

Medivir presenting at

#### Carnegie Health Care Seminar 25 March 2009

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#### Basic facts - March 2009

- o Listed since 1996 (OME: MVIRB SS)
- o **Headquarter in:** Stockholm, Sweden
- o **Partnerships:** Several with Big Pharma and Biotech

#### Selected financials

- o Cash position: SEK 284m (YE-2008)
- o **Revenues:** SEK 97m (FY 2008)
- o Loss:

SEK 99m (FY 2008)

#### o MCap:

~ SEK 940m

#### o Shareholder structure of capital:

Private individual 14,9% Founders 6,2% Swedish Institutions 33,5% EU / US Institutions 27,6% Swedish Retail owners 17,8%





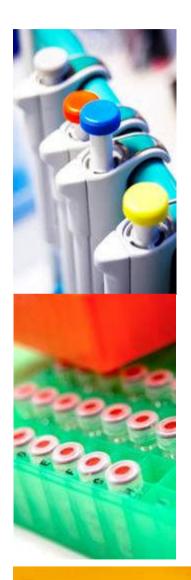
#### Medivir Pipeline March 2009

#### **Prioritized** projects

Project     Indication(s)     of agreement     Terms     markets     tive phase     tion     dev.*     Phase II     Phase III     NDA       Lipsovir® (ME-609)     Labial herpes (ME-609)     In-house     In-house     In-house     In-house     In-house     In-house       TMC435     Hepatitis C     Tibotec/2004     EUR 80.5 m +     Nordic region     In-house     In-house     In-house			Partners/ Date		Medivir's	Explora-	Optimiza-	Preclinical					
(ME-609)       TMC435       Hepatitis C       Tibotec / 2004       EUR 80.5 m + royalties and FTE funding       Nordic region       Inhouse preclinical program         MIV-701       Osteoporosis, osteoarthritis, bone metastases       In-house       Image: State and FTE funding       Nordic region         MIV-710       Osteoporosis, osteoarthritis, bone metastases       Inhouse       Image: State and FTE funding       Nordic region         MIV-710       Osteoporosis, osteoarthritis, bone metastases       Inhouse       Image: State and FTE funding       Nordic region         MIV-710       Osteoporosis, osteoarthritis, bone metastases       In-house       Image: State and FTE funding       Nordic region         MIV-710       Osteoporosis, osteoarthritis, bone metastases       In-house       Image: State and FTE funding       Nordic region         MIV-710       Osteoporosis, osteoarthritis, bone metastases       Inhouse       Inhouse       Inhouse         BACE       Alzheimer's       In-house       Image: State and FTE funding       Nordic region       Inhouse       Inhouse         GOPD PI       COPD       In-house       Vorld       Vorld       Image: State and FTE funding       Image: State an	Project	Indication(s)		Terms					Phase I	Phase II	Phase III	NDA	
INCASS (HCV-R)       Repairs C       INDUE / 2004       EVR 40.5114 royaties and FTE funding       Notic region         MIV-701 (Cath K)       Osteoprosis, bone metastases       In-house       V       V       Nordic region         MIV-710 (Cath K)       Osteoprosis, bone metastases       In-house       V       Nordic region         MIV-710 (Cath K)       Osteoprosis, osteoarthritis, bone metastases       In-house       V       V         MIV-710 (Cath K)       Osteoprosis, osteoarthritis, bone metastases       In-house       V       V       Nordic region + royaties and FTE funding       Inhouse preclinical program       Inhouse       Inhouse		Labial herpes	In-house										Inhouse
MIV-701 (Cath K)       Osteoprinss, bone metastases       In-house         MIV-710 (Cath K)       Osteoprosis, osteoarthritis, bone metastases       In-house         MIV-710 (Cath K)       Osteoprosis, osteoarthritis, bone metastases       In-house         HIVPI       HIV       Tibotec / 2006       EUR 64 m + royalties and FTE funding       Nordic region + royalties and FTE funding         BACE       Alzheimer's       In-house       In-house         Cathepsin S COPD PI       COPD       In-house       World		Hepatitis C	Tibotec / 2004	royalties and FTE	Nordic region								preclinical
MIV-710 (Cath K)       Osteoporosis, osteoarthritis, bone metastases       In-house       Inhouse       Inhouse         HIV PI       HIV       Tibotec/2006       EUR 64 m + royalties and FTE funding       Nordic region       program       program         BACE       Alzheimer's       In-house       FTE funding       Inhouse       program         Cathepsin S       Rheumatoid arthritis, multiple sclerosis       In-house       World       World       Mordi arthritis, and the sclerosis       Inhouse         COPD PI       COPD       In-house       World       World       Inhouse       Inhouse		osteoarthritis,	In-house										program
Interview       Osteoarthritis, bone metastases       Interview	HCVPOL	Hepatitis C	Tibotec / 2008	royalties and FTE	Nordic region			-					
BACE     Alzheimer's     In-house       Gathepsin S     Rheumatoid arthritis, In-house     In-house       Multiple sclerosis     World		osteoarthritis,	In-house					-					preclinical
Cathepsin S     Rheumatoid arthritis, In-house multiple sclerosis     Inhouse preclinical program       COPD PI     COPD     In-house	HIV PI	HIV	Tibotec / 2006	+ royalties and	Nordic region	_							program
COPD PI     COPD     In-house     World	BACE	Alzheimer's	In-house										
COPD PI COPD In-house World	Cathepsin S		In-house										
Renin Hypertension In-house	COPD PI	COPD	In-house		World								<u> </u>
	Renin	Hypertension	In-house										



