projects
- Year end cash position excludes proceeds from the directed share issuance completed in February 2018

Results of directed share issuance

- Medivir completed a directed share issuance of approximately SEK 155 million before transaction related expenses
- The directed issue increased the number of shares in Medivir by 3,968,841 to a total number of shares of 24,287,818
- The directed issue generated strong demand from Swedish and international institutional investors, such as Gladiator and Nyenburgh Investment Partners
- The proceeds together with existing cash enable Medivir to actively drive ongoing research as well as deliver the next step in the clinical projects:
 - completion of the MIV-711 phase IIa osteoarthritis extension study,
 - completion of the birinapant dose escalation portion of phase I/II study in combination with Keytruda[®],
 - start and completion of the MIV-818 (HCC nuc) phase I study, and
 - preparations for the start of the pivotal phase III CTCL study for remetinostat.



Q&A

Improving life for cancer patients through transformative drugs

www.medivir.com

Ticker: MVIR

Exchange: Nasdaq Stockholm

For more information please contact

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