Delivering on the Promise of Therapeutic Antibodies

Aya Jakobovits, Ph.D.

Executive Vice President
Head, Research and Development
Presentation Outline

♦ Speaker background

♦ Therapeutic Monoclonal Antibodies
  ▪ Overview & evolution
  ▪ Key drivers in MAb product development
  ▪ Role in cancer therapies – present and future

♦ Agensys
  ▪ Background and fundamentals
  ▪ Antibody product pipeline
  ▪ Synergies with Astellas R&D activities

♦ Role of MAbs in advancing Astellas as GCL in oncology
Speaker background

Prior affiliations

Academia
- Hebrew University of Jerusalem, Israel
- Weizmann Institute of Sciences, Israel
- Univ. of California, San Francisco

Corporate
- Genentech
- Cell Genesys
- Abgenix

Key scientific activities – pre-Agensys

- Antibody technologies, oncology products, and cancer biology
  - Generation of leading human antibody XenoMouse® technology
    - >20 MAbs in clinical development (Amgen, Pfizer, Novartis)
  - Development of XenoMouse®- derived therapeutic MAbs in multiple indications
  - Development of panitumumab (Vectibix®) – first approved fully human MAb
  - First demonstration of oncogenes function in embryonic development
  - Over 50 scientific publications, over 80 issued patents
Monoclonal Antibodies – The New Therapeutic Wave

♦ Well established and rapidly growing therapeutic class
♦ 24 approved products
  ▪ Multiple disease indications
♦ $35 Billion in worldwide sales in 2008
  ▪ 5 out of 10 top selling biotech drugs are MAb products
♦ Large product pipeline in clinical development
  ▪ Over 150 MAbs in different development stages
♦ Pharma transition to antibody products
  ▪ Partnerships, acquisitions, in-house research
### Approved Antibody Products

- **24 Approved in different disease indications**
- **9 oncology products**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Company</th>
<th>Disease Indication</th>
<th>Year Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthoclone OKT3</td>
<td>Ortho Biotech</td>
<td>Transplantation</td>
<td>1986</td>
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<tr>
<td>ReoPro</td>
<td>Centocor</td>
<td>Cardiovascular</td>
<td>1994</td>
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<td>Zenapax</td>
<td>Roche</td>
<td>Transplantation</td>
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<td><strong>Rituxan</strong></td>
<td>Genentech</td>
<td><strong>Cancer/Inflammation</strong></td>
<td>1997</td>
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<td>Simulect</td>
<td>Novartis</td>
<td>Transplantation</td>
<td>1998</td>
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<td><strong>Herceptin</strong></td>
<td>Genentech</td>
<td><strong>Cancer</strong></td>
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<td>Synagis</td>
<td>MedImmune</td>
<td>Infectious disease</td>
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<td>Centocor/Schering-Plough</td>
<td>Inflammation/Autoimmune</td>
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<td><strong>Mylotarg</strong></td>
<td>Wyeth Ayerst</td>
<td><strong>Cancer</strong></td>
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<td><strong>Campath</strong></td>
<td>Genzyme</td>
<td><strong>Cancer</strong></td>
<td>2001</td>
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<tr>
<td>Humira</td>
<td>Abbott</td>
<td>Inflammation/Autoimmune</td>
<td>2002</td>
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<tr>
<td>Zevalin</td>
<td>BiogenIdec</td>
<td><strong>Cancer</strong></td>
<td>2002</td>
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<td>Bexxar</td>
<td>GlaxoSmithKline</td>
<td><strong>Cancer</strong></td>
<td>2003</td>
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<tr>
<td>Raptiva</td>
<td>Genentech</td>
<td>Inflammation/Autoimmune</td>
<td>2003</td>
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<td><strong>Erbitux</strong></td>
<td>Bristol-Myers Squibb</td>
<td><strong>Cancer</strong></td>
<td>2004</td>
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<tr>
<td>Avastin</td>
<td>Genentech</td>
<td><strong>Cancer</strong></td>
<td>2004</td>
</tr>
<tr>
<td>Xolair</td>
<td>Genentech/Novartis</td>
<td>Allergy</td>
<td>2004</td>
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<tr>
<td>Tysabri</td>
<td>Biogen Idec/Elan</td>
<td>Inflammation/Autoimmune</td>
<td>2005</td>
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<td>Lucentis</td>
<td>Genentech</td>
<td>Ophthalmology</td>
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<td><strong>Vectibix</strong></td>
<td>Amgen</td>
<td><strong>Cancer</strong></td>
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<td>Soliris</td>
<td>Alexion</td>
<td>Hematology</td>
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<td>Cimiza</td>
<td>UCB</td>
<td>Inflammation/Autoimmune</td>
<td>2008</td>
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<tr>
<td>Ilaris</td>
<td>Novartis</td>
<td>Inflammation/Autoimmune</td>
<td>2009</td>
</tr>
<tr>
<td>Simponi</td>
<td>Johnson &amp; Johnson</td>
<td>Inflammation/Autoimmune</td>
<td>2009</td>
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</table>
Antibody Products Among the Top Biotech Drugs in 2008

