



REMIUMS Kapitalmarknadsdag
Clarion Sign Hotel, Norra Bantorget.
7:e september 2010

Medivir presenteras av
Rein Piir, CFO / IR

Medivir in Brief

Swedish Biotech Transforming into a Pharmaceutical Company

Publicly listed on OMX Stockholm, headquartered in Huddinge, Sweden
Spun-out from Astra in 1988, IPO in 1996
Employees: 85

Our Core Competences

A world leader in the understanding of proteases and polymerases and in the development of small molecule drugs with particular emphasis on infectious diseases. Strong presence in hepatitis C

Strong Pipeline and Partners

Enviably positioned with several partnered programs in infectious diseases and a “best in class” hepatitis C drug in late stage clinical development

Our First Product Launch is the Foundation for Transformation to Pharma

In the process of launching our first product, a unique new topical treatment principle for cold sores. Will be marketed as **Xerese™** by our partner Meda in the US and as **Xerclear™** in EU

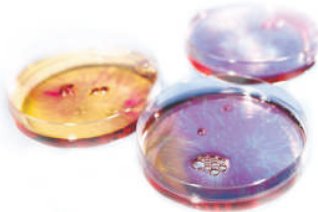
Key investment highlights



Strong presence in developing hepatitis C drugs - TMC435 is the frontrunner in our portfolio, potentially the best in class PI and a future blockbuster



Xerclear™ / Xerese™ has a unique indication text and will be a major step towards becoming a profitable research-based pharmaceutical company



Strong pipeline with many potential blockbuster drugs in development with leading pharma partners

Our first approved product - Xerclear™/Xerese™

Overview

- Patented combination of 5% acyclovir and 1% hydrocortisone in Medivir's proprietary cream formulation
- Market opportunity
 - 7% of the Western population, or 60 million people, suffer from severe labial herpes
 - Approved therapies offer poor results – opportunity to grow the existing market
 - Limited development of current products on the market
- North America – Partner with Meda
 - Prescription (Rx) status for all antiviral treatments (acyclovir, penciclovir)
 - Main competitors are Zovirax, Denavir and Abreva
- EU
 - Market dominated by OTC products

