Aedivir

A specialty pharmaceutical company focused on infectious diseases

Jefferies Health Care Conference New York June 2011

Presenting team

Ron Long CEO



Charlotte Edenius Vice President R&D Projects



Rein Piir CFO / IR



Medivir in Brief

Listed:	1996
Ticker:	MVIR
Exchange:	OMX NASDAQ
Market Cap (SEK):	4,000 Million

First Product Xerclear[™] / Xerese[™] in Global Launch Phase

- Launch begun in Nordic region; Launched in US March 2011
- Nordic infrastructural and commercial capability secured through acquisition of BioPhausia

Focused infectious disease pipeline – multiple paths to value creation

- World leading science in the field of infectious disease R&D
- TMC435 a potential blockbuster in hepatitis C
- 10 projects in clinical and pre-clinical development
- 7 partnerships with pharmaceutical and biotech companies

Experienced international management team

 Company supported by a highly experienced team with a strong skill base to ensure Medivir's success

Strong long-term commitment of institutional shareholders

• Over 1/3 international shareholders



Medivir Vision



Medivir aims to become a profitable research based specialty pharmaceutical company focused on the development and commercialisation of high-value infectious disease treatments



Medivir's Strategy

- Continue to innovate and be "a partner of choice"
 → creating value for our partners and shareholders
- Create and retain more value in our projects
 - \rightarrow later out-licensing, co-development rights, expanded territories
- Continue to look for strategic product in-licensing and acquisition opportunities globally

Our aim is to become a profitable research-based specialty pharmaceutical company focused on the development and commercialisation of high-value infectious disease treatments



Key innovation and commercialisation at Medivir

TMC435 – Considered best in class hepatitis C drug

- Global Phase 3 trials ongoing
- Excellent antiviral activity and strong safety profile demonstrated in Phase 2b studies
- High convenience one pill, once daily, no food interactions



Xerclear® / Xerese[™] - in global launch phase 2011

- Differentiated product profile unique indication text
- Significant blue-chip marketing partners.



Strong Pipeline in development

- Strong pipeline of innovative infectious disease drug candidates in development in-house and with leading pharma partners
- World class expertise in polymerase and protease drug targets



Global Launch of Xerclear®/Xerese® 2011



Ongoing launch of our cold sore product is the first step towards profitability



TMC435 - large commercial opportunity in the Nordic countries

Medivir is in a unique position – Nordic commercial rights retained

- To launch one of the first products of a new treatment paradigm for a patient group with a distinct unmet medical need
- To capture a significant share of the protease inhibitor market due to highly competitive attributes of TMC435
- To give high priority and focus on pre-launch activities to facilitate broad and fast market access for TMC435 well in advance of launch

Unmet medical need – Large market with substantial growth potential

- 115,000 Chronic HCV patients in the Nordics
- 3,000 HCV receive treatment at a yearly treatment cost of SEK 170.000 (SoC)
- Poor efficacy and safety profile with current treatment. Less than 50% of patients reach a sustained virologic response
- This medical need will be addressed for the first time with the introduction of protease inhibitors (PI) on the market in 2011. TMC435 will be second generation protease inhibitor to enter market.

Treatment evolution – Main market driver

- Patient warehousing of HCV patients with G1 is acknowledged Approx 10-20% of these patients are in an acute phase and need treatment immediately
- Share of PI treated naïve patient will increase over time as PI's gain recognition



Acquisition of BioPhausia – our new commercial capability



- Expanded commercial platform
- Customer facing brands maintained
- Strengthened position to facilitate and optimise expected launch of TMC435 in the Nordic region



Key programmes in our early stage pipeline

Strong pipeline with multiple paths to value creation

	Therapy area Par	Partner	Preclinical development		Clinical development			
Project			Research	Develop- ment	Phase 1	Phase 2a	Phase 2b	Phase 3
INFECTIOUS DISEASES								
Hepatitis								
TMC435	Hepatitis C	Tibotec Pharmaceuticals/J&J						
TMC649128 (HCV POL)	Hepatitis C	Tibotec Pharmaceuticals/J&J	(
HCV projects								
Lagociclovir valactate (MIV-210)	Hepatitis B	Daewoong	(
HIV/AIDS								
MIV-410 (PPI-801/802)	HIV	Presidio						
HIV-PI	HIV	Tibotec Pharmaceuticals/J&J						
Herpes virus								
Valomaciclovir (MIV-606)	Shingles	Epiphany	6		1	1		
Dengue virus								
NS3 protease inhibitor	Dengue fever	Janssen Pharmaceutica						
OTHER INDICATIONS								
Cathepsin K inhibitor	Bone disorders		(
Cathepsin S inhibitor	Neuropathic pain							