# Medivir - Key achievements during the last 12 months



- Medivir sharpens the strategic focus and strengthens its financial position. Cost savings to be carried out during 2009.
- Cathepsin K Candidate Drug MIV-710 selected on February 4th, 2009
- Cash position by end of year 2008 (SEK 284m) with present yearly structural burn rate of SEK 200m
- Hepatitis C polymerase Candidate Drug selected on December 9th in the JNJ/Tibotec collaboration program triggering a milestone payment of € 2.6m
- Applications for approval of Lipsovir (labial herpes) filed and validated in the US and Europe. Approval target date late autumn 2009
- Our biggest deal ever signed in May with JNJ/Tibotec for hepatitis C nucleoside polymerase inhibitors (>USD 190m)
- Strong phase IIa data presented for TMC435 (hepatitis C protease inhibitor)







- We filed an NDA with US (FDA) and EU regulatory authorities for Lipsovir® in October
- In December, these authorities announced that they had validated the NDA and that their review and evaluation process had begun
- We expect to receive the outcome of this process in autumn 2009
- The objective is to enter partnerships to commercialize Lipsovir® globally.





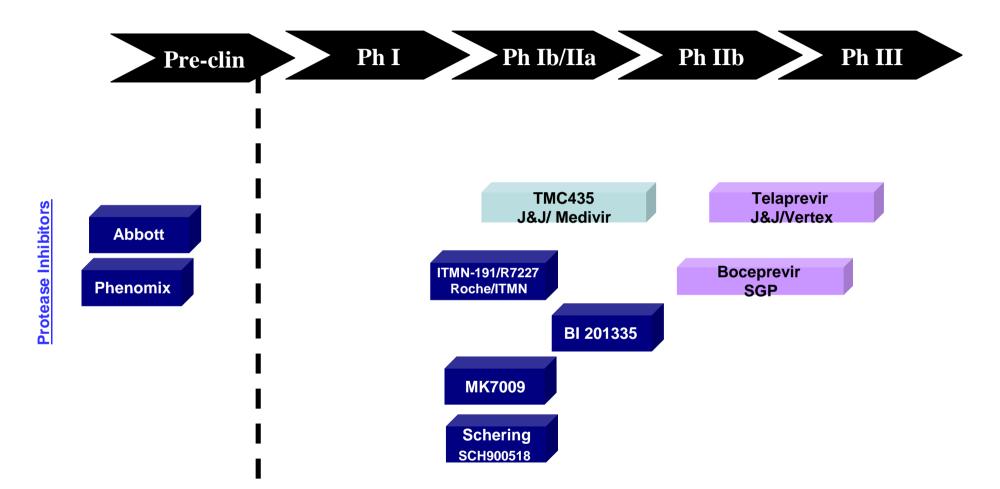
TMC435 - in collaboration with Tibotec / J&J

Presently in final stage of phase IIa for genotype 1 treatment naïve patients and treatment experienced patients

Phase IIb will start in Q2



### **HCV PI Competitive Landscape**





### Hepatitis C protease - TMC435 - Medivir/Tibotec

#### Status

• Phase IIb will start Q2 2009

#### **Results from IIa**

• Data from 25 and 75 mg dose groups in naïve patients presented in November 2008.