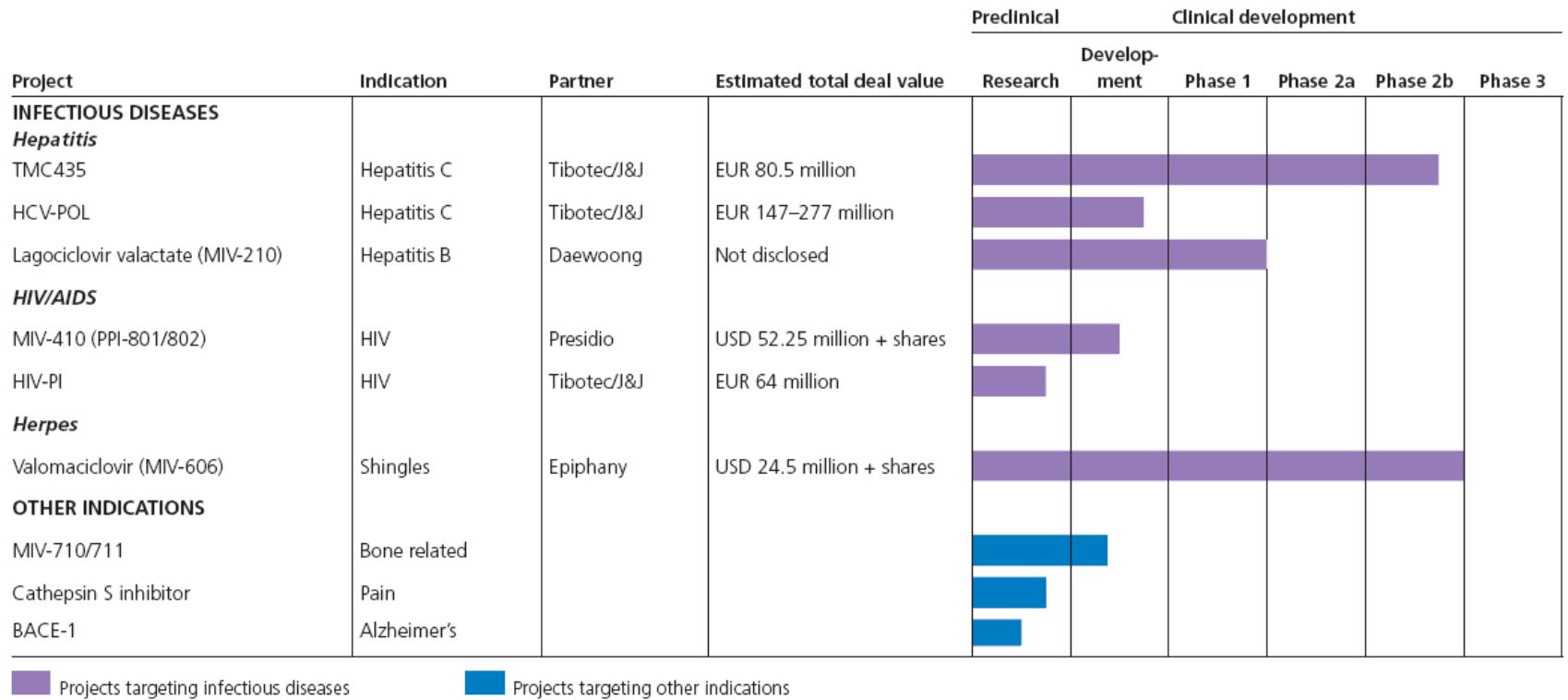
Launch strategy

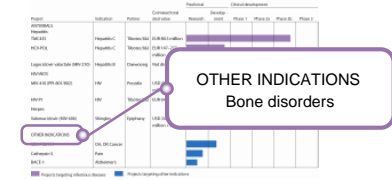
- Nordic region – Medivir
 - Xerclear™ launched Rx in Sweden and Finland
 - OTC launch in Sweden and Denmark to follow during 2010
- North America – Meda
 - Product launch in the US during Q4 2010
 - Xerese™ will be Rx
- EU and Russia – GSK
 - Product launch during Q2-3 2011
 - Initially OTC and Rx, with a switch to OTC over time
- Rest of World
 - Distribution partnerships, Daewoong I South Korea and other discussions ongoing



Strong pipeline with leading pharma partners

Best-in-class protease and polymerase platform





Bone disorders – MIV-710/711

Creating value for shareholders by developing products further under own management

Disease and market

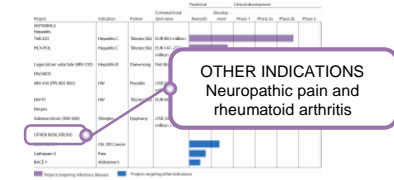
- This class of inhibitors intervene in disease states where there is excessive bone loss, e.g. osteoporosis, osteoarthritis and metastatic bone disease
- Estimated combined global market opportunity in excess of USD 12 billion

MIV-710 and MIV-711

- Cathepsin K inhibitor program
- Targeting multiple indications of great unmet medical need (osteoporosis, osteoarthritis and metastatic bone disease)
- Two Candidate Drugs, MIV-710 and MIV-711
- Maintain the beneficial bone formation, in contrast to other anti-resorptives
- Furnish potent and long duration of activity
- Development status: preclinical development

Upcoming events in the coming 12 month

- Start of phase 1 clinical trials in 2-3 different therapeutic areas



Neuropathic pain and RA – Cathespin S inhibitor

Creating value for shareholders by developing products further under own management

Disease and market

- Approximately 25 million patients worldwide suffer from neuropathic pain
- Estimated global market opportunity for neuropathic pain in excess of USD 2.3 billion, and rheumatoid arthritis (RA) is estimated to USD 7 billion