5 out of 10 top drugs are MAb products

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>2008 Revenue (Million)</th>
</tr>
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<tbody>
<tr>
<td>Enbrel</td>
<td>Inflammation</td>
<td>$5,982</td>
</tr>
<tr>
<td>Rituxan</td>
<td>Cancer</td>
<td>$5,082</td>
</tr>
<tr>
<td>Humira</td>
<td>Cancer</td>
<td>$4,521</td>
</tr>
<tr>
<td>Avastin</td>
<td>Cancer</td>
<td>$4,479</td>
</tr>
<tr>
<td>Herceptin</td>
<td>Cancer</td>
<td>$4,394</td>
</tr>
<tr>
<td>Remicade</td>
<td>Inflammation</td>
<td>$3,748</td>
</tr>
<tr>
<td>Gleevec</td>
<td>Cancer</td>
<td>$3,700</td>
</tr>
<tr>
<td>Neulasta</td>
<td>Neutropenia</td>
<td>$3,318</td>
</tr>
<tr>
<td>Lantus</td>
<td>Diabetes</td>
<td>$3,159</td>
</tr>
<tr>
<td>Aranesp</td>
<td>Anemia</td>
<td>$3,137</td>
</tr>
<tr>
<td>Luentis</td>
<td>Macular Degeneration</td>
<td>$1,761</td>
</tr>
<tr>
<td>Erbitux</td>
<td>Cancer</td>
<td>$1,457</td>
</tr>
</tbody>
</table>

BioWorld® Today; August 2009
M&A in Antibody Space (2006-2009)

Seattle Genetics

Biolex

Affitech

GlycoFi

GlyCart

Abgenix

Xencor

CAT

Ablynx

Antitope

MedImmune

Vaccinex

Dyax

Trubion

Imclone

Rincon

Imclone

Source: Jason Kantor, RBC Capital Markets
Monoclonal Antibodies – the Magic Bullets

- Y-shaped molecules, secreted by B lymphocytes
  - Consist of two heavy and light chains
- A major arm of the body’s defense system against foreign substances (bacteria, viruses, malignant cells)
  - Recognize, neutralize, and eliminate foreign substances
- Specific binding to unique domains on antigens (proteins, lipids, sugars)

Antigen Binding

Interaction with Immune cells
MAbs – The Original Targeted Therapy

- Selected MAb with desired target specificity, affinity, and function modulation
  - Directed to a specific epitope on target
  - Large proteins with high specificity
    - Minimize side effects
  - High affinity
  - Long half-life
    - Reduce dosing frequency
  - New mechanisms of action
    - Target modulation
    - Engage immune cells
  - Reduced overlapping / synergistic toxicities with other therapies
  - Faster timeline to clinical trials
  - Flexibility in therapeutic function
    - Naked antibody
    - Targeting vehicle for toxins, radioisotopes
Evolution of therapeutic MAbs

