ADCs: A Targeted Approach for the Treatment of Cancer

Update of ADC in development at Sanofi

6th world ADC San Diego 2015
October 19th-22nd

Cécile Combeau, Early Development Oncology, Sanofi
Antibody Drug Conjugate (ADC)
Targeted delivery of potent cytotoxic anticancer agents

Therapeutic Window

Antibody Drug Conjugate (ADC) concept

Chemotherapy

ADC concept

Drugs Dose

MTD (max tolerated dose)

MED (min effective dose)

Increase MTD

By Increasing Efficacy using potent cytotoxic molecules

Decrease MED

By Lowering Toxicity through selective delivery to tumor cells

Therapeutic Index = MTD/MED
Antibody Drug Conjugates (ADC) for Oncology

The approval of Adcetris and Kadcyla has created great enthusiasm for the ADC technology as proven paradigm for treating cancer

Around 50 ADCs in Phase I, II, III clinical development

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Around 50 ADCs in Phase I, II, III clinical development

**Preclinical**

- Seattle Genetics (SGN-CD33A, CD33; SGN-CD70A, CD70)
- AbbVie (HuMax-TF-ADC, ABT-414, EGFR)
- Immunomedics (IMMU-130, CEACAM5; IMMU-132, TROP-2)
- GSK (GSK-2857916, BCMA)
- Takeda (MLN0264, GCC)
- Bayer (BAY-1129980, LYPD3)

**Ph I**

- Seattle Genetics (SGN-CD19A, CD19; SGN-LIV1A, LIV-1)
- Bayer (BAY-1129980, LYPD3)
- Sanofi (SAR-408701, CEACAM5; SAR-566658, CA6)
- Immunogen (lorvotuzumab mertansine, CD56; IMGN-853, FOLR1; IMGN-529, CD79b; IMGN-289, EGFR)
- Aspyrian (RM-1929, EGFR)
- Amgen (AMG-595, EGFRvIII; AMG-172, CD70)

**Ph I/II**

- Seattle Genetics (Adoctris, CD30)
- Immunomedics (IMMU-130, CEACAM5; IMMU-132, TROP-2)
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**Ph II**

- Roche (RG7450, STEAP1; RG7841, LY6E)
- Seattle Genetics (SGN-CD19A, CD19; SGN-LIV1A, LIV-1)
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**Market**

- Roche (RG7450, STEAP1; RG7841, LY6E)
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**Others**

- CEACAM5
- EGFR
- CD37
- CD33
- HER2
- CD70
- Mesothelin

**Auristatin Payload**

- Astellas
- AbbVie
- Roche
- Pfizer
- Seattle Genetics
- Biotest
- Sanofi
- Amgen
- Novartis

**Maytansine Payload**

- BMS
- Stein CentRx
- BMS
- Pfizer
- AbbVie
- Aspyrian

**PBD**

- BMS
- AbbVie
- Pfizer

**SN-38**

- BMS
- AbbVie
- Pfizer

**Others**

- CEACAM5
- EGFR
- CD37
- CD33
- HER2
- CD70
- Mesothelin
SANOFI ADCs are developed in collaboration with ImmunoGen

**POTENT CELL-KILLING AGENT**

**DM4:** Maytansinoid derivative
- Highly potent inhibitor of microtubule formation
- 100x > docetaxel or vinca-alkaloid
- Drug Antibody Ratio DAR: 3-4 molecules/antibody

**ANTIBODY**
- Humanized antibody selectively targeting an antigen expressed in tumors
- mAb humanized to limit immunogenicity
- [Humanized IgG1 mAb]

**STABLE LINKER**

**SPDB:** optimized cleavable linker
- [N-Succinimidy-4-(2-Pyridyldithio)butanoic acid]
- Hindered disulfide bond stable in bloodstream
- Cleaved inside tumor cells to release active cell-killing agent
ADCs in early development at Sanofi

- Anti CA6-SPDB-DM4
- Anti CEACAM5-SPDB-DM4
SAR566658

Anti CA6-SPDB-DM4
What is CA6?

