Medivir

A collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C

Q2 2012 Conference Call, 23 August, 14.00 CET

Presenting Team

Maris Hartmanis, CEO
Charlotte Edenius, EVP R&D.
Bertil Samuelsson, Chief Scientific Advisor
Rein Piir, EVP Corporate Affairs & IR

Medivir

"We are passionate and uncompromising in our mission to develop and commercialise innovative pharmaceuticals that improve people's lives"

Highlights from the second quarter 2012

Maris Hartmanis, CEO

Good progress in all parts of the company 1(2)

Stable platform for future growth:

- Original pharmaceuticals continued to deliver a healthy EBITDA contribution for financing of R&D operations. The investments in Cross Pharma, our parallel import business, progressed in a good way.
- Our pipeline assets continued to make progress and moved closer to value inflection points.
- We entered a collaboration with the Swedish University of Agricultural Sciences (SLU) in Uppsala for development of new antibiotics against resistant bacteria, a project in line with our strategy.
- We strengthened the commercial organization and integrated our clinical development operations into the existing R&D organization.

Good progress in all parts of the company 2(2)

In-house R&D projects

- Cathepsin K inhibitor - Clinical phase Ia trial completed and phase Ib trial started
- Cathepsin S inhibitor – Progressing towards CD selection later this year
- HCV Nucleotide project – Work progressing well, our goal is to nominate a CD before year end

Partnered HCV projects

- Simeprevir (TMC435) - Phase III trials on simeprevir are progressing well and top-line clinical data are expected around year end
- Simeprevir (TMC435) and daclatasvir - Entered phase II interferon-free combination studies +- ribavirin, the study is well under way
- Simeprevir (TMC435) and GS7977 - The phase II interferon-free combination study +- ribavirin, is making good progress and we expect the first clinical data late this year

Consolidated Profit Performance

(MSEK)	2012 April – June	2011 April – June	2012 January – June	2011 January – June	2011 January – December
Net sales	147.2	322.9	285.1	444.6	698.6
Gross profit/loss	35.5	284.8	76.4	406.4	458.0
EBITDA	-42.5	169.5	-72.4	221.4	135.3
EBIT	-51.7	165.6	-90.0	215.7	111.9
Profit/loss before tax	-52.6	164.1	-90.1	217.0	111.2
Profit/loss after tax	-60.9	167.4	-98.6	220.3	113.8

Net sales split – Quarterly trend

(MSEK)	2012 April – June	2012 January – March	2011 October - December	2011 July – September
Pharmaceutical sales	38.9	46.3	47.5	47.4
Parallel imports	108.3	91.6	84.7	74.6
Other services	-	-	-0.4	0.2
Total	**147.2**	**137.9**	**131.8**	**122.2**

Strongly committed to innovation driven R&D

Charlotte Edenius, EVP R&D

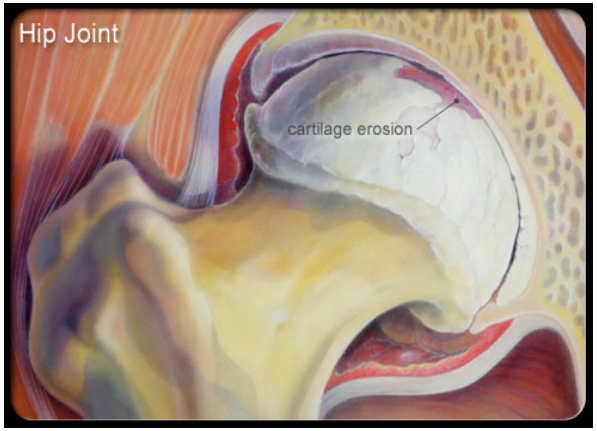
R&D highlights

- New pharmaceuticals against bacterial infections
  - Collaboration with the Swedish University of Agricultural Sciences (SLU) on the discovery and development of new antibiotics
- Cathepsin K inhibitor program entered clinical development
- Cathepsin S inhibitor program made good progress

- Simeprevir (TMC435) – the once daily oral HCV protease inhibitor:
  - Positive final phase IIb data for simeprevir (TMC435) in hard-to-treat hepatitis C patients presented
  - Clinical collaboration extended on Bristol-Myers Squibb's daclatasvir (BMS-790052) on interferon-free combination trials with simeprevir (TMC435)
  - Broad development program on track for filing in H1-2013

