

## Patrys To Present at the 12<sup>th</sup> Annual BIO Investor Forum

**Melbourne, Australia; 9 October, 2013:** Patrys Limited (**ASX: PAB**), a clinical stage biotechnology company today announced that Dr. Marie Roskrow, MBBS, PhD, Chief Executive Officer, will present at the 12<sup>th</sup> Annual BIO Investor Forum on Wednesday 9<sup>th</sup> October, 2013 at 9:00 a.m. Pacific time at The Palace Hotel in San Francisco, CA.

The BIO Investor Forum is an international biotech investor conference focused on early and established private companies as well as emerging public companies. The event features plenary sessions, business roundtables and therapeutic workshops, company presentations, and One-on-One partnering meetings.

“This event is one of the key investment forums in the world and provides a very important platform for Patrys to raise its profile to a global investor audience. Patrys is entering an exciting and pivotal time as our Phase I/IIa clinical trial for multiple myeloma is recruiting the final cohort,” said Patrys CEO and Managing Director Dr. Marie Roskrow.

The presentation will provide an overview of Patrys’ business and portfolio including:

- PAT-SM6 multiple myeloma trial including interim results from the first nine patients;
- Growing body of published evidence supporting PAT-SM6 as a potential cancer treatment for multiple myeloma
- Commercialisation pathway for PAT-SM6 exploring potential deal environment; and
- Updates on PAT-SC1 for the treatment of gastric cancer, the company’s most advanced asset, and pre-clinical asset PAT-LM1 for solid tumours.

The presentation is attached.

**-Ends-**

**For further information, please contact:**

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**About Patrys Limited:**

Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibodies as therapies for cancer and other major diseases. Patrys has a deep pipeline of anti-cancer natural human antibodies that qualify for both internal development and partnering opportunities. More information can be found at [www.patrys.com](http://www.patrys.com).

**About The BIO Investor Forum:**

The 12th Annual BIO Investor Forum is an international investor conference focused on private and emerging public biotech companies. Their mission is to support industry-wide success, and present a broad and unbiased view of investment opportunities. In addition, the BIO Investor Forum draws business development executives from leading global pharmaceutical and established biotechnology companies.



# Investor Presentation

Dr. Marie Roskrow, CEO & Managing Director  
October 2013

**ASX: PAB**

# Safe Harbour Statement

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The following material is for general information purposes only and is not to be relied upon for the making of an investment decision. Any investment in Patrys Limited ACN 123 055 363 (Patrys) is subject to investment risk including the possibility of loss of capital invested and no return of income or payment of dividends. Neither Patrys nor any other entity or person in or associated with the Patrys group of companies guarantees any return (whether capital or income) or generally the performance of Patrys or the price at which its securities may trade.

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Where this presentation does contain any forward looking statements, those statements are only made as the date of the presentation and are to be considered “at-risk statements” not to be relied upon as they are subject to further research and to known and unknown risks, uncertainties and other factors that may lead to actual results differing from any forward looking statement. This is particularly the case with companies such as Patrys which operate in the field of researching, discovering, developing, and commercialising potential drugs intended for safe and effective for human treatments or therapies.

# Human Antibody Therapeutics

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- **Founded in 2007, listed on ASX**
- **Current market cap. \$14.7 M**
- **AU headquarters, R&D in Würzburg, Germany**
- **Core human IgM monoclonal antibody assets in development:**
  - PAT-SM6 Phase I/IIa antibody in multiple myeloma with blockbuster potential
  - PAT-SC1 clinical product with 10-year survival data
  - PAT-LM1 preclinical product against novel target
  - >300 clones available for target characterisation work
- **In 2012 raised \$2.85 million through Australian private share placement**

# Experienced Board & Management

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**Marie Roskrow, BSc (Hons), MBBS, PhD**  
*Managing Director, CEO*  
University of London, GSF Munich, Lazard Ltd.



**John Read, BSc (Hons), MBA, FAICD**  
*Non-Executive Chairman*  
Pro-Pac Packing Ltd, Environ. Gp. Ltd, CVC Private Equity