CA6 is an O-linked sialoglycotope linked to the extracellular domain of the human Mucin-1 (MUC1) glycoprotein

Discovered by ImmunoGen in collaboration with East Carolina University

Results from cancer-induced aberrant glycosylation

MUC1 is an O-linked glycosylated transmembrane protein normally expressed on the apical surface of epithelial cells

CA6 is highly expressed on some epithelial tumors (ovary, breast, bladder, lung, pancreas, head and neck, ...) ⇒ Number of antigens/cell: 70000-1000 000
Different patterns of CA6 expression in tumors

Breast adenocarcinoma

Polarized

Whole membrane

Pancreas adenocarcinoma

Polarized

Whole membrane

Ovary adenocarcinoma

Polarized

Whole membrane
Heterogeneity of CA6 expression in some tumors: case of an ovarian tumor

Ovarian adenocarcinoma

Polarized and whole membrane staining, 2+ and 3+ intensity, ~90%

Polarized staining, 2+ and 3+ intensity, ~30%

Rare positive tumor cells (1%), 1+ intensity
CA6 is expressed in multiple cancer types

<table>
<thead>
<tr>
<th></th>
<th>CA6 positivity (2-3 + in ≥ 30% tumor cells)</th>
<th>Correlation with histological subtype(s)</th>
<th>Expression Heterogeneity</th>
<th>Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder (198 cases)</td>
<td>59%</td>
<td>None</td>
<td>No</td>
<td>Whole membrane in 59% cases</td>
</tr>
<tr>
<td>Breast (300 cases)</td>
<td>29-35 %</td>
<td>No difference whatever hormonal/ her2 status</td>
<td>Yes</td>
<td>Polarized in 65%/43% cases</td>
</tr>
<tr>
<td>Ovary (190 cases)</td>
<td>70%</td>
<td>None</td>
<td>Yes</td>
<td>Polarized in 89% cases</td>
</tr>
<tr>
<td>Pancreas (83 cases)</td>
<td>59%</td>
<td>None</td>
<td>Yes</td>
<td>Polarized in 91% cases</td>
</tr>
<tr>
<td>H&amp;N (200 cases)</td>
<td>17%</td>
<td>None</td>
<td>Yes</td>
<td>Whole membrane in 96% cases</td>
</tr>
</tbody>
</table>
Preclinical In vivo activity of SAR566658 is dependent on CA6 expression

**EFFICACY PROFILE**

**A2780 (ovarian)**
- Inactive

**UISO-BCA-1 (breast)**
- 16.4mpk, No PR

**Ovcar5 (ovarian)**
- 19.6mpk, No PR

**CaPan2 (pancreas)**
- 16 mpk, 5/5 CR

**WISH (cervix)**
- 2.6mpk, 1/5 CR

**EXPRESSION PROFILE**

**Low CA6 expression**
- 0

**Medium CA6 expression**
- 30%, M2+ apical

**High CA6 expression**
- 50%, M2+/3+ apical + WM

**PR** = partial tumor regression

**CR** = complete tumor regression

**WM** = whole membrane staining
Enroll solid tumor patients with CA6 positive tumor

Determined on archival or fresh biopsy,

By centralized IHC: ≥30% of tumor cells with membrane staining ≥2+

SAR566658 given intravenously, on day 1 every 3 weeks

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SAR566658 given intravenously, on day 1 every 3 weeks
**FIH STUDY – ESCALATION PART**

- **Accelerated dose escalation** from DL1 to DL2 (1pt, +100%)
  - Then from DL3, classical dose escalation « 3+3 » design

**Selected dose**

- **MAD**: Maximum Administered Dose

<table>
<thead>
<tr>
<th>Dose level (DL)</th>
<th>Dose (mg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
</tr>
<tr>
<td>4</td>
<td>60</td>
</tr>
<tr>
<td>5</td>
<td>90</td>
</tr>
<tr>
<td>6</td>
<td>120</td>
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<tr>
<td>7</td>
<td>150</td>
</tr>
<tr>
<td>8</td>
<td>190</td>
</tr>
<tr>
<td>9</td>
<td>240</td>
</tr>
<tr>
<td>10</td>
<td>300</td>
</tr>
</tbody>
</table>

- **DLT at 240 mg/m²**: diarrhea (cy1) & keratitis (cy2)

- **Late occurrence (cycle 2)** of reversible corneal toxicity at doses ≥150mg/m²
  - Rare grade 3 hematological toxicity, few peripheral neuropathy, 1 interstitial pneumonitis

- **3 PRs**: in breast, ovarian & lung cancers

- **Initial RD**: 190 mg/m² q3w secondarily reduced to 150mg/m² q3w due to high incidence of keratitis

**SANOFI ONCOLOGY**

MAD: Maximum Administered Dose
**FIH study – Pharmacokinetics**

**SAR566658**

Overall, low CL (~0.7 L/day) and Half-life of ~5 days

Dose proportional increase of SAR566658 exposure

Low inter-patient variability

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**DM4 and Me-DM4 metabolites**