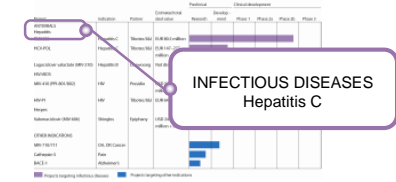
Upcoming events in the coming 12 month

- Candidate drug selection

Cathespin S inhibitor program

- Potent, selective and orally bioavailable inhibitors developed
- Proof-of-principle has been demonstrated for Medivir lead inhibitor in a preclinical rodent model of neuropathic pain
- Strong link to neuropathic pain
 - Upregulated in DRG infiltrating macrophages and near site of peripheral injury in rodent models
 - Secreted by activated microglial cells in CNS in rodent models
 - Cathepsin S is essential for the activation of the soluble fractalkine on neurons
- Strong link to RA
 - Crucial role in MHC Class II antigen presentation
 - Performs final step in processing of invariant chain
 - Antigen presentation is key to establishing an immune response

Hepatitis C



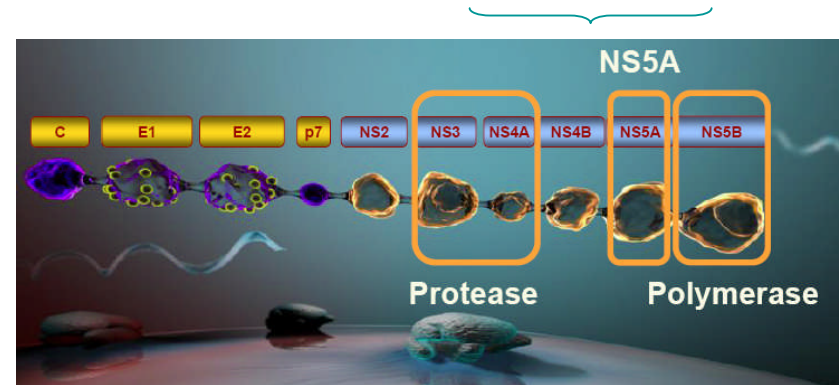
Disease and market

- Approximately 170 million worldwide chronically infected with hepatitis C virus
- Approximately 12 million infected in the US, Europe and Japan
- Estimated market value of over USD 10 billion in 2015

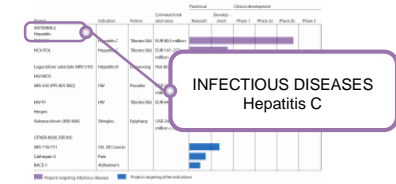
Medivir HCV commitment

- HCV PI – TMC435 – Tibotec/Johnson & Johnson
- HCV nucleoside NS5B inhibitor – Tibotec/Johnson & Johnson
- HCV in-house discovery programs

Programs in collaboration with



In-house HCV programs

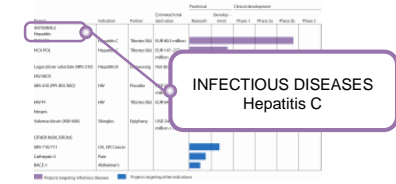


Hepatitis C – the competitive landscape

Pre-clinical	Phase 1a	Phase 1b	Phase 2a	Phase 2b	Phase 3
Intermune	VPY-376	ACH-1625	Danoprevir ITMN-191	TMC435	Telaprevir VX-950
Taigen	PHX1766		ABT-450	BI201335	Boceprevir SCH-503034
Novartis	IDX320		BMS-650032	Vaniprevir MK-7009	
Vertex	MK-5172		GS-9256		
AVL-181,192					
ACH-2684					

HCV PI's in combination with SoC

- Combinations of DAA agents:
 - Telaprevir in phase 2a in combination with VX-222 (NNRTI) +/- SoC
 - Danoprevir in phase 2a in combination with R7227 (NI) +/- SoC
 - BMS-650032 in phase 2a in combination with BMS-790052 (NS5A inh) +/- SoC
 - GS-9256 in combination with GS-9190 (NNRTI) +/- Ribavirin
- ITMN-191 and ABT-450 require ritonavir-boosting



TMC435 clinical trial overview

Phase 1 studies

- Extensive drug-drug interaction program ongoing with commonly used drugs

Phase 2a studies

Opera-1 (C201)