Cathepsin K- general background

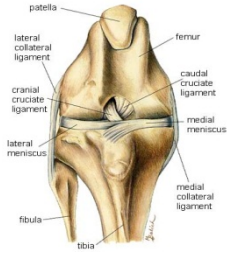
- **Cysteinyl protease**
- **Predominantly expressed in the osteoclasts**
- **Osteoporosis (OP):**
  - cat K is responsible for dissolving the collagen I, the major organic component of bone
  - animal models demonstrate that cat K inhibition improves bone quality
- **Osteoarthritis (OA):**
  - In OA cat K is upregulated in chondrocytes.
  - The major organic component of cartilage is collagen-II, which is broken down by cat K
- **Metastatic bone disease (MBD):**
  - invasive tumour cells express high levels of cat K, which increase bone resorption and the invasiveness of cancer cells



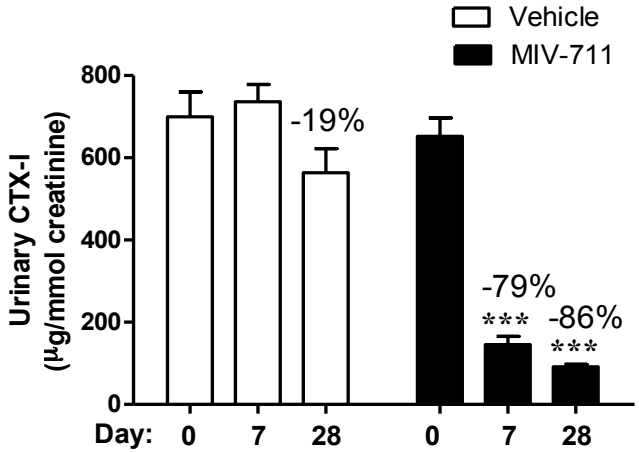
Cat K inhibitors - a potential therapeutic in many bone related disorders

APC: Specialised immune cells that present antigen derived peptides to T-cells

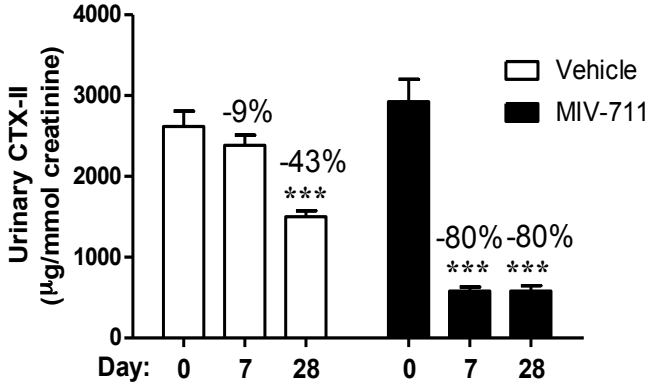
MIV-711 – Partial medial meniscectomy; an experimental osteoarthritis model in dog



Reduced urinary levels of bone resorption biomarker CTX-I



Reduced urinary levels of cartilage resorption biomarker CTX-II



MIV-711 dosed at 30 µmol/kg (p.o.) once daily for 28 days, n=15

MIV-711 reduced bone and cartilage degradation biomarkers in dog osteoarthritis model

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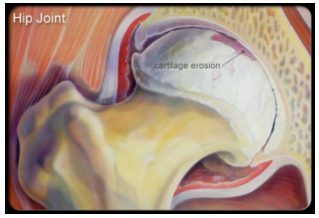
MIV-711 – an in house developed cathepsin K inhibitor in clinical phase I



Disease

- **Osteoporosis, osteoarthritis and metastatic bone disease**

Mechanism of action

Cathepsin K inhibition leads to:

- Reduced bone resorption and cartilage breakdown
- Maintained bone formation in contrast to other anti-resorptives

MIV-711: efficacious in dog OA model

- MIV-711 markedly reduced biomarkers for bone and cartilage resorption
- MIV-711 reduced bone and cartilage pathology

MIV-711: Phase I ongoing

- Adaptive, placebo controlled, double-blind study in healthy volunteers incl . post meno-pausal women
- Ascending single and multiple once daily dosing
- Biomarkers for bone and cartilage turnover
- Phase I data available around year end