**Mike Stork, BBA**  
*Non-Executive Director*  
Dspfactory Ltd, Unitron Industries Ltd.



**Roger McPherson, CPA, GAICD**  
*CFO, Company Secretary*  
Cerylid Biosciences Ltd, Amrad Corporation Ltd



**Alan Robertson, BSc, PhD**  
*Non-Executive Director*  
Faulding Ltd, Amrad Ltd, Pharmaxis Ltd.



**Frank Hensel, PhD**  
*Vice President R&D*  
OncoMab GmbH



**Suzy Jones**  
*Non-Executive Director*  
Genentech, DNA Ink

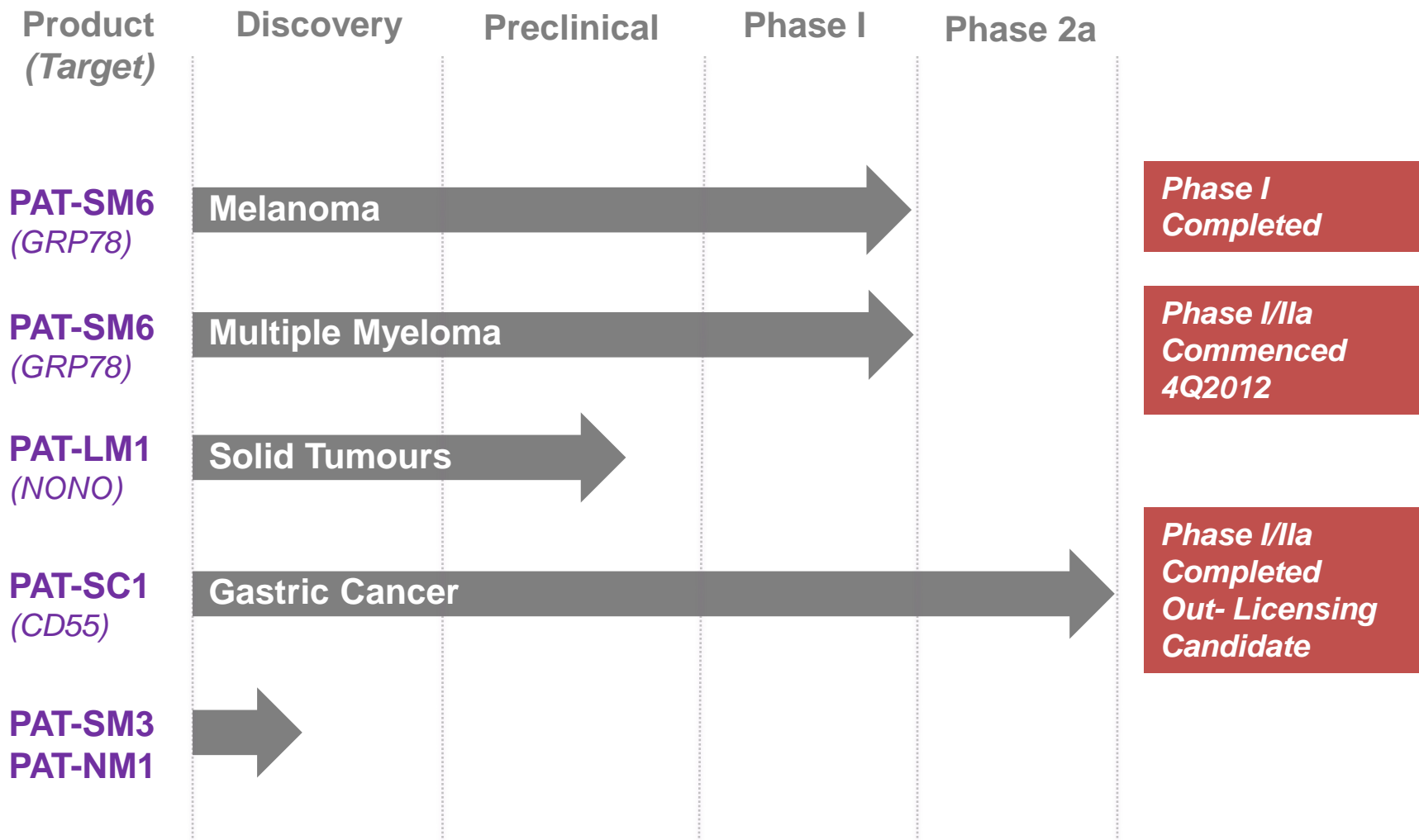
# A Diversified Portfolio

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Patrys' strategy is to discover and develop natural human antibodies for the treatment of cancer with a focus on partnering products at key value points to maximise shareholder value

- **IgM antibodies:**
  - Body's 1st line of defence as part of innate immune response
  - Large biologic structures capable of binding & killing several tumour cells at the same time
- **Each antibody produced binds a unique cancer-specific target**
- **Strong evidence of safety and tolerability in patients:**
  - PAT-SC1 Phase I/IIa trial in stomach cancer
  - PAT-SM6 Phase I trial in melanoma & Phase I/IIa in multiple myeloma
- **Strong evidence of long-term effectiveness in patients:**
  - 10 yr survival data from 1st proof-of-concept clinical trial (PAT-SC1 in stomach cancer)
- **Able to be manufactured to commercial scale using PER.C6® cell line**
- **Avoid large royalty stack payable on IgG antibodies**

# Pipeline



**PAT-SM6**





# Patrys' Lead Antibody: PAT-SM6

## PAT-SM6:

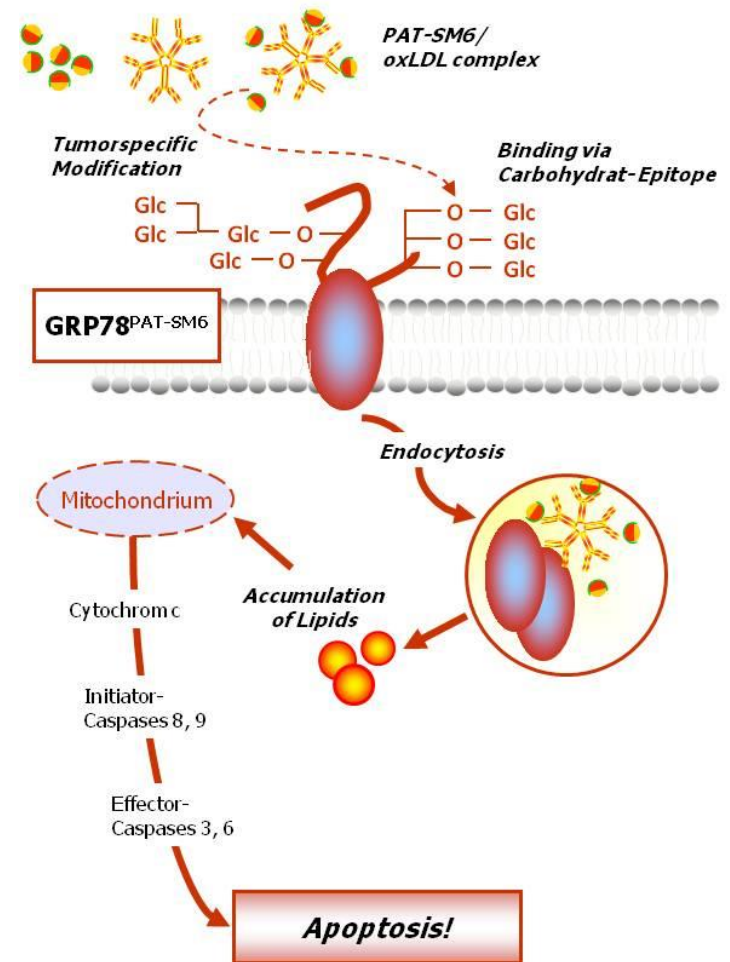
- IgM isotype,  $\lambda$ -light chain
- Isolated from stomach cancer patient
- Targets tumour specific epitope on GRP78
- Binds also to oxidised LDL and VLDL

## 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



# PAT-SM6 Melanoma Phase I Trial

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- 9 Patients enrolled at Royal Adelaide Hospital and Princess Alexandra Hospital, Brisbane: October 2010 – February 2012