- 4-week antiviral activity, safety and PK data available
- TMC435 shows potent antiviral activity and is well tolerated in treatment-naïve and treatment-experienced patients with genotype-1 HCV infection
- Doses between 75 and 150 mg selected for phase 2b

Opera-2 (C202)

- PoC study in patients with non-genotype-1 HCV infection – completed

Phase 2b studies ongoing

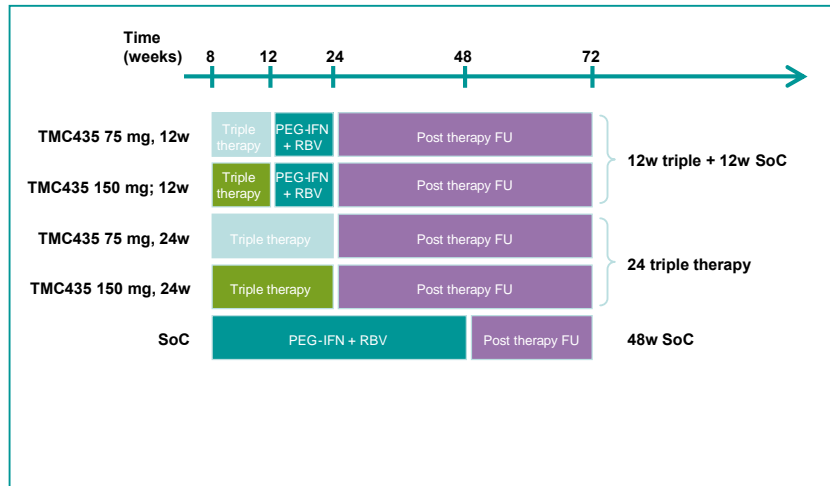
– includes approximately 950 patients

- **PILLAR (C205)** – genotype-1 infected treatment-naïve patients
- **DRAGON (C215)** – genotype-1 infected treatment-naïve patients
- **ASPIRE (C206)** – genotype-1 infected treatment-experienced patients

TMC435 phase 2b trial design

PILLAR (C205)

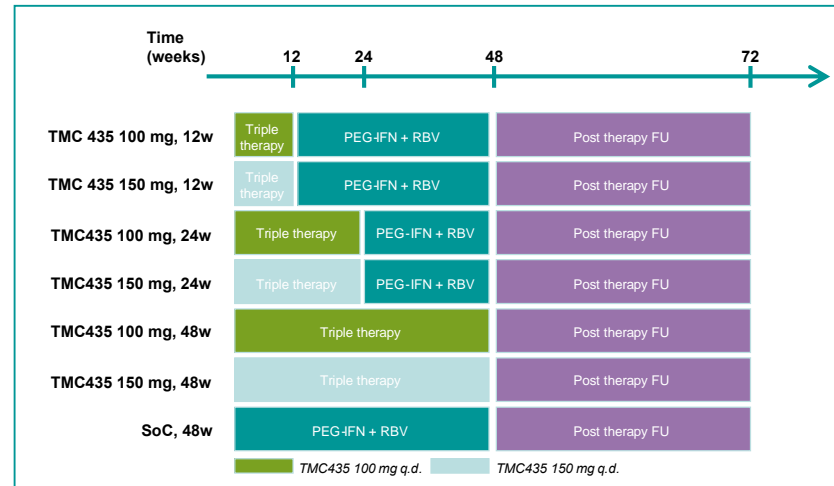
- A global phase 2b study in approximately 400 treatment-naïve HCV patients
- Study start date: May 2009
- Once daily (*q.d.*), 75 mg and 150 mg, of TMC435 + SoC:
 - 12-week triple therapy followed by SoC alone up to week 24
 - 24-week triple therapy



- **Primary endpoint:** Proportion of patients with undetectable virus levels 24 weeks after planned end-of-treatment (SVR24)
- **SoC:** Ribavirin 1,000-1,200 mg BID + pegIFNalpha-2A 180 µg weekly

