



# Annual General Meeting

Dr. Marie Roskrow, CEO & Managing Director  
23 October 2013

**ASX: PAB**

# Safe Harbour Statement

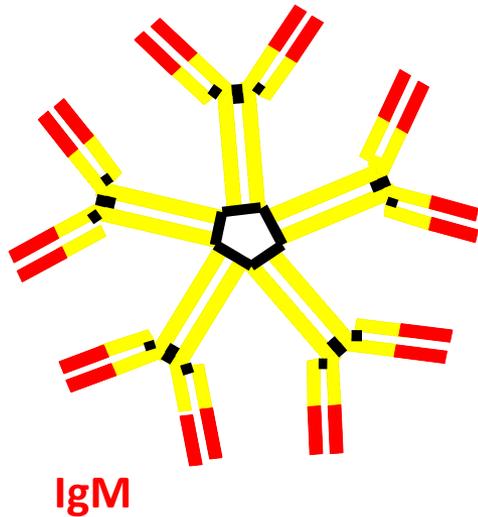
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This presentation contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks that may cause the actual results, performance or achievements of Patrys Limited to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of the Company's patent protection.

# Patrys in 2013

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- Oncology-focussed clinical-stage Company
- Deep pipeline of novel cancer-specific IgM monoclonal antibodies
- Treasure-trove of novel cancer targets
- Significant intellectual property portfolio
- Network of Internationally-renowned collaborators
- Experienced Board of Directors and Management Team