## Primary endpoint:

- No adverse events recorded in any patient

## Secondary endpoints:

- Half-life of 5.7 hours reported (pharmacokinetics)
- No evidence of anti-PAT-SM6 antibodies (immunogenicity)
- Presence PAT-SM6 detected by IHC in 3 post-treatment biopsies
- Cell-death (apoptosis) detected in 2 post-treatment biopsies

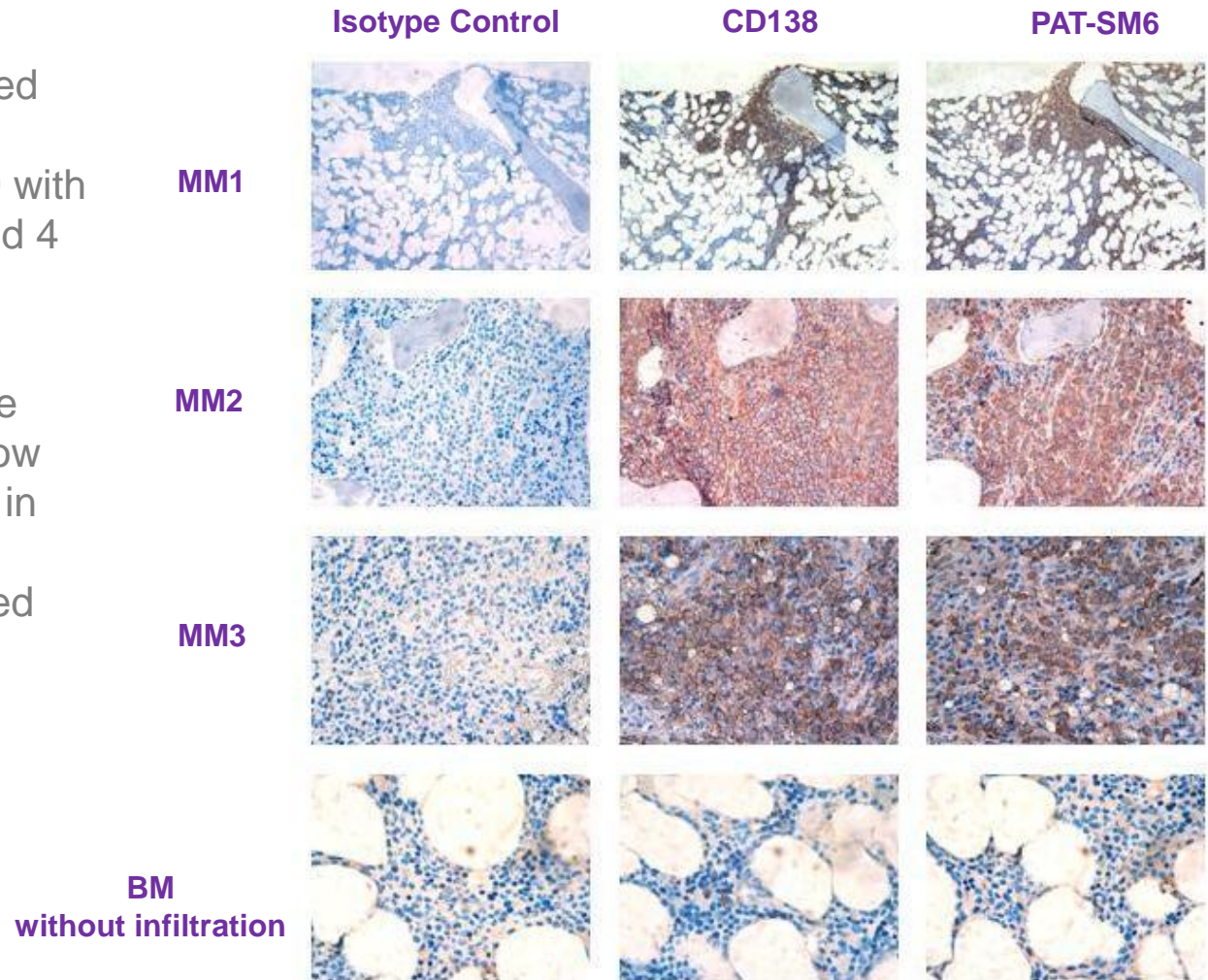
# Multiple Myeloma – Opportunity

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- A cancer of the plasma cells in bone marrow. These 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 MAb 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

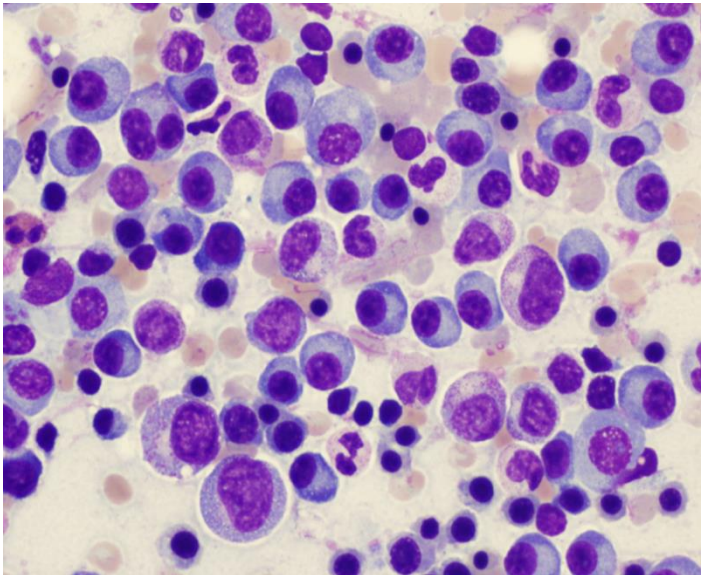
# Preclinical Data – Multiple Myeloma

- Patient tissue sourced from 11 patients at primary diagnosis, 9 with relapsed disease and 4 healthy controls
- IHC staining on bone marrow sections show binding of PAT-SM6 in 20/20 MM patients (primary and relapsed disease)