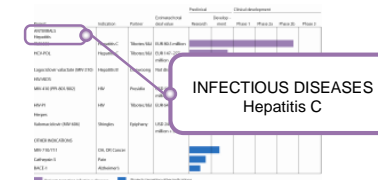
ASPIRE (C206)

- A global phase 2b study in approximately 455 treatment-experienced HCV patients
- Study start date: September 2009
- Once daily (*q.d.*), 100 mg and 150 mg, of TMC435 + SoC:
 - 24-week triple therapy followed by 24 weeks of SoC
 - 48-week triple therapy



- **Primary endpoint:** Proportion of patients with undetectable virus levels 24 weeks after planned end-of-treatment (SVR24)
- **SoC:** Ribavirin 1,000–1,200 mg BID + pegIFNalpha-2A 180 µg weekly

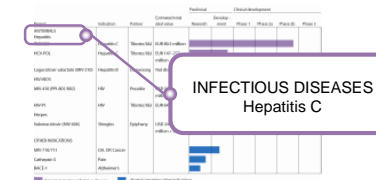
Press Release on 12 July 2010



TMC435-C205 PILLAR Phase 2b study: 24-week Interim Results in 386 Treatment-naïve HCV Patients

- 83% of patients were able to stop all therapy at Week 24 in TMC435 treatment groups
 - Response guided design in TMC435-C205 PILLAR Phase 2b study
 - Patients stopped all treatment at week 24 if HCV RNA levels at week 4 were < 25 log₁₀ IU/mL detectable or undetectable and HCV RNA levels at week 12, week 16 and week 20 were < 25 log₁₀ IU/mL undetectable. Patients who did not meet the above response-guided criteria continued with SOC until week 48
- Potent and consistent antiviral efficacy was demonstrated at 24-week end-of-treatment
- Interim SVR4 and SVR12 data:
 - For the interim SVR4 and SVR12 rates there were no major differences between TMC435 doses or length of triple therapy
 - 92% of patients taking TMC435 and Peg-IFN/RBV (SoC) achieved undetectable HCV RNA levels at week 4 and 92% at week 12 after cessation of treatment, i.e. SVR4 and SVR12
 - SVR4 and SVR12 data, at the time point of the interim analysis, were available for 82% and 42% of the TMC435-treated patients respectively who had stopped all therapy before or at Week 24 and had completed the follow-up visits
- Both the viral breakthrough rate (4.9%) and relapse rate (1.6%) were low in the TMC435 treatment groups.

Virologic Response Overview – Trial C205 - (Week 24 Interim Analysis)



ITT Population, Frequency of Undetectable* HCV RNA Levels During and After Treatment					
Treatment week	TMC12PR24 75mg q.d. N=78	TMC24PR24 75mg q.d. N=75	TMC12PR24 150mg q.d. N=77	TMC24PR24 150mg q.d. N=79	SoC N=77
N (%)					
Week-24, EoT***	67/73 (92%)	65/67 (97%)	68/74 (92%)	73/78 (94%)	4/18 (22%)**
Follow-up at Week-4 and Week-12 after EoT					
SVR4	59/65 (91%)	56/60 (93%)	57/61 (93%)	63/68 (93%)	NA****
SVR12	32/33 (97%)	27/29 (93%)	32/36 (89%)	29/32 (91%)	NA

* < 25 log₁₀ IU/mL undetectable

** End of treatment

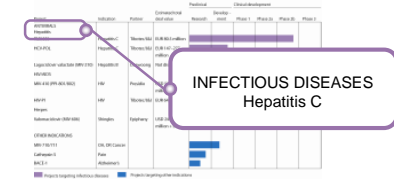
*** EoT: End of Treatment

**** Patients in the control arm continue SoC till Week 48 and SVR data are not available

q.d.: once daily, PR: pegIFNalpha-2A and ribavirin

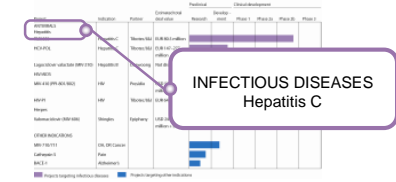
SVR4: undetectable HCV RNA at EoT & undetectable HCV RNA 4 weeks after planned EoT