♦ Discovery of mouse MAb technology – 1975
  ▪ Nobel Prize to inventors

♦ Adaptation of technology to human B cells failed

♦ Immunogenicity of mouse MAbs limited development
Realization of MAb Promise

Advancement of MAb development in the last decade
  • 22 products approved in 1997-2009

♦ Key drivers
  ▪ Availability of human antibody technologies
    • Increased safety and efficacy
    • Permit chronic administration
  ▪ Good safety profile and well-established regulatory path
  ▪ Advances in large scale antibody production
    • Production cells > 2 gr/L
From Mouse to Human Monoclonal Antibodies

♦ Minimize immunogenicity
♦ Increase safety
♦ Increase efficacy

1975

Mouse

100% Mouse protein

1984

Chimeric

34% Mouse protein

1986

Humanized

10% Mouse protein

1996

Fully Human

100% Human protein

Authentic fully human MAbs from transgenic mice
Mice Engineered to Produce Authentic Human MAbs

Engineer mouse genome with human antibody system

- Mouse embryonic stem cells
  - Inactivate mouse antibody loci
  - Clone and introduce human antibody loci
- Mice incapable of producing mouse antibodies
- Mice producing human antibodies
- XenoMouse®

Mice with majority of human antibody repertoire

- **XenoMouse®** - 1996 (Abgenix/Amgen)
  - First approved fully human MAb (Vectibix®)
  - >20 products in clinical development
- **VelocImmune®-mice** – 2005 (Regeneron)
  - Chimeric MAbs (variable region human)
## Cancer Treatment Revolutionized by Therapeutic MAbs

<table>
<thead>
<tr>
<th>MAb Product</th>
<th>Target</th>
<th>Cancer Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campath</td>
<td>CD52</td>
<td>Leukemia</td>
</tr>
<tr>
<td>Rituxan</td>
<td>CD20</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>Zevalin (y⁹⁰)</td>
<td>CD20</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>Bexxar (I¹³¹)</td>
<td>CD20</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>Herceptin</td>
<td>HER-2</td>
<td>Breast</td>
</tr>
<tr>
<td>Erbitux</td>
<td>EGFR</td>
<td>Colon, Head and Neck</td>
</tr>
<tr>
<td>Avastin</td>
<td>VEGF</td>
<td>Colon, Lung, Breast</td>
</tr>
<tr>
<td>Maytotorg (calceamicin)</td>
<td>CD33</td>
<td>Leukemia</td>
</tr>
<tr>
<td>Vectibix</td>
<td>EGFR</td>
<td>Colon</td>
</tr>
</tbody>
</table>
Next Generation MAb Products in Oncology

MAbs with enhanced potency

♦ Antibody-Drug Conjugates (ADC)
  • specific delivery of toxins to tumor cells

♦ Enhanced communication with immune system
  • engage tumor–killing cells

♦ Bi-specific antibody
  • dual targets or cells

♦ Antibody cocktail
MAB Mode-of-Action in Oncology

Naked MAbs
- Modulation of tumor cell growth, survival, migration
- Modulation of angiogenesis pathways
- Recruitment of immune system
- Modulation of immune system

Antibody-Drug Conjugates
- Release of free toxin to kill tumor cell
- Internalization of MAb-target complexes

Naked MAbs
- Bind and modulate target function
- Inhibit critical function to affect growth/survival

Antibody Conjugates – delivering payload to cells
- Toxins and radioisotopes
ADC Emergence as a Prominent Therapeutic Modality in Oncology

♦ ADC are clinically active at well tolerated doses
  ▪ Potent toxins
  ▪ Stable linkers
♦ Strong clinical data in early stages of development
  ▪ Lower clinical doses as compared to naked MAbs