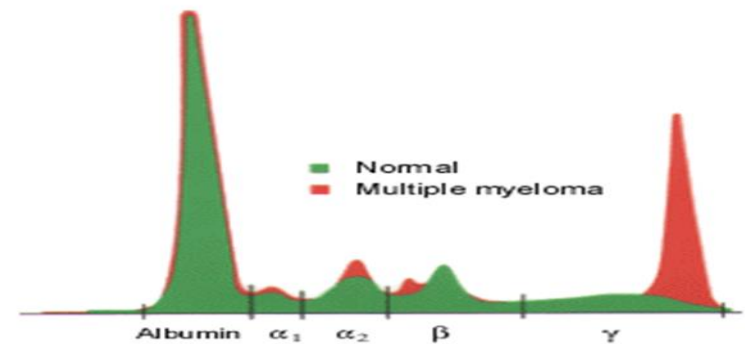
# Multiple Myeloma - Pathology

- 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)

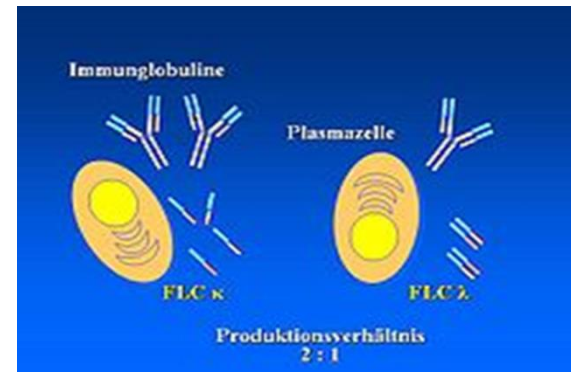


- Monoclonal gammopathy detected by electrophoresis

**Serum Protein Electrophoresis**



- Abnormal proteins (Bence Jones) detected in urine



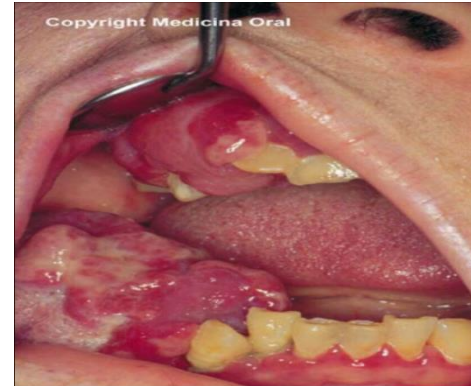


# Multiple Myeloma – Presentation

- Bone disease and hypercalcaemia



- Evidence of bone marrow failure



# Therapies for Multiple Myeloma

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## Proteasome inhibitors

- Bortezomib (Velcade)
- Carfilzomib (Kyprolis)