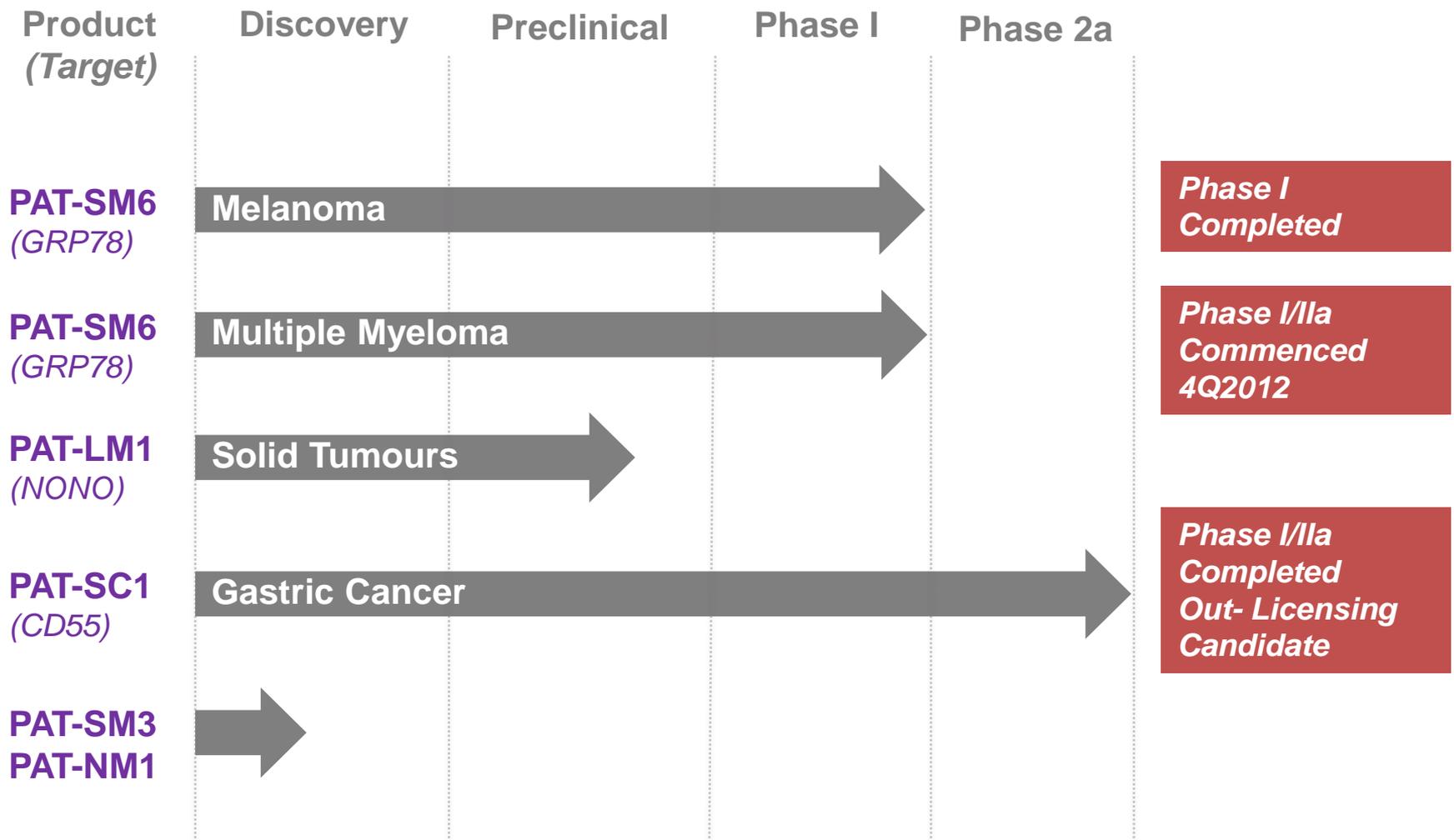
# Experienced & Capable Team

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Marie Roskrow	CEO & MD
Frank Hensel	VP Research & Development
Deanne Greenwood	Senior Director Business Development
Valentina Dubljevic	Senior Director Operations
Stephanie Brändlein	Research Group Leader Immunology
Roger McPherson	CFO & Company Secretary

- International clinical and business development expertise
- Dedicated R&D team based in Würzburg, Germany
- Experienced in corporate financings, licensing and M&A transactions
- Extensive big biotech & pharma contacts

# Pipeline



# FY13 Programme Highlights – I

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## PAT-SM6:

### Phase I/IIa multi-dose multiple myeloma trial:

- Conducted at University Hospital, Würzburg, Germany
- Commenced Nov. 2012, estimated 1yr complete enrolment
- Currently in 4<sup>th</sup> (final) dosing cohort
- Full data to be released 1Q 2014
- Ongoing data presented at multiple clinical / scientific meetings in Europe, USA and Japan. Data accepted for presentation ASH Dec. 2013