Very low DM4 and me-DM4 plasma levels (accounting for ~0.5% and 6% of SAR566658 exposure on a molar basis)
**FIH study - Extension part**

- **Open in June 2013**
- **Enroll « selected » CA6 positive tumors:**
  - Pancreas, ovarian, and breast cancer patients

- **Two alternative schedules under evaluation with the objective to improve the benefit /risk ratio**

- **Recruitment on-going**
Imaging Companion Diagnostic

DS6-ICD
Feasibility on non-invasive diagnostic

Whole antibodies have inherent limitations for imaging
Slow kinetics for tumor accumulation and blood clearance

Bivalent target binding 50 - 75 kDa molecular weight for optimal PK

IgG (150 kDa)

CODV-Fab (70 kDa)

B-Fab (70 kDa)

Diabody (55 kDa)

Tumor Blood Optimal Imaging time post probe injection

120 h

20 h

3 h
Preclinical validation of the B-Fab format

PET imaging of $^{64}$Cu-DOTA-B-Fab (24hr post administration)

Collaboration with Stanford University (Pr S. Gambhir)
**Imaging companion diagnostic**
Quantitative and non-invasive – real-time information

**FIH trial objectives**
Evaluate biodistribution, dosimetry & safety of 64Cu-DOTA-B-Fab
Ability to detect ovarian cancer lesion
Pre-surgery 64Cu-DOTA-B-Fab PET/CT vs 18F FDG PET/CT scans
Ability to detect CA6 expression of ovarian cancer lesions
Imaging findings vs IHC analysis of the surgical specimens

*Imminent start of the PET study at Stanford in ovarian carcinoma patients eligible for surgical resection*
SAR408701

Anti-CEACAM5-SPDB-DM4
**CEACAM5: Carcinoembryonic antigen**

Described as a tumor associated antigen in human colon cancer tissue extracts (CEA)

Highly glycosylated cell adhesion protein

Large family with 2 subgroups
- CEACAM (7 members) and Pregnancy-specific glycoprotein (10 members)
- CEACAM subdivided in transmembrane-bound members (TM) and Glycosyl phosphatidyl inositol anchor (GPI) members: CEACAM-5, -6, -7, -8

Mediates intercellular adhesion through homophilic and heterophilic interactions

Unclear function in cancer (tumor cell adhesion, invasion, metastasis)

Used as a biomarker for screening patients with CRC and follow-up of recurrence
Discovery of Anti-CEACAM5 antibody (1/2)

First generation anti-CEA antibody 15B4 identified by ImmunoGen in collaboration with East Carolina University from mice immunized with colorectal tumors

Target found attractive for an ADC approach

- Antigen expression drives potential indications with unmet medical need
  - CRC, stomach, NSCLC adenocarcinoma, ...
- Limited expression in normal tissue
  - Columnar absorptive cells of the colon (non-dividing)

Two concerns

- No cross reactivity with CEACAM5 from toxicology species
- Cross reactivity with other CEACAM family members (CEACAM6 and to a lower degree CEACAM1)

Second generation anti CEA antibody 769 identified by sanofi cross reactive with monkey and selective for CEACAM5
**Discovery of Anti-CEACAM5 antibody (2/2)**

**Data of mAb 769**

1830 mAbs 18 mAbs

Selectivity towards CEACAM5 (ELISA) Apparent Affinity on colon PDX (FACS) Monkey CEACAM5 Cross reactivity (ELISA) Domain mapping (ELISA)

**Hu CEACAMs**

**Cyto CEACAMs**

18 mAbs exhibit expected profile
- Selectivity
- Affinity
- Monkey cross-reactivity (5/18)

Epitope diversity

- EC50 = 0.53 nM
- huCEAM5 EC50= 0.10 nM
cyCEAM5 EC50= 0.29 nM
CEACAM5: An attractive target for ADC therapy

**high expression** in several cancer types

- Colon Adca
- Lung Adca
- Stomach Adca
- Stomach Scc
- Cervix Scc
- Pancreas Adca