## IMiDs

- Lanalidomid (Revlimid)
- Pomalyst (Pomalidomide)
- Thalidomide

## Chemotherapeutics

- Melphalan
- Cisplatin
- Cyclophosphamide
- Doxorubicin

## Stem cell transplantation

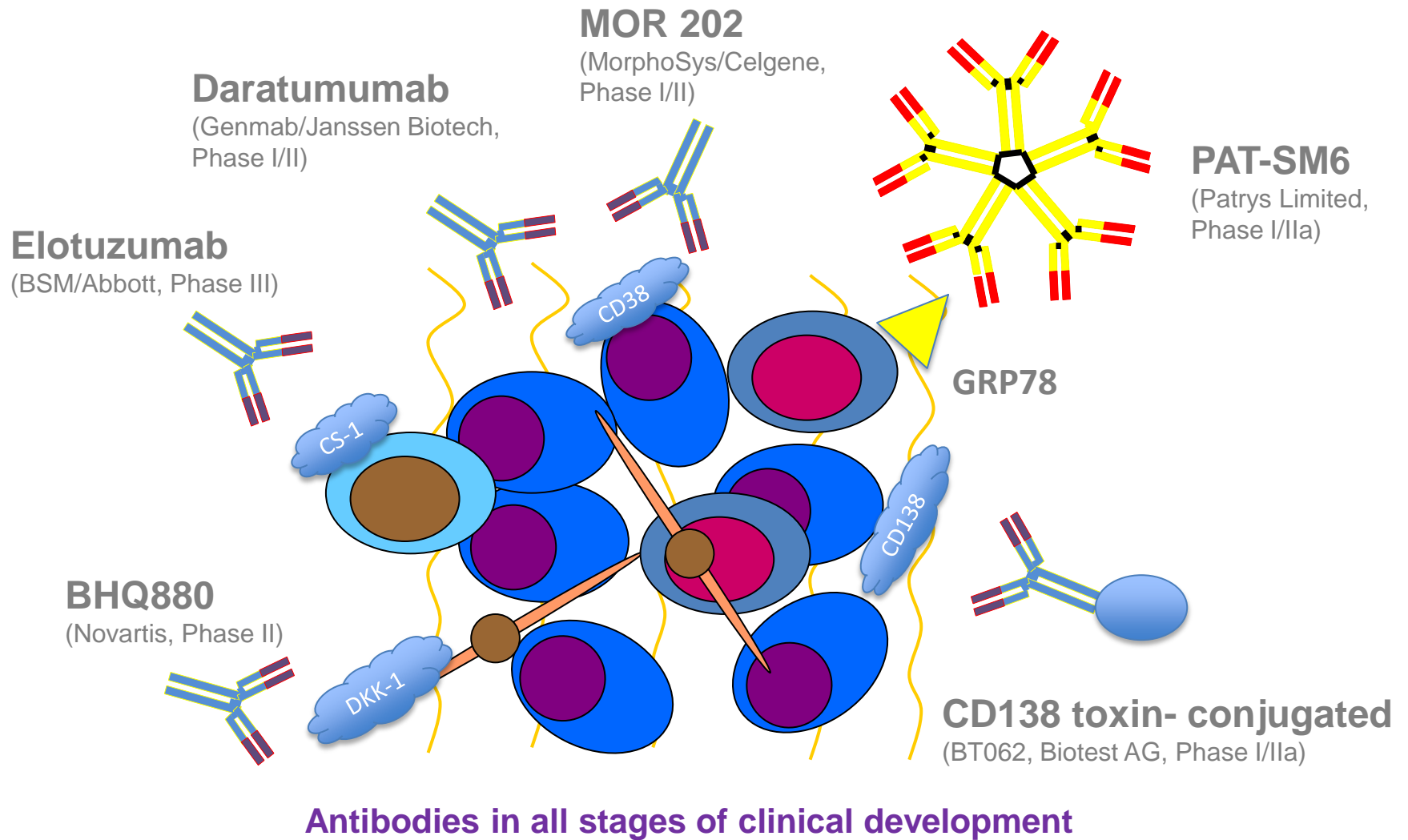
- Autologous
- Allogeneic

## Clinical studies

- Small molecules
- Antibodies, peptides



# Antibodies in Clinical Trials for MM

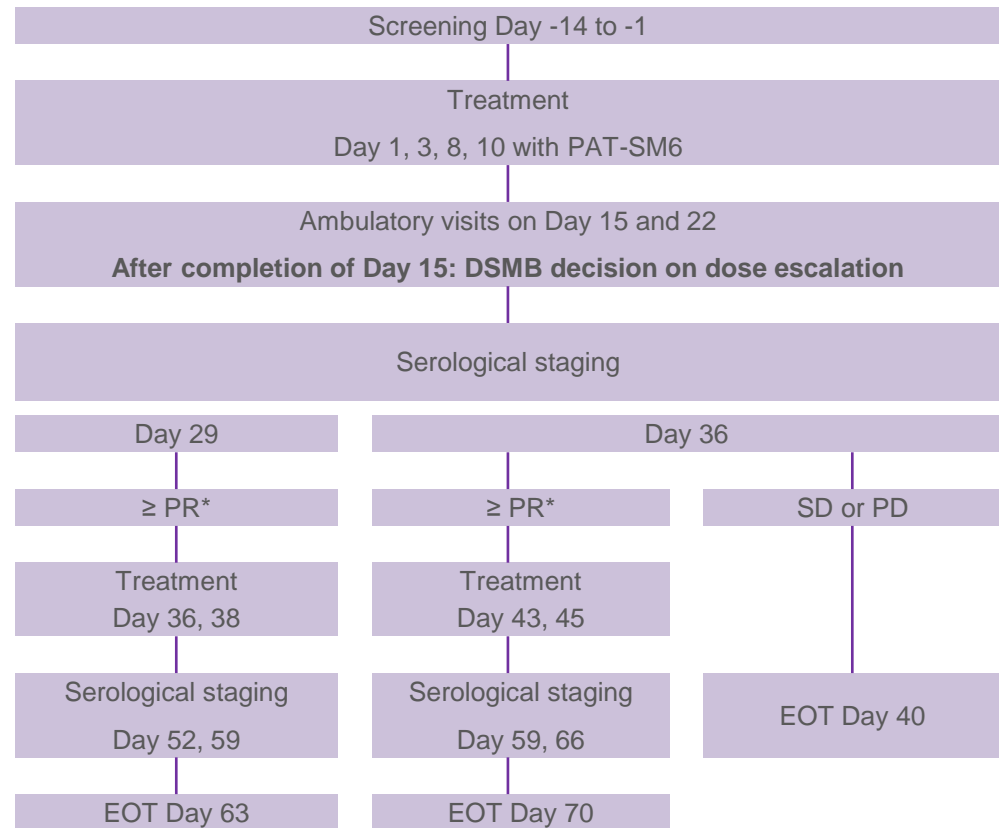




# Multiple Myeloma Clinical Trial

- 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

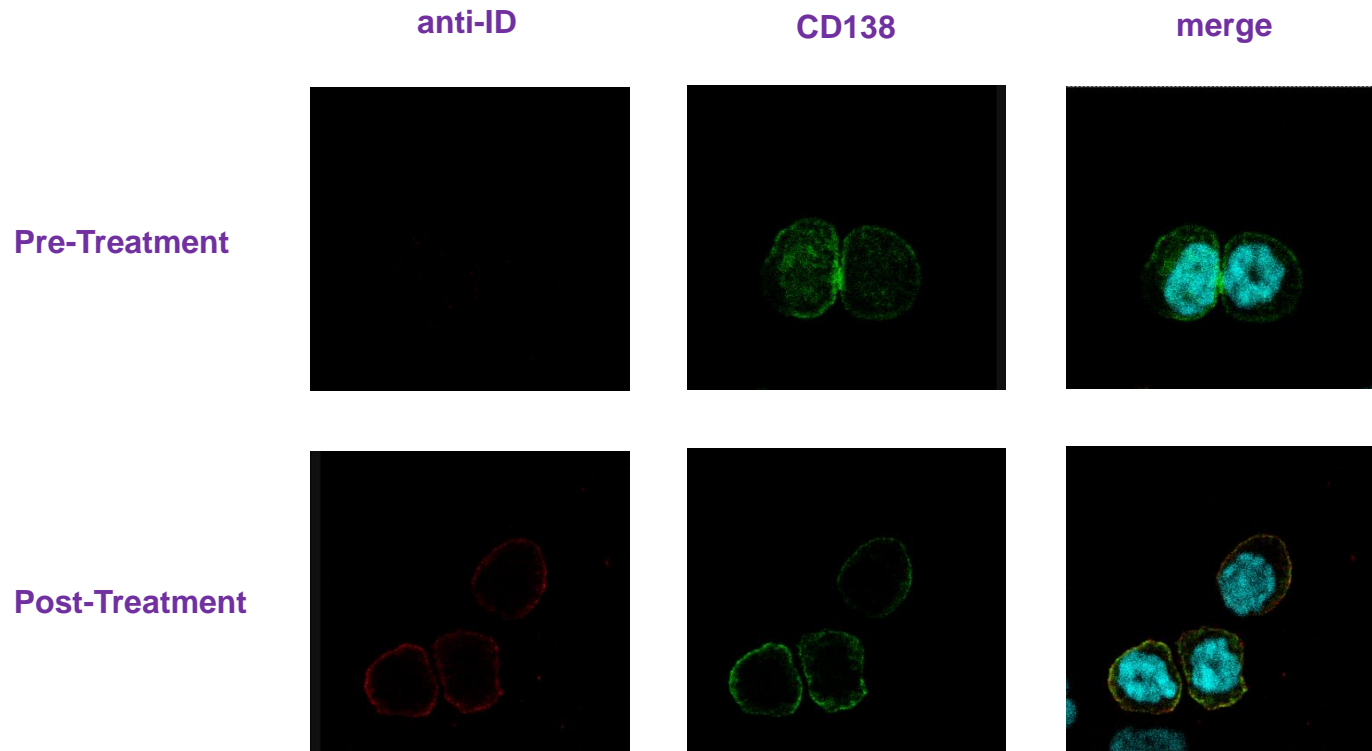


**PR = Partial Response**  
**SD = Stable Disease**

**PD = Progressive 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

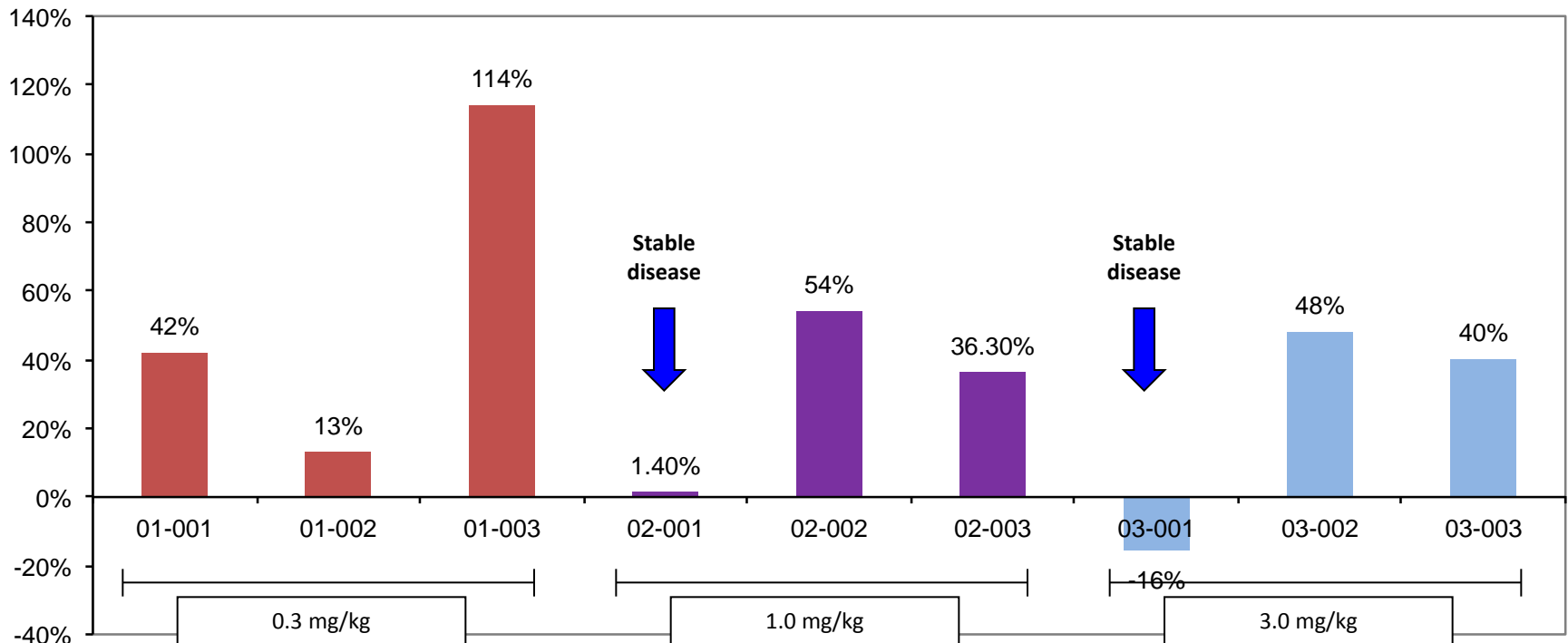
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- To date: 9 patients treated with 4 doses PAT-SM6 in 3 dose cohorts (0.3mg/kg, 1mg/kg, and 3mg/kg). 4th cohort (6mg/kg/dose) currently underway
- PAT-SM6 safe in all patients so far. No dose limiting toxicity (DLT), no related serious adverse events (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 had stable disease for 127 days post treatment
- 7 / 9 patients responded very 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 Prior to 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