- Received Orphan Drug Designation Europe Sept. 2013

### Preclinical:

- 4 publications published in peer-reviewed journals
- ARC linkage grant awarded with Macquarie University
- Expanded external collaborations with CSIRO, University Brussels, Myelomax

# FY13 Programme Highlights – II

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## PAT-LM1:

- Key patent granted around use of PAT-LM1 for treatment / prevention of metastatic cancer
- Moved recombinant cell line through development / early scale-up
- Promising preclinical data in leukemia (ongoing)
- External collaboration with Bioprocessing Technology Institute, Singapore

## PAT-SC1:

- Out-licensing programme ongoing. Expanded to include China & India

## PAT-SM3, PAT-NM1:

- Promising preclinical data in various leukemias, lymphomas
- Hosted International IgM Workshop, Frankfurt

**PAT-SM6**



# Patrys' Lead Antibody: PAT-SM6

## PAT-SM6:

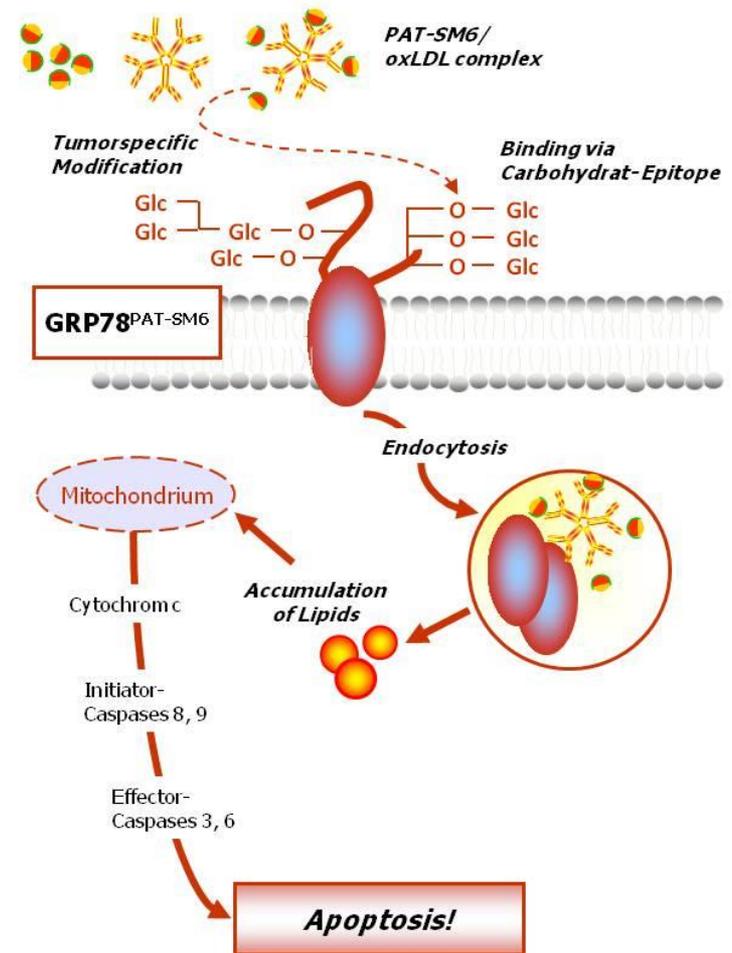
- IgM isotype,  $\lambda$ -light chain
- Isolated from stomach cancer patient
- Targets tumour specific epitope on GRP78
- Binds also to oxidised LDL and VLDL