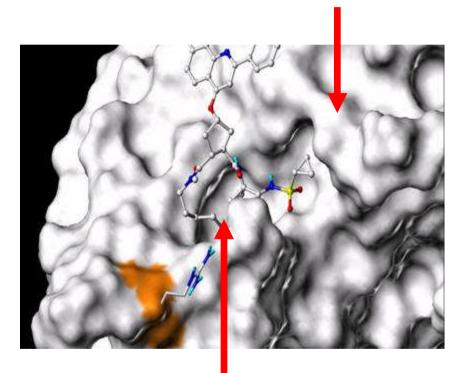
#### New data to be presented in April

• Data from 200 mg dose group in naïve patients and data in non-responders and relapsers from the 75, 150 and 200mg dose groups to be presented at EASL 23-25 April 2009

#### Licensing agreement

- Upfront & milestones of EUR 80.5m (EUR 47m remains)
  - + royalties on sales
- All development costs covered by Tibotec
- Nordic rights retained by Medivir

NS3/4A: Key protease for virus replication



Enzyme inhibiting compound



### Opera-1 (cohort 1): Antiviral efficacy in 25 and 75 mg

Table 3: Mean HCV RNA changes from baseline and number of patients with HCV RNA levels below lower limit of quantification (LLQ) and detection (LLD) per treatment arm.

Dose/Treatment	Time point (Day)	Mean HCV-RNA change (Log <sub>10</sub> , IU/mL)	< LLQ n/N <25 IU/mL	< LLD n/N <10 IU/mL	
Panel A Placebo	7	-0.08	0/6	0/6	
Panel A TMC435 25 mg	7	-2.63	1/9	0/9	
Panel A TMC435 75 mg	7	-3.43	0/9	0/9	
Panel B Placebo	7	-1.77	0/6	0/6	
	14	-2.56	0/6	0/6	
	28	-3.83	3/6	2/6	
Panel B TMC435 25 mg	7	-3.47	1/9	0/9	
	14	-4.19	3/9	1/9	
	28	-4.74	6/9	3/9	
Panel B TMC435 75 mg	7	-4.55	1/9	0/9	
	14	-5.15	7/9	3/9	
	28	-5.52	9/9	8/9 🗲	RVR of 89%
HCV RNA levels were assesse 25 IU/mL and an LLD of ~10 imputed with 24 IU/mL and v	IU/mL. To calc	ulate mean HCV RNA v			