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Indication</th>
<th>Status</th>
<th>Disclosed Phase I Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>SGN-35 (α CD30-VcMMAE)</td>
<td>SeaGen</td>
<td>Hodgkin’s</td>
<td>Phase 2 (under SPA)</td>
<td>54% CR/PR; 32% CR (≥1.2 mg/kg)</td>
</tr>
<tr>
<td>Herceptin-DM1</td>
<td>Genentech</td>
<td>Metastatic Breast</td>
<td>Phase 3</td>
<td>38% CR/PR (3.6 mg/kg)</td>
</tr>
</tbody>
</table>

♦ Significant increase in number of clinical and pre-clinical ADC products
  ▪ Major biotech and pharma
    ▪ Genentech, Seattle Genetics, ImmunoGen, Medarex, sanofi-aventis, BiogenIdec, MedImmune, Bayer, Daiichi-Sankyo, Pfizer
  ▪ >10 ADCs are in clinical development
  ▪ >40 ADCs in preclinical development
  ▪ most of Genentech pipeline is driven by ADC products
Targets – the Key Driver for MAb Products

♦ Established targets

Pros
- Target structure and function are well studied

Cons
- Sought after by many companies – high competition
  - IGFR-1 – 6 (Amgen, Merck, Pfizer, Roche, Sanofi-Aventis, BiogenIdec)
  - DR5 – 7 (Amgen, Genentech, Pfizer, Novartis, Imclone)
- Scarcity of targets – most are taken

♦ Novel targets

Pros
- Derived from genomics and proteomics efforts
  - IP protected – provide competitive edge and exclusivity in development
  - Potential novel mechanism of action/therapeutic path
  - Novel products attract clinical investigators

Cons
- Validation of role in disease development is required

♦ For both types of targets – clinical relevance to be validated in patient populations
Background

♦ Operations commenced in 1997
  ▪ Initial focus: cancer target discovery and validation

♦ Transition to product development in 2002/2003

♦ 130 Employees

♦ 58,000 sq. ft. in Santa Monica, CA
  ▪ R&D laboratories
  ▪ Vivarium
  ▪ GMP Manufacturing facility
  ▪ Offices

Agensys – Developing Therapeutic MAbs to Novel Cancer Targets
Agensys Fundamentals

Novel therapeutics to unmet clinical needs in cancer

- Fully integrated activities from target discovery to clinical trials
  - Expertise in all related R&D areas

- Novel proprietary targets in multiple cancer indications
  - Strong patent estate on targets and related products

- Focus on antibody products directed to validated targets

- Multiple proprietary in-vivo cancer models for target discovery and product evaluation and selection

- Complete set of core capabilities for MAb product development
  - Leading human antibody and drug conjugate technologies
  - GMP manufacturing facility

- Multiple programs in parallel – different cancer indications
  - Increase chances for success

- Highly coordinated activities among cross-functional teams streamline process and expedite product development

- Entrepreneurial culture
  - Novelty, creativity, speed, prudent risk taking
Agensys Strength in Antibody Therapeutics

- Expertise in MAb product generation and development

- High Quality Proprietary Targets
  - Clinically relevant
    - Significant expression in tumors
    - Limited expression in normal tissues
    - Involved in tumor development
  - Applicable for functional MAb and ADC approaches
  - Multiple cancer indications

- High Quality MAbs – naked & ADCs
  - High affinity, fully human MAbs
  - Capable of modulating target function
    - Inhibit tumor growth and metastasis, prolong survival
  - ADCs regress/eradicate large established tumors
  - Established safety and long half-life in man

- Targets and related products protected by large patent estate
  - > 190 patents
Growing In-House Antibody Product Pipeline

**AGS Program**
- AGS-PSCA/1C4D4: prostate, bladder, pancreas
- AGS-16M18: kidney, liver
- AGS-8M4: ovary
- ASG-5ME: prostate, pancreas, gastric