MIV-711 - a phase I clinical candidate efficacious on bone and cartilage biomarkers in models of osteoarthritis and osteoporosis

Cathepsin S inhibitor –
neuropathic pain and autoimmune disease

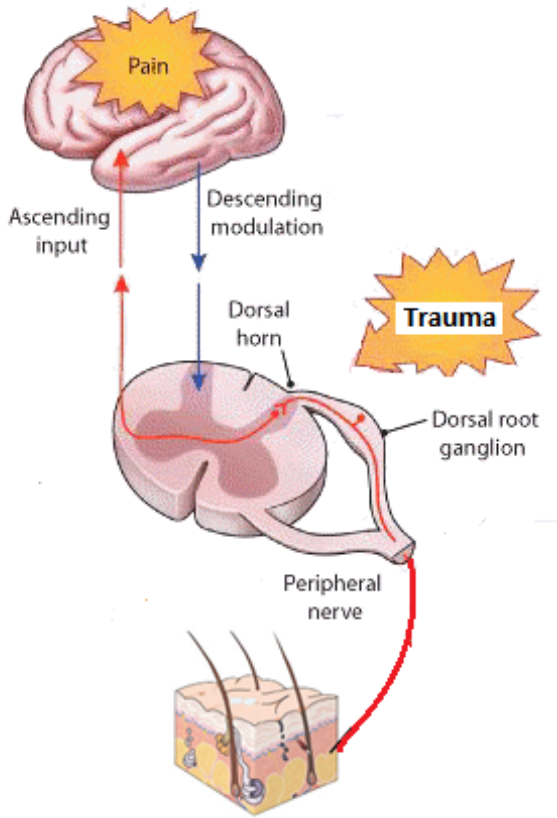
Disease and market

- Approximately 25 million patients 7MM suffer from neuropathic pain; 75% patients inadequate response to existing therapies
- Estimated global market opportunity for neuropathic pain in excess of 2.7 BUSD, and rheumatoid arthritis is estimated to 19 BUSD

Mechanism of action:

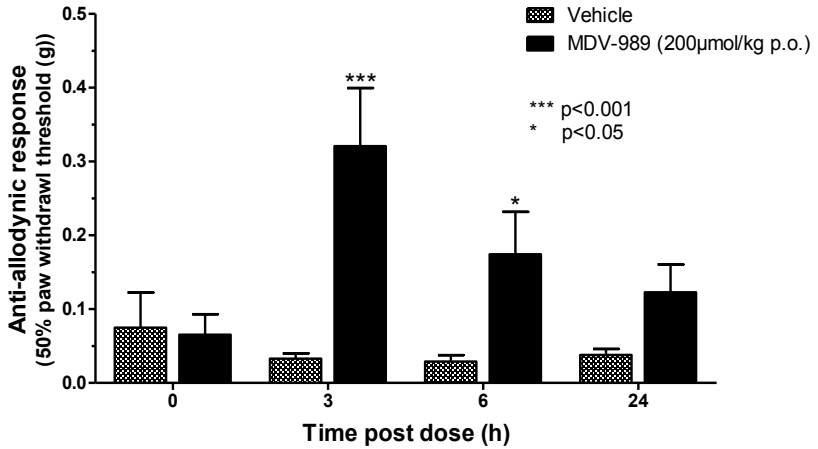
- **Neuropathic pain**
  - Cathepsin S is essential for activation of the soluble fractalkine on neurons → neuro-inflammation
  - Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking Fractalkine activation
- **Autoimmune disease**
  - Crucial role in MHC Class II antigen presentation, which is key to establishing and perpetuating an immune response

Principle for neuropathic pain



Cathepsin S inhibitor –
neuropathic pain and autoimmune disease

Cathepsin S inhibition and neuropathic pain



Cathepsin S inhibitor program

- Potent, selective and orally bioavailable inhibitors developed by Medivir
- Proof-of-principle demonstrated in a rodent models of neuropathic pain, arthritis and multiple sclerosis

Next step

- Aiming for candidate drug selection in Q4 2012

Excellent efficacy of a Medivir cathepsin S selective inhibitor in a murine model of neuropathic pain