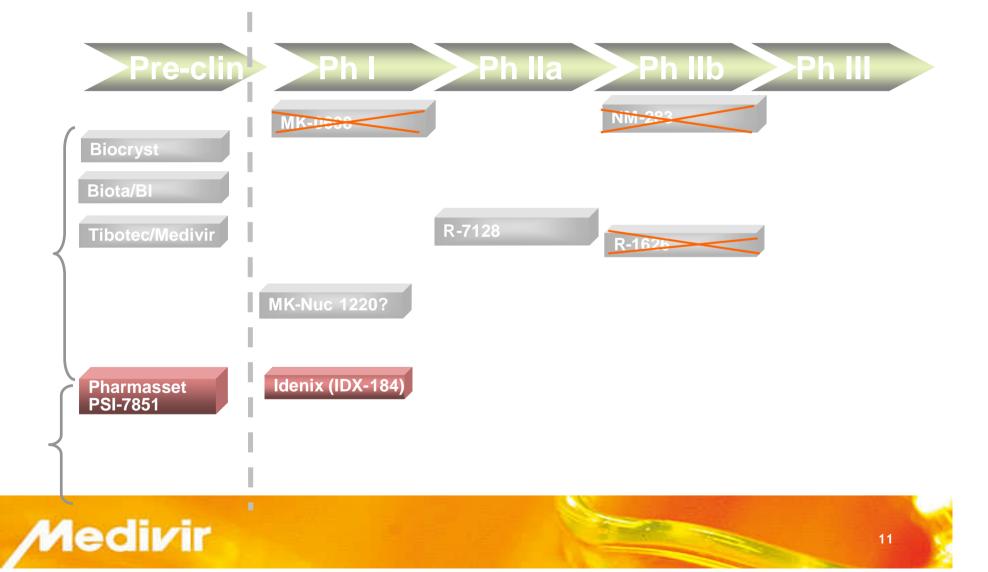


In collaboration with Tibotec / JNJ

### Nucleoside HCV Polymerase Inhibitors



#### **HCV Nucleoside Competitive Landscape**



### Hepatitis C Polymerase - Medivir/J&J program

#### Status

- Partnership with Tibotec / Johnson & Johnson since May 15 2008
- Candidate Drug selected on December 9th, 2008, triggering a milestone of € 2.6m
- The selected CD now in preclinical development towards phase I

#### Patents

• Extensive and non-limiting IP filed

#### Licensing agreement

- Remaining milestones of € 137m + royalties on sales for one product reaching market.
- Additional € 130m for second compound and indication reaching market + royalties on sales.
- FTE Funding for one year, ends May 2009
- All development costs covered by JNJ
- Nordic rights retained by Medivir





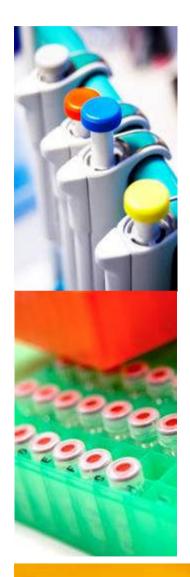


### Cathepsin K inhibitors

#### **Osteoporosis and Osteoarthritis**



### Medivir Cathepsin K Inhibitor Program - Status



- MIV-710 was selected as Candidate Drug in February 2009. This is a follow-on to MIV-701 having superior pharmacokinetic properties
- A program for a dual Cathepsin S & K inhibitors targeting rheumatoid arthritis, RA, is investigated and could be a part of the future partnering package.
- Strong IP position
- A broad initiative to identify a partner for the full program is now under way



### Cathepsin K Inhibitor - many possibilities

- Major market opportunity in both osteoporosis (OP) and osteoarthritis (OA)
- Metastatic bone disease is a major and debilitating adverse complication of several advanced cancers, including breast cancer. Cathepsin K is up-regulated in tumour cells and hence in addition to its direct effect on bone, a cathepsin K inhibitor may well represent a more effective therapy for the prevention of bone metastases
- Cathepsin K inhibitors demonstrate potent and reversible antiresorptive activity whilst not causing suppression of the beneficial bone formation as expected with other antiresorptives