**XenoMouse**
- 1: kidney, liver
- 2: melanoma, ovary
- 3: breast, pancreas, bladder
- 4: bladder, glioblastoma
- 5: colon, pancreas, stomach
- 6: breast, lung, pancreas
- 7: B cell lymphoma/leukemia
- 8: prostate, colon
- 9: breast, pancreas, ovary, multiple myeloma
- 10: colon, liver, esophagus
- 11: breast, lung, pancreas, gastric, prostate

**MAb Generation**
- Preclinical Testing
- MAb Product Selection
- Phase I
- Phase II

*MAb in vivo efficacy*
PSCA- A Novel Target for Epithelial Tumors

- Involved in tumor cell proliferation and migration
- Restricted expression in normal tissues
- Significant expression in epithelial tumors:

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Expression Frequency</th>
<th>Specimens Tested</th>
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</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>&gt; 80%</td>
<td>&gt; 500</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>&gt; 70%</td>
<td>&gt; 150</td>
</tr>
<tr>
<td>Bladder</td>
<td>&gt; 70%</td>
<td>&gt; 200</td>
</tr>
</tbody>
</table>
AGS-PSCA Inhibits Growth of Established Orthotopic Human Prostate Tumors

Patient-derived Androgen-Dependent Prostate Cancer Xenografts

- AGS-PSCA Inhibited tumor growth by 85% (p<0.0001)
- AGS-PSCA eradicated established tumors in 7 out of 15 treated mice
- Lung metastases detected in all control mice; no metastases detected in treated mice
AGS-PSCA + Gemzar Enhanced Tumor Growth Inhibition

Established orthotopic pancreatic tumors

Mean tumor weight (g)

<table>
<thead>
<tr>
<th></th>
<th>AGS-PSCA</th>
<th>AGS-PSCA + Gemzar</th>
<th>Control MAb + Gemzar</th>
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</thead>
<tbody>
<tr>
<td>Tumor Growth Inhibition (%)</td>
<td>38</td>
<td>88</td>
<td>43</td>
</tr>
<tr>
<td>p value</td>
<td>&lt;0.01</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
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</tbody>
</table>

* Metastases in multiple sites of all control mice; only 1 of 15 treated mice
AGS-16 – A Novel Target for Kidney and Liver Cancers

- Involved in tumor cell proliferation, invasion, and angiogenesis
- Highly restricted normal tissue expression
  - Up-regulated expression:
    - >90% kidney cancer
    - >40% liver cancer

Clear Cell Carcinoma  Metastasis to Lymph Node  Normal Adjacent Tissue
AGS-16M18 Inhibits the Growth of Established Renal and Liver Carcinoma Xenografts

- UGK-3 patient derived renal clear cell carcinoma
- HepG2 hepatocellular carcinoma

AGS-16M18 inhibited tumor growth by (A) 61% (p<0.01) & (B) 82% (p<0.0003)
AGS-8 – A Novel Target for Ovarian Cancer

♦ Functions as an oncogene involved in tumor cell growth, migration, invasion, and angiogenesis
♦ Highly restricted normal tissue expression
♦ Expressed in >70% of ovarian cancer specimens
  ▪ Advanced serous adenocarcinoma (stage II, III, IV)
AGS-8M4 Prolongs the Survival of Ovarian Tumor-Bearing Mice

- Tumors implanted intraperitoneally for 7 days prior to treatment

AGS-8M4 prolongs survival by 32 days (37 vs. 69 days, p=0.0032)
## Agensys ADC Pipeline

### Seattle Genetics drug platform technology

<table>
<thead>
<tr>
<th>AGS Program</th>
<th>Major Cancer Indications</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ ASG-5ME</td>
<td>Prostate, pancreas, gastric</td>
<td>• product progressing</td>
</tr>
<tr>
<td>♦ 1</td>
<td>Kidney, liver</td>
<td>• product selected</td>
</tr>
<tr>
<td>♦ 3</td>
<td>Breast, pancreas, bladder</td>
<td>• product being selected</td>
</tr>
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<td>♦ 4</td>
<td>Bladder, glioblastoma</td>
<td>• product being selected</td>
</tr>
<tr>
<td>♦ 7</td>
<td>Lymphoma</td>
<td>• product being selected</td>
</tr>
<tr>
<td>♦ 2</td>
<td>Melanoma, ovary</td>
<td>• Product being selected</td>
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</tbody>
</table>
AGS-5 Protein Expression in Epithelial Tumors