Projects targeting infectious diseases



Cathepsin K inhibitors for bone disorders – MIV-710/711

Creating value for shareholders by developing products further under own management

Disease and market

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

MIV-710 and MIV-711

- Maintain the beneficial bone formation, in contrast to other anti-resorptives
- Two Candidate Drugs selected: MIV-710 and MIV-711
- · Potent and long duration of activity
- A low once daily human efficacious dose at 50 mg QD estimated
- Strong IP position

Upcoming events in 2011

- The two Candidate Drugs selected are progressing in preclinical studies
- Start of phase 1 clinical trials for MIV-711 expected in Q3 2011



Cathepsin S inhibitor – Neuropathic pain and Rheumatoid arthritis

Creating value for shareholders by developing products further under own management						
Disease and market	Cathepsin S inhibitor program					
 Approximately 25 million patients worldwide suffer from neuropathic pain 	 Strong link to Neuropathic pain Cathepsin S is essential for activation of the soluble fractalkine on neurons → neuro- 					
 Estimated global market opportunity for neuropathic pain in excess of USD 2.3 billion, and rheumatoid arthritis (RA) is estimated to USD 7 billion 	 Inflammation Secreted by activated microglial cells in CNS in rodent models Overexpressed in DRG infiltrating macrophages and near site of peripheral injury in rodent models 					
	 Potent, selective and orally bioavailable inhibitors developed by Medivir 					
Upcoming events in the coming 12 month	 Proof-of-principle demonstrated in a rodent model of neuropathic pain 					
Candidate drug selection	 Strong link to Rheumatoid arthirtis 					
	 Crucial role in MHC Class II antigen presentation 					
	 Antigen presentation is key to establishing an immune response 					
	 Proof of principle demonstrated in preclinical CIA disease models 					



Dengue Fever Joint Venture

Co-development collaboration with Janssen Pharmaceutica N.V.

- Strengthens Medivir's presence in infectious diseases
- Utilises strong know-how in the discovery of protease inhibitor drugs
- Approach focussed on inhibition of the dengue NS3 protease involved in viral replication

Commercial strategy

- Both parties are contributing 50:50 resources to the research program
- Increased potential upside from co-development deal

Market opportunity

- Dengue virus infection is a major problem in subtropical regions where the incidence has increased 30-fold over the last 50 years
- Up to 50 million infections occur annually in more than 100 endemic countries and the annual death rate from dengue infection is approximately 30,000
- This growing prevalence has not been met by any significant advances in treatment¹

¹ World Health Organisation, Fact sheet N°117, March 2009.



Our hepatitis C franchise

Partnered and in-house product portfolio

Hepatitis C - A blockbuster potential market

The Hepatitis C Market

- Globally ~180 million (3-4% of world population) infected with hepatitis C virus, of which 80% develop chronic disease
- The difficult to treat genotype 1 (G1a/b) account for ~70% of the HCV population
 - Sustained viral response (SVR) in G1 patients is very low, 42-48% on PEG/RBV, SoC
- Approximately 12 million HCV infected in the US, Europe and Japan
 - Prevalence in JPN ~1.9 million with ~55% being diagnosed (~25% worldwide)
 - Health care burden in the US ~ 5 BUSD / year

Market Value

- Estimated market value of over USD 10 billion in 2015 and increasing
- Treatment-experienced patients, currently ~ 0.5 million, comprise ~half of the market value

TMC 435 potential

Analysts estimate TMC435 annual peak sales of 2-4 BUSD







Medivir commitment to HCV - 2nd DAA programs

TMC649128 (HCV Pol)