SVR12: undetectable HCV RNA at EoT & undetectable HCV RNA 12 weeks after planned EoT



Safety and Tolerability

- TMC435 was well tolerated at all doses and regimens studied.
 - TMC435 was generally safe and well tolerated with no relevant differences in adverse events (AEs) between placebo and TMC435 treatment groups. Most AEs were mild to moderate in severity and the discontinuation rate due to AEs was low and not different from placebo.
- Type and incidence of adverse events (AEs) were similar across all treatment groups.
 - When looking at particular adverse events of interest, the incidence of rash, pruritis, GI side effects and anemia were similar in TMC435 groups and placebo and were generally mild to moderate in nature.
- In laboratory parameters, there were no clinically relevant differences between any TMC435 groups and placebo except for mild bilirubin elevations.
 - Mild increases in bilirubin (total, direct and indirect) were observed in the TMC435 150-mg dose groups. This pattern of mild, non-progressive, rapidly reversible bilirubin elevations which are not associated with abnormalities in other hepatic parameters is consistent with the underlying mechanism of a benign competitive inhibition of biliary transporter systems in the hepatocyte
- Significant decreases in transaminases (ALT and AST) were observed in all treatment groups.
- There were no clinically significant findings on vital signs and ECG parameters.
- AEs leading to treatment discontinuation were reported in 7.8% of placebo subjects (SoC) and 7.1% of TMC435 subjects, with no differences between the TMC435 dose groups.
- Further safety and virology data will be presented at the upcoming AASLD meeting in October 2010



TMC435 news flow

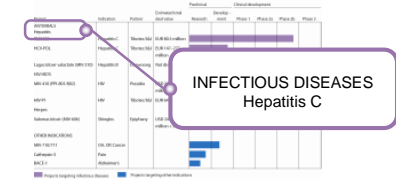
Events in the next 6 months

- DRAGON (C215)
 - Presentation of 12 week interim data from the phase 2b study in treatment-naïve Japanese genotype-1 HCV patients
- PILLAR (C205)
 - Presentation of top-line 24 week interim data at the AASLD meeting in Boston
 - 48 week end of treatment data available during Q4
- Opera-2 (C202)
 - Presentation of data from the phase 2a study in treatment-naïve genotype 2–6 HCV patients at the AASLD meeting in Boston
- Presentation of mechanism of action (MOA) behind the transient reversible increases in bilirubin
 - The AASLD meeting in Boston
- ASPIRE (C206)
 - Top-line 24 Week interim data from the phase 2b study in treatment-experienced genotype-1 HCV patients available in 4Q10
- Phase 3
 - Start of phase 3 in treatment-naïve genotype-1 HCV patients

TMC435 is a potential blockbuster in hepatitis C



- Leading next generation protease inhibitor
- Superior profile compared with first generation PIs (telaprevir, boceprevir)
- Potent anti-viral activity shown in phase 2b clinical trials in different patient groups
- Low pill burden: convenient one pill, once daily
- No food interactions
- No significant adverse events over current SoC



Hepatitis C – HCV-POL



Status

- Partnership entered with Tibotec/Johnson & Johnson in May 2008
- Presently in late preclinical development phase towards phase 1 clinical trials
- Synergy shown with both TMC435 and non-nucleoside NS5B inhibitors (DAA agents)

Nucleoside/nucleotide NS5B polymerase inhibitor characteristics

- Nucleoside/nucleotide inhibitors are chain-terminators
- High *in vivo* potency demonstrated
- Wide genotype coverage
- High barrier to resistance
- An ideal DAA agent for future TMC435 combination regimens
- 4 nucleoside/nucleotide analogues in clinical development (phase 1 and 2)

Events in coming 12 month - HCV Pol

- Start of phase 1 clinical trials
- Presentation of phase 1 clinical trial data
- Presentation on antiviral potency, mechanism of action and DAA synergy data