Medivir

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Medivir is well positioned for the future

- Discovery and research based pharmaceutical company with 16 marketed Rx pharmaceuticals in the Nordics
- World leading expertise in polymerase and protease drug targets
- Solid financial position and on the way to profitability
- Extensive collaboration and partnership track record with major global pharma companies
- Two in-house products developed from early research to commercialization
- Six projects currently in the R&D portfolio
- 130 employees, 90 of which are in R&D, from 16 nations

Solid foundation and track record







Our R&D pipeline is the engine of Medivir

			Preclinical phase		Clinical phase				
Field	Project	Partner	Re- search	Deve- lopment	Phase I	Phase Ila	Phase IIb	Phase III	Market

Anivirals

Labial herpes	Xerclear (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)				
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals			_ ∧ i	Approved in Japan
Hepatitis C	NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals				
Hepatitis C	NS5B nucleotide-based polymerase inhibotor	Unpartnered				
HIV	Protease inhibitor	Janssen Pharmaceuticals				

Other indications

Bone related disorders	Cathepsin K inhibitor	Unpartnered			Phase	e I data	
Neuropathic pain	Cathepsin S inhibitor	Unpartnered	CD	nomina	ated		

Recent milestones have generated significant momentum for Medivir



MIV-711 - A cathepsin K inhibitor for osteoarthritis (OA) and other bone related disorders

Mechanism of action

- Cathepsin K degrades collagen in both bone and cartilage
- Pathological processes in both cartilage and bone occur in OA
- Genetic, animal and human data shows that cathepsin K inhibition improves bone quality



Phase I study recently finished

- Placebo controlled, double-blind study in healthy subjects
- Ascending single and multiple (7 28 days) once daily dosing
- Included biomarkers for bone and cartilage turnover
- Multiple dose data recently presented*
- Partnering activities initiated aiming for partnership for further clinical development

Our clinical data support further development of MIV-711 for osteoarthritis and other bone related disorders



* American Society for Bone and Mineral Research, Baltimore, 4 -7 Oct 2013

Cathepsin S inhibitor to address unmet needs in treatment of neuropathic pain (NP)

Neuropathic pain

- Associated with a lesion or disease affecting the somatosensory system
- e.g. diabetic neuropathic pain, post-herpetic neuralgia & neuropathic lower back pain
- Inhibition of Cat S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine release



Big market with high medical need

- Current treatments incl. anticonvulsants and antidepressants
 - Pain persists in 75% patients with at best a 50% reduction in overall pain
 - Significant side effects e.g. dizziness, somnolence
- 25M people in the 7 MM suffer from NP

Day 10 contralateral

- Vehicles alone
- MV-CATSI (50):Gabapentin (146)
- MV-CATSI (50)
- Gabapentin (146)

(µmol/kg)



Wholly owned HCV nucleotide program is an important strategic asset

- Medivir has leveraged nucleoside experience to pursue high value nucleotide compounds
- Current Medivir effort focused on novel uridine-based series
- Medivir's compounds are structurally distinct from existing nucleoside starting points
- Initial protide series features include:
 - EC50 values <100nM
 - High in vitro selectivity indices
 - Attractive early pharmacokinetic profile





Simeprevir and HCV market overview



Simeprevir: a next generation HCV protease inhibitor

- Approved in Japan with a broad label
- Under review in US and EU



- Activities underway to expand commercial opportunity of triple regimen
- An important cornerstone in coming IFN free treatment options
 - currently studied in a large number of IFN and ribavirin free combinations

Simeprevir – High cure rates in broad patient populations and a favorable safety profile



Simeprevir - pivotal global phase III studies highlight differentiated profile

Excellent efficacy, safety and tolerability in phase III (150 mg, OD)

- ~80% overall cure rates
- up to 91% could stop all treatment at 24 weeks (83-91% cured)
- comparable adverse event profile to IFN/ribavirin



Simeprevir showed robust overall efficacy in all studies



Additional phase III studies of simeprevir triple therapy to enhance commercial profile

Regional expansion - China

 A pivotal study of Efficacy, Safety & Tolerability and Pharmacokinetics in treatment naive GT1 HCV patients (fully enrolled; n=444)

Patient population expansion

- HIV/HCV co-infected patients
 - Interim results: 77% SVR12 (10/13) in naïve/relapser patients (final results at EACS, Brussels, Oct 18th)
- Genotype 4 HCV infected patients
 - Interim results to be presented at EACS, Brussels, Oct 18th