A major commercial opportunity

- EUR 147 million deal value
 - EUR 95 million outstanding
 - Royalties on global sales
- Medivir retain Nordic market rights
 - Prevalence of chronic HCV infected ~115,000
 - Current treatment rates ~ 3 000





Summary & Status

- Nucleoside/tide NS5B inhibitor
- An ideal DAA agent for future TMC435 combination regimens
- High barrier to resistance and broad genotype coverage
- Long patent life
 - IP extending to 2027 and 2029
- Phase 1 trials well under way

Preclinical In-House Programs

- An NS5B nucleoside/tide program
- An NS5A program in LO phase



TMC435 – considered to be "best in class" protease inhibitor



- Strong safety profile: no adverse events over SoC in the Phase 2b studies
- Excellent anti-viral efficacy shown in Phase 2b PILLAR and ASPIRE studies
- Convenient: one pill and once daily, no food interactions
- Global Phase 3 clinical trials ongoing



Medivir commitment to HCV - TMC-435



The commercial opportunity

- EUR 80.5 million deal value
 - EUR 30 million still outstanding
 - Royalties on sales worldwide
 - Medivir retain all rights to the Nordic market
- The Nordic Region
 - Current treatment cost in Sweden is ~20,000 EUR which is estimated to double with the introduction of the first DAA agents.

Decision Resources, Report March 2011:

-TMC-435 has the potential to emerge as the future gold-standard therapy in our Drug Comparator Model because of its superior clinical profile over the current therapies we evaluated-.

Summary & Status

- Potent HCV NS3/4A protease inhibitor
- TMC435, the backbone of future DAA combination therapies (combination studies to be communicated)
- Long patent life
 - IP extending to 2026 and 2028
- Global Phase 3 trials ongoing
- Regulatory filings expected in 2013





Hepatitis C PI – the competitive landscape

Phase 1a	Phase 1b	Phase 2a	Phase 2b	Phase 3	Registration
VPY-376	ACH-1625	ABT-450	Danoprevir R-7227 ?	TMC435	Telaprevir VX-950
PHX1766			BMS-650032		Boceprevir SCH-503034
IDX320			GS-9256		
MK-5172			Vaniprevir ? MK-7009		
			BI201335		
			Narlaprevir?		



TMC435 Late Stage Clinical Trial Programme

Follow Up Phase

Phase 2b studies

PILLAR (C205) – 386 genotype-1 infected treatment-naïve patients

DRAGON (C215) – 92 genotype-1 infected treatment-naïve patients

ASPIRE (C206) – 462 genotype-1 infected treatment-experienced patients

Recently Initiated

Phase 3 studies

QUEST 1 (C208) 375

genotype-1 infected treatment-naïve patients

QUEST 2 (C216) 375

genotype-1 infected treatment-naïve patients

PROMISE (C3007) 375 genotype-1 infected relapsed patients

Phase 3 studies started in Japan

- both in naïve and treatment experienced
- genotype-1 infected patients

For additional information on inclusion and exclusion criteria for these studies, please see www.clinicaltrials.gov



TMC435 Phase 2b (PILLAR C205) - study design

- 386 genotype-1 treatment-naïve patients
- Once daily (*q.d.*), 75 mg and 150 mg TMC435 + SoC:
 - 12-week triple therapy followed by SoC alone up to week 24 or
 - 24-week triple therapy

- Response-guided TMC435 treatment duration:
 - End treatment at Week 24, if
 - HCV RNA <25 IU/mL detectable or undetectable at Week 4, and
 - HCV RNA <25 IU/mL undetectable at Weeks 12, 16, and 20
 - All other patients continued Peg/RBV for up to 48 weeks





TMC435 Phase 2b (PILLAR C205)

- <u>48-week interim analysis</u> of safety and efficacy (SVR24)

Patient population:	Treatment-naïve genotype-1 treatment naïve patients
Efficacy:	83% of patients were able to stop all therapy at week 24 in the TMC435 treatment groups
	Potent and consistent antiviral efficacy was demonstrated with <u>SVR24</u> rates of up to 84%
Safety:	No clinically relevant difference in safety and tolerability between TMC435 and placebo groups