## Mode of Action:

- Internalisation upon binding of oxidised LDL & GRP78<sup>PAT-SM6</sup>
- Internalisation triggers apoptosis

## *In vivo* & *In vitro* Reactivity:

- Effective in multiple xenograft models
- Expression data show specific expression in wide range of tumours incl. melanoma and myeloma



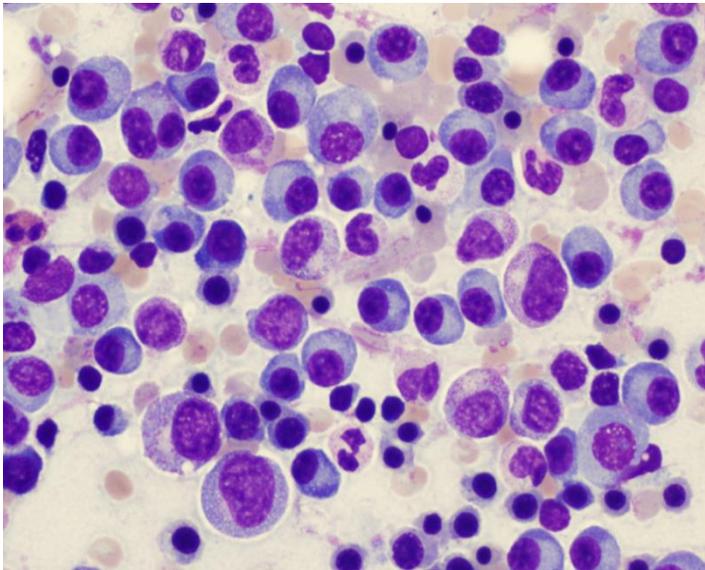
# Multiple Myeloma – Opportunity

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- Cancer of the plasma cells in bone marrow. Cells grow out of control and form tumours in solid bone, cause damage to other organs
- Estimated to be more than 220,000 cases worldwide and incidence increasing
- 5 year survival of ~30%
- Market expected to increase from ~\$6B (2012) to >\$10B (2018)
- Market dominated by 3 products:
  - Revlimid (net sales \$3.7B in 2012)
  - Velcade (net sales \$2B in 2012)
  - Thalidomide (net sales \$302M in 2012)
- Several MAbs currently in clinical development but none approved to date. Likely to be used in combination therapies
- Significant interest in MM from both large pharmaceutical and biotechnology companies

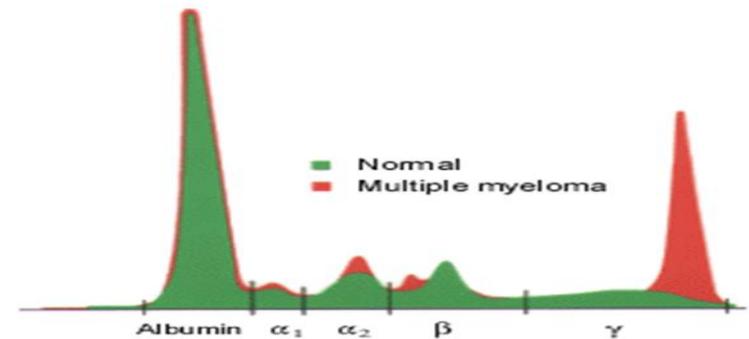
# Multiple Myeloma – Pathology

- Abnormal plasma cells (myeloma cells) secrete lots of “useless” antibodies (M proteins)
- Myeloma cells crowd out other blood cells resulting in anaemia, thrombocytopenia (bleeding) and leucopenia (infections)