Shortened treatment duration

- **12 weeks full stop triple combination study,** open-label, single-arm study in treatment naïve GT1 patients
 - Recruitment ongoing



Simeprevir will play a central role in the future

We are committed to advancing the treatment of hepatitis C





Data driven approach to exploring different interferon free simeprevir combinations (with or w/o ribavirin)

Simeprevir given in combination with:	Investigational compound	Study informtation	
Nucleotide	Sofosbuvir	COSMOS : Cohort A: nulls ; Cohort B: nulls + naives (F3&4)	
	VX-135	DDI finished, Ph II to start H213	
NG5A inhibitor	Daclatasvir	Naives and nulls, F0-F4	
	Samatasvir	HELIX-1: Phase II on-going (Gt1b and 4)	
NS5A inhibitor	TMC647055 + Samatasvir	HELIX-2 to start, DDI ongoing	
+ NNI	TMC647055 + GSK2336805	Phase II, in planning phase	
+ NNI	TMC647055	Naives/relapser and nulls	



We are in the late stages of the evolution to all oral, interferon-free treatment



Shortened treatment duration

Different combinations of direct acting antivirals (DAAs) have shown good efficacy in various patient populations



SVR12; Sustained Virologic Response 12 weeks (cure rate) IFN: Peginterferon; Rbv: ribavirin; Nuc: nucleotide; NS5A; NS5A inhibitor; 14 NNI: non-nucleotide inhibitor; TVR: telaprevir; BOC: boceprevir

Phase II data of various PI based combinations have shown promising results





COSMOS study – results from 12 weeks treatment arms

	Col	hort 1	Cohort 2		
	Null re: (META)	sponders /IR F0-F2)	Null responder a (METAVIF	nd treatment naïve R F3 or F4)	
0/_	SMV / SOF+ RBV	SMV / SOF	SMV / SOF + RBV	SMV / SOF	
/0	(n=27)	(n=14)	(n=27)	(n=14)	
SVR4	96 (26/27)	93 (13/14)	96 (26/27*)	100 (14/14**)	
SVR12	96 (26/27)	93 (13/14)	-	-	
SVR4/12 (GT1a Q80K positive)	89 (8/9)	83 (5/6)	88 (7/8)	100 (3/3)	

*null responders 93 (14/15) ** null responders 100 (7/7)

High efficacy in hardest to cure HCV patients also without ribavirin





HCV market overview



Hepatitis C dynamics can provide long-term market growth through increases in treatment and diagnosis rates



Genotype	US (%)	5EU (%)
1a	54	15
1b	20	55
2	16	9
3	7	14
4	1	6
5&6	2	1
	_	

Source: Datamonitor (2011)



Japanese HCV market has similar dynamics to US/EU but is larger and more concentrated than many realize



Genotype distribution in Japan

Genotype	JP (%)
1a	3
1b	66
2	30
3	1
4	0
5&6	0
	Source: Datamonitor (2011)

Known pricing data from Japan	
 Telaprevir price lower than US and EU 	Approx. \$13,000
 Potential for price premium 	
 30% premium possible for the same mechanism 	1
 Higher levels can only be negotiated for new mechanisms 	



Simeprevir has a head start on the competition in Japan





Summary of Japanese HCV market dynamics

- Large prevalence (1.5-2 M) of HCV infection, >500 K diagnosed, with ~50-60 K patients treated annually
- Competition at less advanced stage than in US/EU
- With the majority of patients infected with genotype 1b virus, Japan is an ideal market for a DAA combo treatment containing an HCV PI, NS5A or nucleotide
- Pricing of TPV (~13 K USD) plus IFN/RBV substantially lower than EU/US; higher prices can be negotiated for improved regimens or new mechanisms, i.e. IFN-free combos

Simeprevir is well positioned to be a leading HCV therapy in the Japanese market



Financial Summary

Market Capitalization:	SEK 2,850M	\$435M USD
Cash (as of June 30):	400SEKM	\$61M USD
Debt (as of June 30):	SEK 42M	\$6M USD
Revenues (ttm):	SEK 180M	\$28M USD
Operating Cash Flow (ttm):	SEK (180)M	\$(28)M USD
Shares Outstanding:	Class B: 30,600,027 Class A: 660,000 Options: 404,374 Fully Diluted: 31,664,401	



www.medivir.com

Ticker: MVIR Exchange: OMX / NASDAQ

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