- Expression in ~90% patients with prostate, pancreatic and gastric cancers

Prostate Cancer

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<tr>
<th>Primary Tumor</th>
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<tbody>
<tr>
<td><img src="image1" alt="Prostate Cancer Primary Tumor" /></td>
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Pancreatic Cancer

<table>
<thead>
<tr>
<th>Primary Tumor</th>
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<tbody>
<tr>
<td><img src="image2" alt="Pancreatic Cancer Primary Tumor" /></td>
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Gastric Cancer

<table>
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<th>Primary Tumor</th>
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<td><img src="image3" alt="Gastric Cancer Primary Tumor" /></td>
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Primary Tumor

<table>
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<th>Metastatic Tumor</th>
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Pancreatic Cancer

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<tbody>
<tr>
<td><img src="image5" alt="Pancreatic Cancer Metastatic Tumor" /></td>
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Gastric Cancer

<table>
<thead>
<tr>
<th>Metastatic Tumor</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image6" alt="Gastric Cancer Metastatic Tumor" /></td>
</tr>
</tbody>
</table>
ASG-5ME (ADC) regressed established tumors

- ASG-5ME MAb conjugated to vcMMAE toxin
- Patient-derived androgen independent prostate cancer xenograft
- Patient-derived pancreatic cancer xenograft AG-Panc4

- 3mg/kg, 4 doses, started at day 0
- 5mg/kg, 4 doses, started at day 0

Last administration
Agensys Portfolio-Derived Clinical Products

Leading pipeline of products to novel genomics targets

♦ AGS-1C4D4 for prostate, pancreatic and bladder cancers
  ▪ Phase 2 study in pancreatic cancer on-going

♦ AGS-16M18 for kidney and liver cancers
  ▪ Phase 1 study on-going

♦ AGS-8M4 for ovarian cancer
  ▪ Phase 1 study on-going

♦ ASG-5ME for prostate, pancreatic and gastric cancers
  ▪ Progressing to clinical studies
  ▪ Co-development with Seattle Genetics

♦ ADC product for kidney and liver cancers selected
Astellas-Agensys Team – Key Synergies

♦ Focus on innovative therapies to critical unmet need indications

♦ Activities driven by high quality science, aggressive timelines

♦ Commitment to collaborate and exploit complementary expertise, capabilities, and resources
  ▪ Antibodies
  ▪ Small molecules

♦ Strong collaboration with Research, Development and Technology divisions
Strong Collaboration with Astellas Research Team

♦ Building and Sharing Expertise and Capabilities

- Target discovery and validation
  - Mining Agensys proprietary gene database

- Antibody product selection in different disease indications

- Development of small molecule drugs based on Agensys targets (cancer and other indications)

- Translational research

- Evaluation and implementation of new antibody technologies
Therapeutic MAbs – a key player in Astellas GCL Oncology Mission

Astellas well positioned to be a leader in cancer therapeutic MAbs

♦ Capitalize on Agensys 12 years of activities and accomplishments in oncology

♦ Access to leading antibody technologies
  ▪ Human MAb
  ▪ ADC

♦ Proprietary clinically relevant cancer targets

♦ Growing pipeline of proprietary MAb products (naked, ADCs)

♦ Proprietary patient-derived xenograft models for efficacy studies

♦ Expertise in cancer biology and oncology

♦ Expertise and capabilities in antibody research and development

♦ Expertise and capabilities in antibody manufacturing

♦ Potential synergy between in-house developed MAbs and small molecule drugs
Antibodies – The Highway to Oncology GCL