Sustained Virological Response 4 and 24 Weeks after Planned End of Treatment (EoT);						
% (n/N)	TMC435 12PR24 75mg q.d. N=78	TMC435 24PR24 75mg q.d. N=75	TMC435 12PR24 150mg q.d. N=77	TMC435 24PR24 150mg q.d. N=79	Placebo N=77	
SVR4	87.2 (68/78)	86.5 (64/74)	84.9 (62/73)	88.5 (69/78)	71.2 (42/59)	
SVR24	83.6 (61/73)	76.1 (51/67)	83.1 (59/71)	84.4 (65/77)	N/A	

* < 25 log10 IU/mL undetectable

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

SVR4 and SVR24: patients with undetectable HCV RNA 4 and 24 weeks after planned EoT, respectively.

N/A: Patients in the control arm continue SoC until Week 48 and SVR24 data was not available



TMC435 Phase 2b (ASPIRE C206, treatment experienced) - study design

- 462 genotype-1 treatment-experienced patients (relapser, partial- and null responder patients)
- Once daily (*q.d.*), 100 or 150 mg TMC435 + SoC:
 - 12-week triple therapy followed by 36 weeks of SoC
 - 24-week triple therapy followed by 24 weeks of SoC
 - 48-week triple therapy





TMC435 Phase 2b (ASPIRE C206)

- 48 week interim analysis of safety and efficacy

Patient population:	Treatment experienced patient group 62 percent (287/462) of patients had advanced liver disease (Metavir F2-F4)
Excellent Efficacy:	 TMC435 shows <u>high SVR4 rates in prior treatment failures</u>, also so in the very difficult to treat partial and null responder patient groups, compared to PEG/RBV alone: 87% vs. 50% in prior relapsers, 77% vs. 11% in prior partial responders and 57% vs. 23% in prior null responders

Promising Safety: TMC435 was safe and well tolerated at all doses and treatment durations

Virologic Response Rates in TMC435 Dose Groups (150 mg q.d.) vs Placebo						
% (n/N)		TMC435 12 PR48 N=66	TMC435 24 PR48 N=68	TMC435 48 PR48 N=65	All TMC435 PR48 N=199	Placebo PR48 N=66
Prior Relaps er	EoT SVR4	92 (24/26) 84 (21/25)	93 (25/27) 93 (25/27)	92 (24/26) 85 (22/26)	92 (73/79) 87 (68/78)	70 (19/27) 50 (12/24)
Prior Partial Respon der	EoT SVR4	78 (18/23) 64 (14/22)	83 (20/24) 86 (18/21)	86 (19/22) 82 (18/22)	83 (57/69) 77 (50/65)	17 (4/23) 11 (2/18)
Prior Null Respon der	EoT SVR4	65 (11/17) 56 (9/16)	71 (12/17) 60 (9/15)	77 (13/17) 56 (9/16)	71 (36/51) 57 (27/47)	25 (4/16) 23 (3/13)



TMC435 Phase 2b (ASPIRE C206)

- treatment experienced patients

Conclusions 48-week interim analysis:

- ✓ TMC435 treatment arms demonstrate excellent SVR4 response rates in all patient subgroups
- Notably, the partial and null responder groups demonstrated significant response rates
- ✓ TMC435 was safe and well tolerated

Bertil Samuelsson, CSO, Medivir: *"With several global phase 3 clinical trials ongoing in hepatitis C patients we are expecting the momentum to continue with regards to the development of TMC435" (press release May 20th, 2011)*



Upcoming News Flow



Expected key news flow highlights during 2011

- ✓ Q2 TMC435, 48-week interim data from the phase 2b C206 (ASPIRE) trial in treatment-experienced patients
- Q2 Closing of the BioPhausia offer
- Q3 Phase 2b C205 (PILLAR) full SVR24 data on TMC435
- Q3 Start of phase 1b trials with TMC649128 (HCV-POL)
- Q4 Start of phase 3 trials with TMC435 in treatment-experienced null and partial responders patients
- Q4 Phase 1a/1b results with TMC649128
- Q4 Start of phase 1 trials with the Cat K inhibitor MIV-711
- Q4 AASLD meeting additional data on TMC435
- Q4 OTC launch of Xerclear® in Europe by GSK