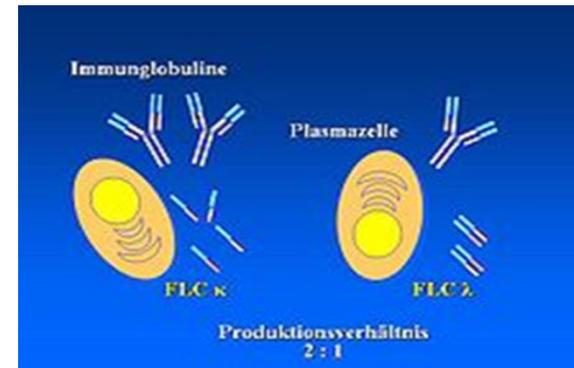


- Monoclonal gammopathy detected by electrophoresis

**Serum Protein Electrophoresis**



- Abnormal proteins (Bence Jones) detected in urine



# Multiple Myeloma – Presentation

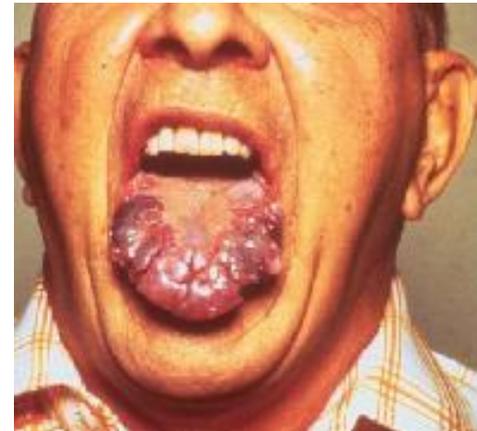
- Bone disease and hypercalcaemia



- Abnormal protein deposits



- Bone marrow failure



# Therapies for Multiple Myeloma

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## Proteasome inhibitors

- Bortezomib (Velcade)
- Carfilzomib (Kyprolis)