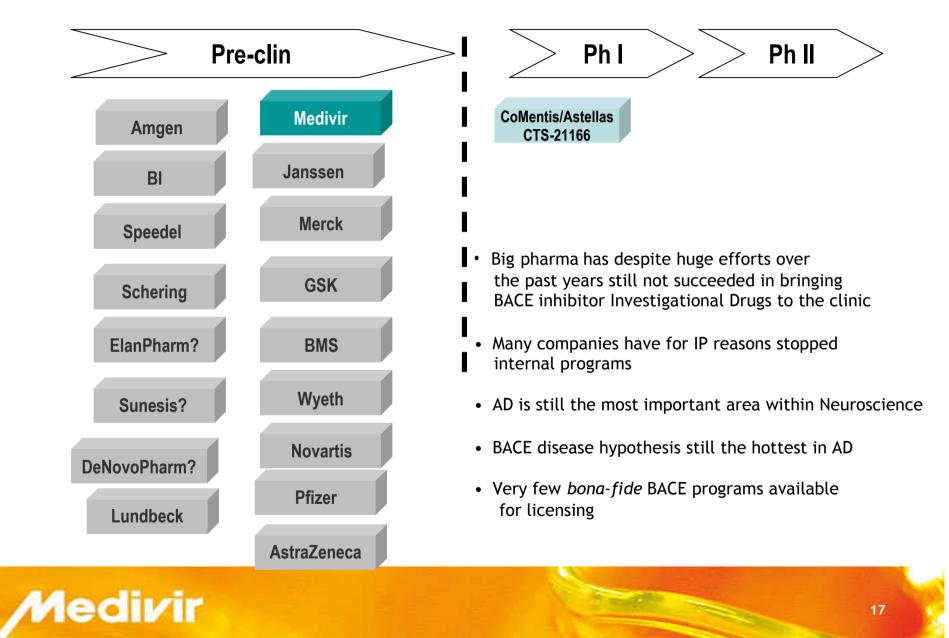


### **BACE Inhibitors**

### Alzheimer's disease



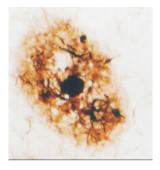
### **BACE-1** Inhibitors in development



#### Alzheimer's disease, AD

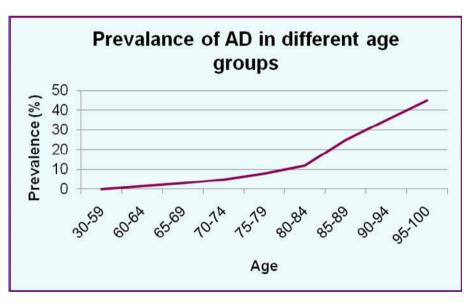
- Around 24 million AD cases world-wide
- Life expectancy from diagnosis: Approx. 10 years
- Stage 1 (1-3 y):
  - Memory impairment
- Stage 2 (2-6 y):
  - Difficulties to recognize people and objects
- Stage 3 (4-6 y):
  - Very passive, hard to reach
  - Need help with hygeine, dressing, eating
  - Psycotic problems (paranoia, aggression...)
  - Incontinence, low blood pressure, infections
- The cost for dementia care in Sweden is around 40 billion SEK/ year (≈ heart/vascular diseases and cancer together)
- 60% of all institutional care places are kept by demented persons (30% in the 70s)
- No available drugs cures/prevents the disease
  - Acetylcholine esterase inhibitors
  - Glutamate antagonist





Reduced brain volume Neuronal cell death Synaptic degeneration

Plaque (Amyloid  $\beta$  -peptide)





### Medivir BACE Program

Novel and patentable lead series

- ✓ 3 validated novel Lead Series
- ✓ 2 additional series are at an earlier stage
- 1 series at advanced stage

Strong IP (patent) position

- Extensive and non-limiting IP filed on the 3 Lead Series
- ✓ Novelty on 2 earlier series where IP is still not filed

Potent BACE inhibitors both on enzyme and in cell-based assay

 Lead inhibitors display potent IC50< 5 nM in both BACE enzyme and in cell-based assay, measuring AB40 release

Activity *in vivo* on reduction of AB40 release in the CNS upon administration of BACE inhibitor

CD selection expected in approximately 12 month

Partnering discussions have been initiated



# Commercial focus in the coming 12 months

LIPSOVIR	<ul> <li>Regulatory approval in EU &amp; US</li> <li>Secure optimal partnership structure for both EU, US &amp; RoW</li> </ul>
HEPATITIS C	<ul> <li>HCV PI, TMC435: start of phase IIb clinical trials</li> <li>HCV PI, TMC435: Present more data from the phase IIa study</li> <li>HCV-Polymerase inhibitors: Completion of preclinical GLP safety studies and start of phase I clinical trials</li> </ul>
CATHEPSIN K	Partnering process initiated
HIV PI	Candidate Drug selection by Tibotec/J&J
BACE, Alzheimer's	• CD selection and partnering of the BACE program
PHARMA SALES	<ul> <li>Strategic evaluation of Lipsovir for the Nordic markets</li> <li>Secure new co-promotion deals and potential own product(s)</li> </ul>
Financial	Secure a lower cost base
Иedivir	20