<b>02-001</b>	<b>8 days</b>	<b>Benda, Velcade</b>	<b>PR</b>	<b>Pomalyst, Revlimid</b>
02-002	41 days	Benda, Velcade, Dex	SD	Velcade, Thalidomide
02-003	50 days	Velcade, Melphalan	SD	Revlimid
<b>03-001</b>	<b>127 days</b>	<b>Carfilzomib</b>	<b>na</b>	<b>Bortezomib</b>
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
- Seven patients responded to drugs to which they had been refractory before the trial

# Future Options for PAT-SM6

## *Option 1: Do a deal post current clinical trial*

Partners	Date	Values	Product (Type)	Stage of Development
Amgen & Onyx	September 2013	<ul style="list-style-type: none"> <li>Upfront \$10.4B</li> </ul>	Kyprolis (2 <sup>nd</sup> gen. Proteasome inhibitor)	Marketed
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 α 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 α CD38)	Phase I/IIa for relapsed / refractory myeloma

## *Option 2: Do a deal post Phase II trial*

Raise significant cash and continue clinical development alone

**PAT-LM1**

# PAT-LM1 Antibody & Target

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## PAT-LM1:

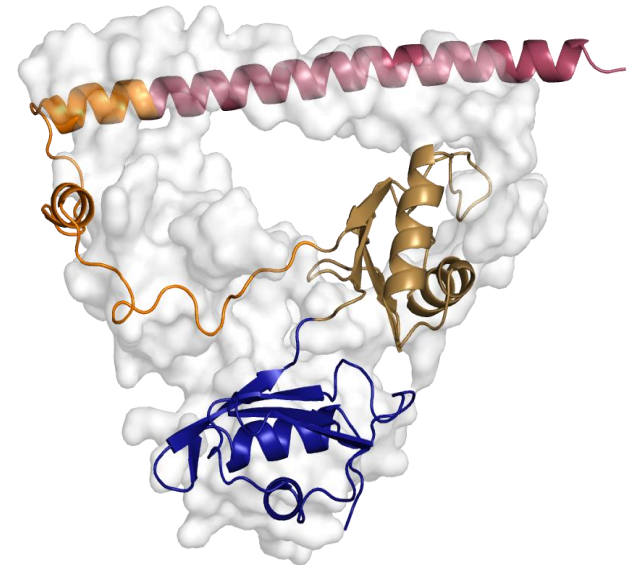
- IgM isotype,  $\lambda$ -light chain
- Isolated from a lung cancer patient
- Targets tumour-specific epitope of surface-expressed NONO (non-POU-domain-containing octomer binding protein)