## IMiDs

- Lenalidomide (Revlimid)
- Pomalyst (Pomalidomide)
- Thalidomide

## Chemotherapeutics

- Melphalan
- Cisplatin
- Cyclophosphamide
- Doxorubicin

## Stem cell transplantation

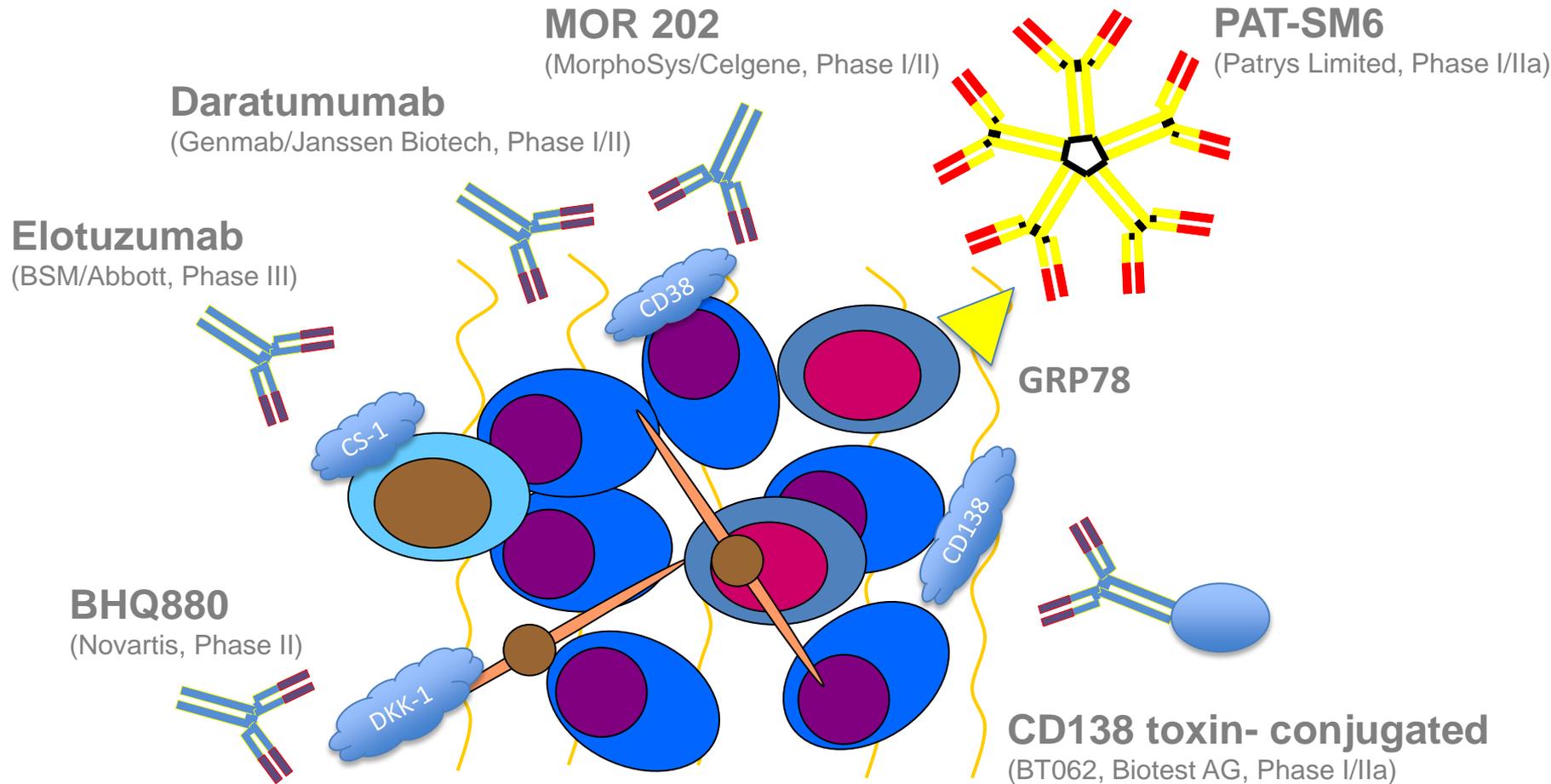
- Autologous
- Allogeneic

## Clinical studies

- Small molecules
- Antibodies, peptides
- Immunotherapeutics



# Antibodies in Clinical Trials for MM

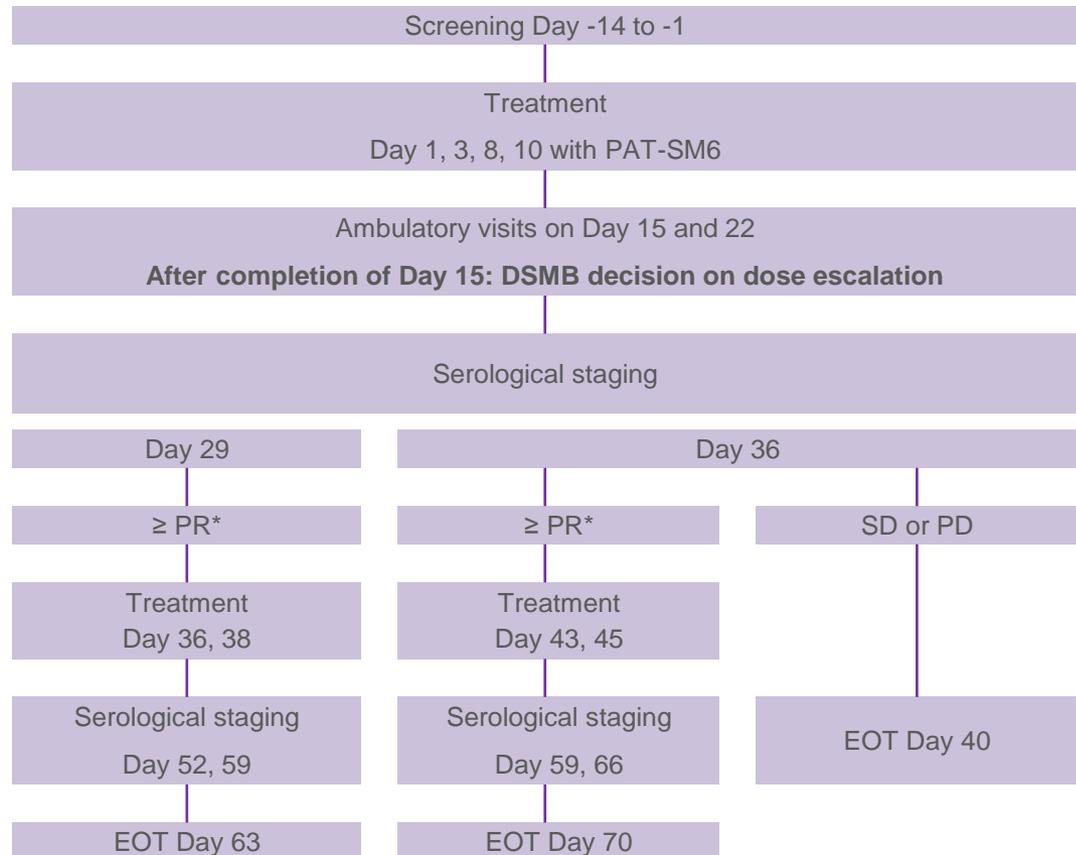


Antibodies in all stages of clinical development

# Multiple Myeloma Clinical Trial

- Phase I/IIa open-label multi-dose trial in relapsed and multi-resistant patients (N=12 in 4 escalating dosing groups)
- 4 cohorts (0.3mg/kg, 1mg/kg, 3mg/kg, 6mg/kg)
- Patients receive 4 doses of PAT-SM6 given i.v. over 2 weeks
- Primary endpoint = safety and tolerability
- Secondary endpoints include Pk, immunogenicity, measures of response and Progression Free Survival (PFS)

