



**STRATEGY
PROGRAM
“NEXT LEVEL”**

BERLIN, 9 JUNE 2016

Disclaimer

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New Strategy “Next Level” – Shift from Research- to Product- and Market-Oriented Company

- Strong market- and product-oriented strategy program
- Focus on close-to-market compounds:
 - Lead product immunomodulator lefitolimod (MGN1703)
 - EnanDIM[®]: Lefitolimod successor molecules and new generation technology
- MGN1601: Shelve clinical development – backup compound
- MIDGE[®] technology: Divestment or spin-off
- Streamline company’s organizational structure
- Accelerate commercialization of products via out-licensing



Create added value

Target Portfolio: Focus on Lead Product Lefitolimod and Its Next-Generation Compound EnanDIM[®]

DNA-based TLR9 agonists (ISRs)

- Bind to TLR9 receptors
- Several **Immune Surveillance Reactivators (ISR)** in development:
 - Lefitolimod (MGN1703): Four trials
 - EnanDIM: New class of linear TLR9 agonists
- Suitable for mono- and combination therapies

Focus

MIDGE[®] Vector System

- DNA-based, non-viral vector system: gene ferries
- Three products in development:
 - MGN1404 (malignant melanoma)
 - MGN1331 (leishmaniasis)
 - MGN1333 (hepatitis B)

Divestment/Spin-off

Cell-based therapeutic vaccination (MGN1601)

- Genetically modified human renal cancer cell line using MIDGE[®] platform – combined with low-dose lefitolimod as adjuvant
- Phase I/II data available
- Orphan drug status

Backup

Target Product Portfolio – Focus on TLR9 Product Family: Lefitolimod and EnanDIM®

Platform	Compound	Indications	PC	PH I	PH II	PH III	Study	Cooperation partners
DNA-based TLR9 agonists (ISR)	Lefitolimod (MGN1703)	▪ Metastatic colorectal cancer (mCRC)	█				IMPALA	-
		▪ Small cell lung cancer (SCLC)	█				IMPULSE	-
		▪ HIV	█				TEACH	Aarhus University Hospital
		▪ Advanced solid malignancies	█				Lefitolimod & ipilimumab	MD Anderson Cancer Center
	EnanDIM	▪ Cancer / anti-infective therapies	█					
Therapeutic Vaccine (cell-line)	MGN 1601	▪ Renal cancer	█				On hold: backup compound	

ISR Immune Surveillance Reactivator | PC pre-clinical

Lean and Effective Corporate Structure

- Focus on products in late-stage and clinical development
- Shut down majority of research activities and outsource where still necessary
- Shut down own production activities and outsource to enable larger production volume (upscale) for a potential market entry
- Reduce headcount



Variability of costs and increased flexibility

Next Steps

- Complete reorganization by the end of 2016
- Ensure financing based on the new strategy
- Continue partnering discussions – Supported by external Pharma and Biotech Business Development Team



No substantial impact on guidance for FY 2016

Financial Calendar and Contact Details

- **12 May 2016**
Quarterly Statement as of 31 March 2016
- **11 August 2016**
Annual General Meeting
- **11 August 2016**
Half-Yearly Financial Report as of 30 June 2016
- **07 November 2016**
Quarterly Statement as of 30 September 2016



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Appendix

Advanced Product Pipeline with Strong Focus on Cancer Immunotherapies (As May 2016)

Preclinical	Phase I	Phase II	Phase III
EnanDIM¹ Oncology & Anti-infectives	Lefitolimod (MGN1703)¹ Other solid tumors	Lefitolimod (MGN1703)¹ SCLC	Lefitolimod (MGN1703)¹ Colorectal cancer
MGN1331² Leishmaniasis ⁵	Lefitolimod (MGN1703)^{1,6} HIV		
MGN1333² Hepatitis B	Lefitolimod (MGN1703)¹ + ipilimumab (Yervoy®)⁷ Advanced solid malignancies		
	MGN1601³ Renal cancer		
	MGN1404^{2,4} Malignant melanoma		

- Oncology
- Infectious diseases
- Oncology & Infectious diseases
- Oncology combination trials

¹ Immune Surveillance Reactivator and TLR9 agonist
² MIDGE® vector system
³ Cell line modified using MIDGE technology with adjuvant low-dose Lefitolimod
⁴ Collaboration with Max-Delbrueck-Center for Molecular Medicine and Charité Universitaetsmedizin, Berlin
⁵ Various diseases caused by parasites; mainly present in subtropical and tropical regions (major neglected disease)
⁶ Collaboration with University Hospital Aarhus, Denmark
⁷ Collaboration with MD Anderson Cancer Center, Texas, US; study is expected to start shortly

SCLC small cell lung cancer

Lefitolimod (MGN1703) – Ongoing Clinical Trials

IMPALA	IMPULSE	TEACH	Combination trial
Metastatic Colorectal Cancer (mCRC)	Small Cell Lung Cancer (SCLC)	HIV (Infectious Disease)	Advanced Solid Malignancies
<ul style="list-style-type: none"> • Pivotal trial (phase III) • 540 patients • 8 European countries: Austria, Belgium, Estonia, France, Germany, Italy, Spain, UK • Currently Recruiting 	<ul style="list-style-type: none"> • Randomized study • 100 patients • 4 European countries: Austria, Belgium, Germany, Spain • Recruitment completed (Oct 2015) 	<ul style="list-style-type: none"> • Early Stage Study (phase I) • 15 patients (first phase); 15 patients in extension phase • Denmark • Extension phase to start shortly 	<ul style="list-style-type: none"> • Lefitolimod (MGN1703) + ipilimumab (Yervoy®) • Early Stage Study (phase I) • 50-60 patients • Texas, US • Study expected to start shortly

Lefitolimod (MGN1703) – Milestones Clinical Trials

	IMPALA (mCRC) – Pivotal study	IMPULSE (SCLC) – Randomized study	TEACH (HIV) – Phase I	Combination trial – Phase I
2014	First patient in (FPI) ✓	First patient in (FPI) ✓		
2015		Recruitment completed ✓	Start/end of first phase ✓	
2016	Recruitment completed	Start of primary analyses	Initial results of first phase; start extension	First patient in (FPI) *
2017	Start primary endpoint analysis (OS)	Results	Final results	End of recruitment
2018				

mCRC metastatic colorectal cancer | SCLC small cell lung cancer | * Study expected to start shortly



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