Simeprevir (TMC435) status update

Simeprevir (TMC435) – triple combination summary

- Potent → low dose (150mg), one tablet once daily, 12 weeks duration
- As demonstrated in three large phase IIb trials highly efficacious in;
  - G1a and G1b
  - treatment naïve **(SVR24: 81-86%)** and treatment experienced **(SVR24: 51-85%)**
  - cirrhotic and non-cirrhotic patients,
  - regardless of IP-10 level or *IL28B* genotype
- Safe and well tolerated
  - Close to 1800 patients have completed TMC435 treatments showing it to be safe and well tolerated - important for compliance once on the market
- Long patent life, IP extending to 2026 and 2028

Simeprevir + PegINF/Ribavirin – A best-in-class triple combination

ASPIRE study:

A Phase IIb, randomised, double-blind clinical trial in treatment experienced HCV genotype 1 infected patients (n=462)

Patients treated with Simeprevir (TMC435) 150 mg in combination with PegIFN/ RBV achieved the following SVR24 rates:

- 85% of prior relapsers
- 75% of prior partial responders
- 51% of prior null responders

} Including patients with severe liver disease (62% Metvir score F3-F4)

- Subgroup analysis of cirrhotic patents: 31% – 82% SVR24 vs 0% in placebo
- Once-daily TMC435 was well tolerated in this population

Simeprevir + PegINF/Ribavirin – A best-in-class triple combination in difficult to treat patients

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Simeprevir (TMC435) - triple combination in phase III
broad clinical development program in genotype-1

Ongoing pivotal phase III studies:

QUEST 1 treatment-naïve; n=375

QUEST 2 treatment-naïve; n=375

PROMISE (C3007) prior relapsed; n=375

Japan naïve & experienced; n=417 (four studies)

Top line data expected around year end

Selected other ongoing studies:

C3001 comparing TMC435 vs telaprevir, in prior null or partial responders; *n=744*

C3011 open label, single arm phase III trial in treatment naïve or treatment experienced, HCV genotype-4 infected patients; *n=100*

C212 open-label study in patients co-infected with HIV; *n=94*

Simeprevir to be broadly filed H1 2013 (EU, US and Japan)

Simeprevir (TMC435) – interferon free combinations

Simeprevir and GS-7977 (nucleotide NS5B inhibitor)

- genotype 1 prior null responders, including cirrhotic patients, n=180
- 12 and 24 weeks treatment durations, +/- RBV
- *On-going*

Simeprevir and daclatasvir (NS5A inhibitor), clinical phase II and III collaboration

- genotype 1 naïve and null responder patients, including cirrhotic patients, n=180
- 12 and 24 weeks treatment durations, +/- RBV
- *On-going*

Simeprevir and BMS-986094 (former INX-189; a nucleotide NS5B inhibitor)

- *Clinical evaluation to be started with a DDI study – on hold*

Simeprevir (TMC435), a best in class PI, strongly positioned to become the principal component of future IFN-free therapies

Expected key news flow highlights in the coming quarters

- ✓ Q2-12 Full simeprevir * results presented at EASL from the ASPIRE trial
- ✓ Q2-12 Janssen creates new division to launch simeprevir in EMEA
- ✓ Q2-12 Start of DAA phase II combination study with simeprevir and daclatasvir
- ✓ Q3-12 Start of Phase Ib clinical trials with MIV-711 (cathepsin K inhibitor)
- Q4-12 Partial SVR4-data from Cohort 1 with simeprevir and GS7977 DAA phase II study
- Q4-12 Potential CD selection in Cathepsin S (Neuropathic pain) program
- Q4-12 Results from the phase I-study with MIV-711 (bone related disorders)
- Q4-12 Potential CD selection in our internal Nucleotide NS5B inhibitor program
- Q1-13 Top line results from phase III trials with simeprevir (Quest 1+2 and Promise)
- Q1-13 Goal to start phase 1 trials with Medivir/Janssen Nucleotide NS5B inhibitor
- Q2-13 Partial SVR-data from the DAA phase II combination study with simeprevir and daclatasvir
- Q2-13 Filing of simeprevir in US/EU and Japan
- Q2-13 SVR4 data from Cohort 2 with simeprevir and GS7977 DAA phase II study
- H1-13 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets

*** = TMC435, now known as its generic name, simeprevir**

Q / A