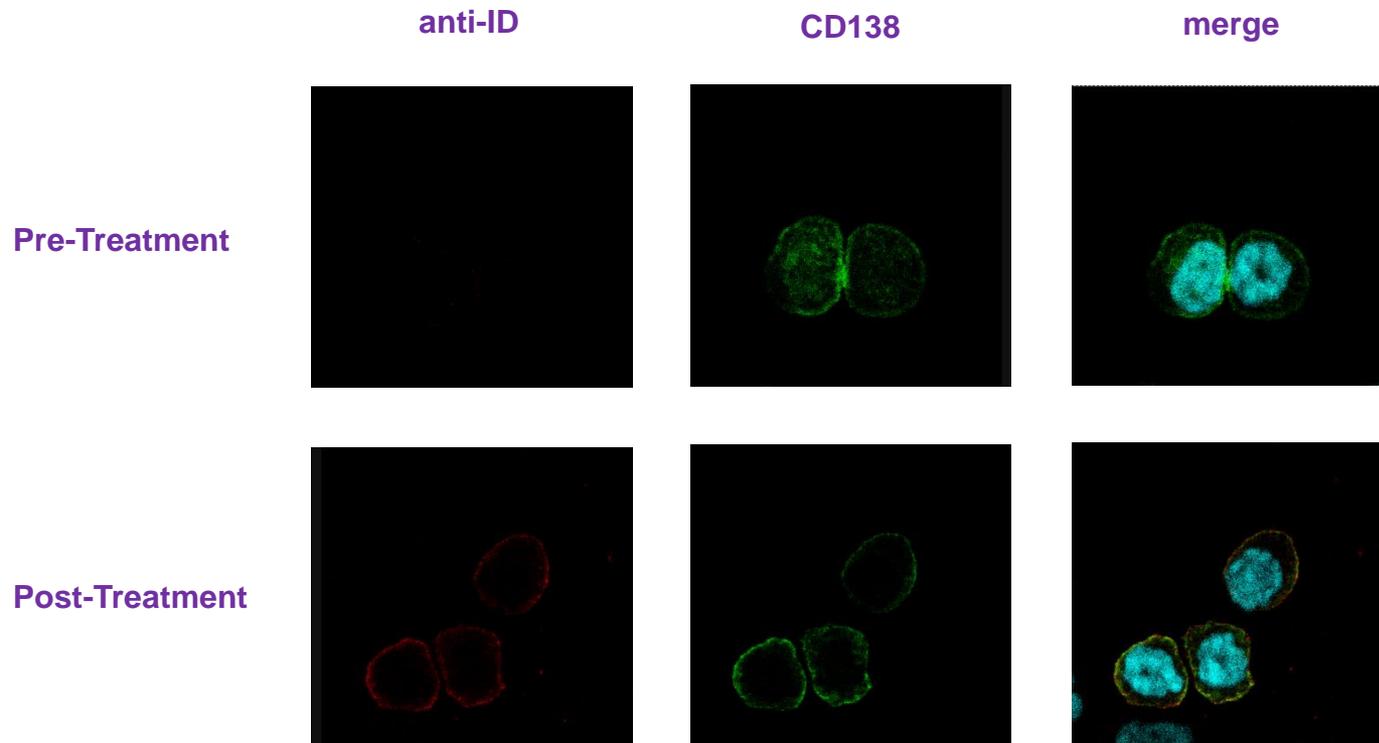
## Clinical Trial Design



**PR = Partial Response    PD = Progressive Disease**  
**SD = Stable Disease      EOT = End of Trial Visit**

# PAT-SM6 Binds to MM Cells *in vivo*

- CD138 positive tumour cells obtained from peripheral blood (Patient 02-002) before and after treatment with PAT-SM6



# Initial Clinical Data – I

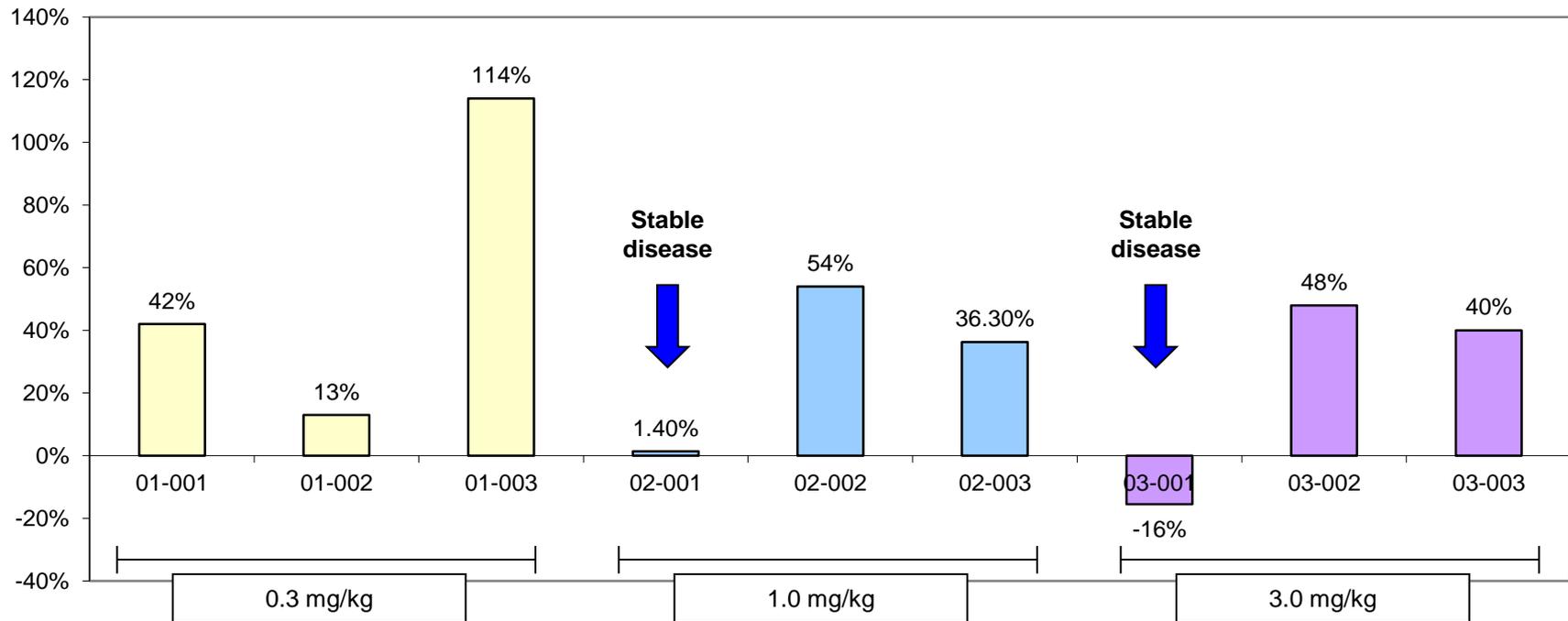
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- To date: 9 patients treated with 4 doses PAT-SM6 in 3 dose cohorts (0.3mg/kg, 1mg/kg, and 3mg/kg). 4th cohort (6mg/kg/dose) currently underway
- PAT-SM6 safe in all patients so far. No dose limiting toxicity (DLT), no related serious adverse events (SAE) and no related adverse event grade  $\geq 4$
- 2 / 9 patients had stable disease (day +35 post treatment) with a significant reduction in protein M levels in the peripheral blood
- Median time to next therapy is 42 days (clinically significant). One patient has stable disease for 127 days post treatment
- 7 / 9 patients responded positively to drugs that they had previously been resistant to (i.e PAT-SM6 makes cancer cells more sensitive to other drugs)