## Mode of Action:

- NONO mainly found in nucleus: involved in transcriptional & post-transcriptional gene regulation
- Unknown mechanism-of-transport to cell membrane

## In Vivo & In Vitro Reactivity:

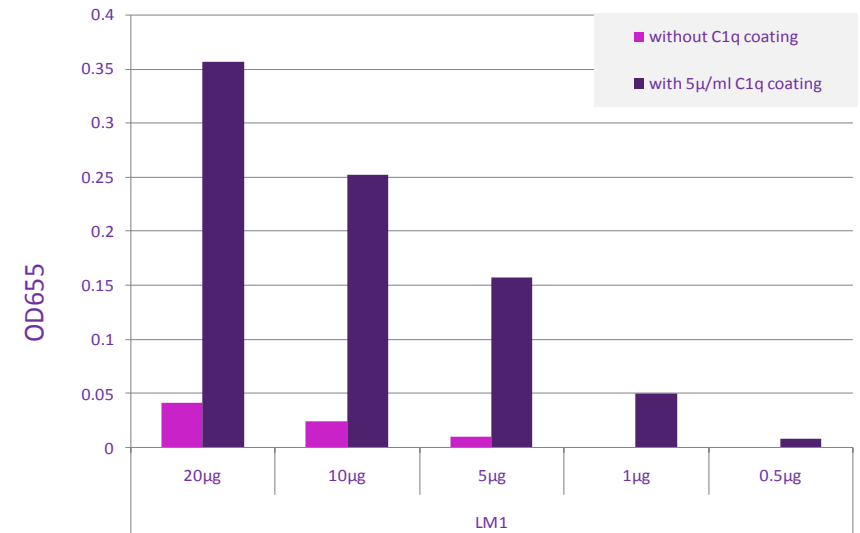
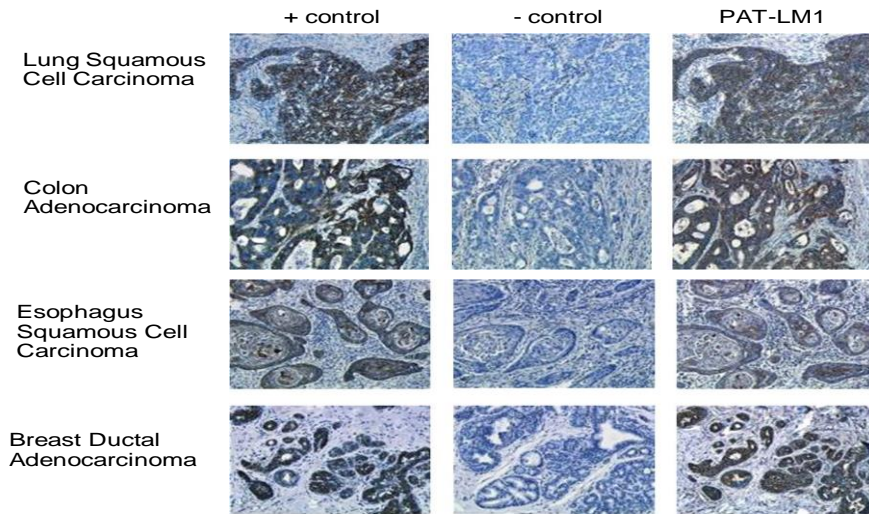
- Effective in several xenograft models
- Expression data show specific expression in a wide range of tumors incl. lung, pancreas, colon, leukaemias



**Crystal structure of NONO with PSC1**  
Passon et al PNAS 2012

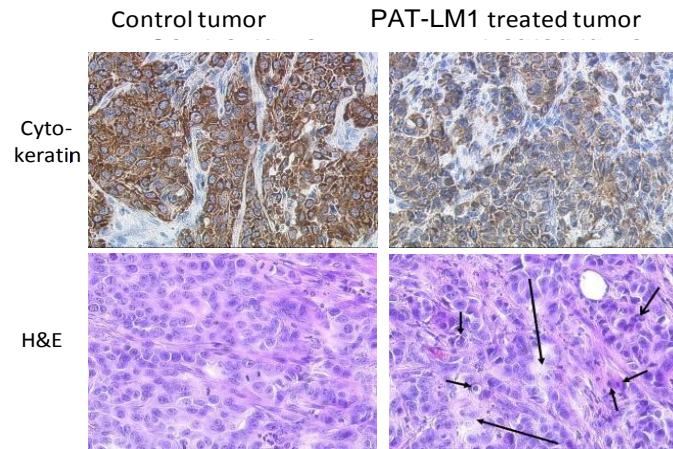
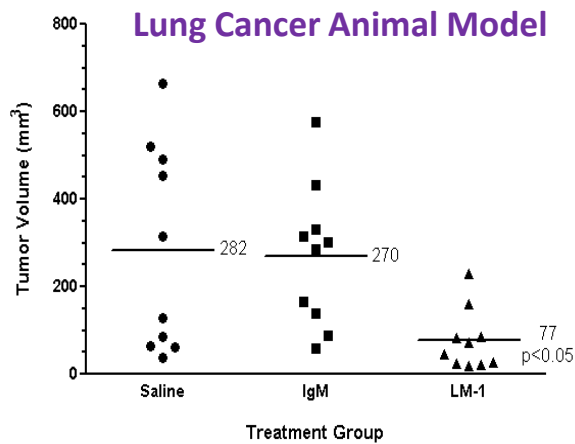