# Initial Clinical Data – II

## Preliminary Efficacy

Changes in M-Protein from baseline at D36/EOT



- 2 patients showed stable disease according to the IMWG criteria

# Initial Clinical Data – III

Patient	Time to next therapy	Salvage regimen	Response to salvage	Novel agents before PAT-SM6
01-001	28 days	VRCD	PR	Velcade
01-002	9 days	Benda, Pred, Thal	VGPR	Revlimid, Bortezomib
01-003	75 days	Treosulfan	SD	Revlimid
02-001	8 days	Benda, Velcade	PR	Pomalyst, Revlimid
02-002	41 days	Benda, Velcade, Dex	SD	Velcade, Thalidomide
02-003	50 days	Velcade, Melphalan	SD	Revlimid
03-001	127 days	Carfilzomib	na	Bortezomib
03-002	43 days	Pomalyst, Dex	PD	Carfilzomib, Revlimid
03-003	12 days	Carfilzomib, Cyclo./Dex	PR	Revlimid

- PAT-SM6 showed a median time to next therapy of 42 days which is a clinical benefit

# Future Options for PAT-SM6

**Option 1: Look for a partner now. No further internal clinical development**

Partners	Date	Values	Product (Type)	Stage of Development
Amgen & Onyx	September 2013	<ul style="list-style-type: none"> <li>\$10.4B cash</li> </ul>	Kyprolis (Proteasome inhibitor)	Marketed US
MorphoSys & Celgene	June 2013	<ul style="list-style-type: none"> <li>Upfront \$92 M</li> <li>Milestones \$60 M</li> <li>Double digit royalties</li> </ul>	MOR202 (Fully human MAb $\alpha$ CD38)	Phase I/IIa for relapsed / refractory myeloma
Genmab & J&J Jansson Biotech	August 2012	<ul style="list-style-type: none"> <li>Upfront \$55M</li> <li>Milestones \$1B</li> <li>Equity \$80M</li> <li>Double digit royalties</li> </ul>	Daratumumab (Human MAb $\alpha$ CD38)	Phase I/IIa for relapsed / refractory myeloma

**Option 2: Continue internal clinical development and look for partner in parallel. Financing dependent**

# End 2013 / 2014 Projected Milestones

Key Milestone	Projected Timing (CY)	
<p><b>PAT-SM6:</b></p> <ul style="list-style-type: none"> <li>○ MM, melanoma and GRP78 preclinical data published</li> <li>○ European orphan drug status obtained</li> <li>○ Complete Phase I/IIa multiple myeloma (MM) trial enrolment</li> <li>○ MM data presented at ASH</li> <li>○ Final results from MM trial</li> <li>○ Potential out-licensing deal</li> </ul>	<p>1H, 2013</p> <p>2H, 2013</p> <p>4Q, 2013</p> <p>4Q, 2013</p> <p>1Q, 2014</p> <p>2H, 2014</p>	<p>✓</p> <p>✓</p>
<p><b>PAT-LM1:</b></p> <ul style="list-style-type: none"> <li>○ Proceed with cell line development &amp; GMP scale-up</li> <li>○ Preclinical data published</li> </ul>	<p>2013-2014</p> <p>1H, 2014</p>	
<p><b>PAT-SC1:</b></p> <ul style="list-style-type: none"> <li>○ Preclinical &amp; clinical trial (gastric cancer) data published</li> <li>○ Out-licensing deal</li> </ul>	<p>2H, 2013</p> <p>2014</p>	
<p><b>Other:</b></p> <ul style="list-style-type: none"> <li>○ Continue early-stage development of PAT-SM3 &amp; PAT-NM1</li> </ul>	<p>2013-2014</p>	
<p><b>Corporate:</b></p> <ul style="list-style-type: none"> <li>○ Potential Capital raising</li> </ul>	<p>2H,2013/1H,2014</p>	

# For Further Information

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