# PAT-LM1 Preclinical



IHC staining with PAT-LM1 on various tumour tissues

PAT-LM1 binds C1q, suggestive of CDC



PAT-LM1 reduced tumour volume & tumours showed areas of apoptosis & necrosis



**PAT-SC1**



# PAT-SC1 (Gastric Cancer)

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## PAT-SC1:

- Pentameric IgM isotype,  $\lambda$ -light chain
- Isolated from a stomach cancer patient
- Targets isoform of CD55 (Decay Accelerating Factor) expressed on surface of multiple types of cancer cells

## Trial Results:

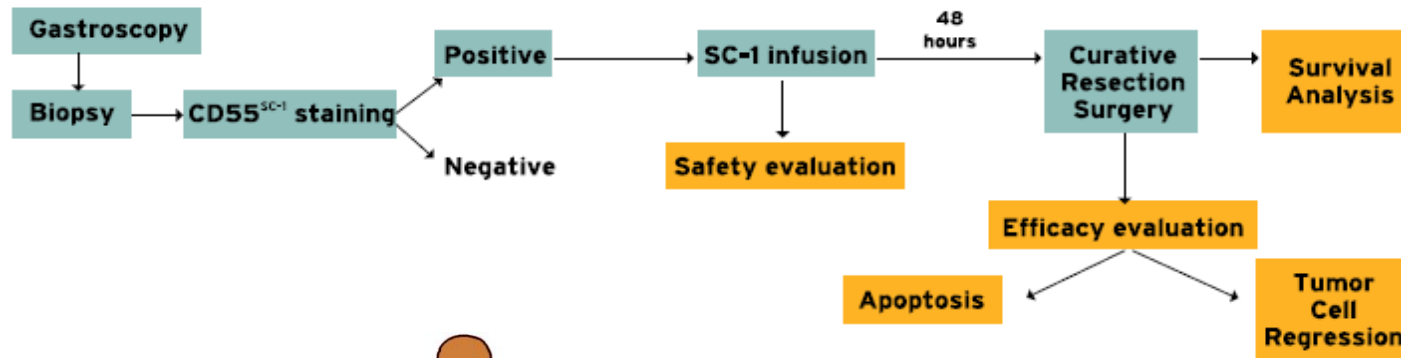
- Phase I/IIa open-label trial conducted 1997-2001 (Germany)
- Safe in 51 pts receiving single 20 mg dose PAT-SC1
- Significant 10 year survival benefit for 30 pts with minimal residual disease (R0) post-surgery vs. untreated pts (historic control)

## Current Stage/Competition:

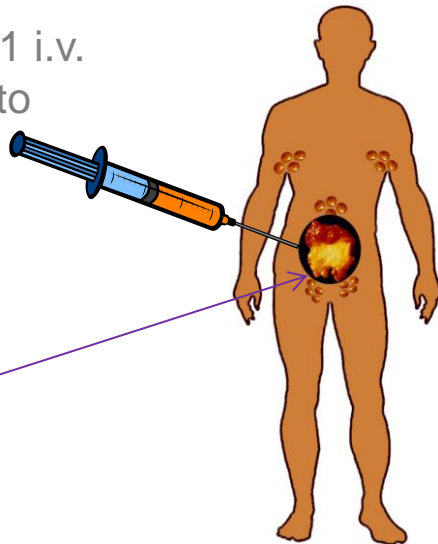
- Currently in out-licensing process
- No other know clinical products targeting CD55

# PAT-SC1 Human Trial

- Open-label Phase I/II study (1997 – 2001) conducted at the University of Würzburg, Germany

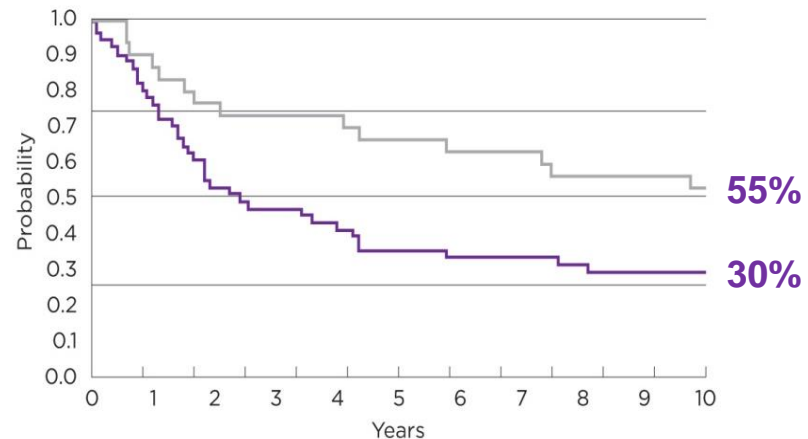


20 mg PAT-SC1 i.v.  
48 hours prior to  
gastrectomy



Stomach  
Cancer

## 10-Year Survival Data



— Group 3 (CD55<sup>SC1</sup> positive; N=30) — Group 1 (CD55<sup>SC1</sup> positive; N=30)

# 2013 & 2014 Projected Milestones

Key Milestone	Projected Timing (CY)	
<b>PAT-SM6:</b> <ul style="list-style-type: none"> <li>○ MM, melanoma and GRP78 preclinical data published</li> <li>○ 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>○ Out-licensing deal</li> </ul>	1H, 2013 2H, 2013 4Q, 2013 4Q, 2013 1Q, 2014 2H, 2014	✓ ✓
<b>PAT-LM1:</b> <ul style="list-style-type: none"> <li>○ Proceed with cell line development &amp; GMP scale-up</li> <li>○ Preclinical data published</li> </ul>	2013-2014 1H, 2014	
<b>PAT-SC1:</b> <ul style="list-style-type: none"> <li>○ Preclinical &amp; clinical trial (gastric cancer) data published</li> <li>○ Out-licensing deal</li> </ul>	2H, 2013 2014	
<b>Other:</b> <ul style="list-style-type: none"> <li>○ Continue early-stage development of PAT-SM3 &amp; PAT-NM1</li> </ul>	2013-2014	
<b>Corporate:</b> <ul style="list-style-type: none"> <li>○ Potential fund raising</li> </ul>	2H,2013/1H,2014	

# For Further Information

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