**No or low expression** in normal tissues

- Cervix
- Tonsil
- Larynx
- Esophagus
- Colon
- Stomach

**high Prevalence** in several cancer types

<table>
<thead>
<tr>
<th>Indications</th>
<th>#Samples</th>
<th>Prevalence Membrane CEA+ samples</th>
<th>Intensity</th>
<th>%+ tumor cells</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colon adenocarcinoma</td>
<td>219</td>
<td>87%</td>
<td>2,5+</td>
<td>60%</td>
</tr>
<tr>
<td>Gastric adenocarcinoma</td>
<td>203</td>
<td>48%</td>
<td>2,5+</td>
<td>50%</td>
</tr>
<tr>
<td>Gastric Signet Ring Cell Ca</td>
<td>15</td>
<td>67%</td>
<td>2,5+</td>
<td>88%</td>
</tr>
<tr>
<td>NSCL-adenocarcinoma</td>
<td>58</td>
<td>38%</td>
<td>1,8+</td>
<td>50%</td>
</tr>
<tr>
<td>NSCL-squamous</td>
<td>143</td>
<td>20%</td>
<td>1,5+</td>
<td>10%</td>
</tr>
<tr>
<td>NSCL-adenosquamous</td>
<td>19</td>
<td>58%</td>
<td>1,5+</td>
<td>40%</td>
</tr>
<tr>
<td>Endometrium adenocarcinoma</td>
<td>14</td>
<td>7%</td>
<td>2+</td>
<td>50%</td>
</tr>
<tr>
<td>Ovary epithelial tumor</td>
<td>77</td>
<td>4%</td>
<td>2+</td>
<td>40%</td>
</tr>
<tr>
<td>Cervix SCC</td>
<td>14</td>
<td>79%</td>
<td>2+</td>
<td>20%</td>
</tr>
<tr>
<td>Pancreas adenocarcinoma</td>
<td>34</td>
<td>53%</td>
<td>2+</td>
<td>5%</td>
</tr>
<tr>
<td>Esophagus SCC</td>
<td>51</td>
<td>33%</td>
<td>2+</td>
<td>6%</td>
</tr>
<tr>
<td>Gallbladder adenocarcinoma</td>
<td>10</td>
<td>50%</td>
<td>1+</td>
<td>10%</td>
</tr>
<tr>
<td>Bladder transitional Cell Ca</td>
<td>20</td>
<td>20%</td>
<td>1,8+</td>
<td>50%</td>
</tr>
<tr>
<td>Cholangiocarcinoma</td>
<td>6</td>
<td>33%</td>
<td>1,5+</td>
<td>75%</td>
</tr>
<tr>
<td>Prostate ca</td>
<td>13</td>
<td>8%</td>
<td>2+</td>
<td>50%</td>
</tr>
<tr>
<td>Skin SCC</td>
<td>6</td>
<td>25%</td>
<td>1,5+</td>
<td>23%</td>
</tr>
<tr>
<td>Breast Invasive ductal carcinoma</td>
<td>18</td>
<td>0%</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>Thyroid Papillary carcinoma</td>
<td>18</td>
<td>0%</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>Melanoma</td>
<td>15</td>
<td>0%</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>RCC</td>
<td>19</td>
<td>0%</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>Lymphoma (HL &amp; NHL)</td>
<td>22</td>
<td>0%</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>HCC</td>
<td>21</td>
<td>0%</td>
<td>-</td>
<td>0%</td>
</tr>
</tbody>
</table>

Formalin Fixed Paraffin Embedded Tissue microarray (FFPE TMA) samples using m769 Ab
Different patterns of CEA expression in tumors

Distribution of CEA expression in commercial TMA

<table>
<thead>
<tr>
<th>Indications</th>
<th># samples (prevalence)</th>
<th>Sub-localization distribution in positive samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Polarized</td>
</tr>
<tr>
<td>Colon</td>
<td>219 (87%)</td>
<td>80%</td>
</tr>
<tr>
<td>Gastric adenocarcinoma</td>
<td>203 (48%)</td>
<td>51%</td>
</tr>
<tr>
<td>Gastric signet ring ca</td>
<td>15 (67%)</td>
<td>0%</td>
</tr>
<tr>
<td>Lung adenocarcinoma</td>
<td>58 (38%)</td>
<td>23%</td>
</tr>
</tbody>
</table>
SAR408701 antitumor activity (1/2)

Antitumor activity demonstrated in the patient-derived model representative of CRC highly expressing CEACAM5
**SAR408701 antitumor activity (2/2)**

Antitumor activity confirmed in several PDX after a single administration

Control                      2.5 mg/kg                      5mg/kg                      10mg/kg

![Graph showing tumor volume over time for different doses and tumor types](image)

<table>
<thead>
<tr>
<th></th>
<th>Lung</th>
<th>Colon</th>
<th>Stomach</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUN-NIC-083</td>
<td>1-3+ (50-90%)</td>
<td>2-3+ (50-100%)</td>
<td>2-3+ (100%)</td>
</tr>
<tr>
<td>LUN-NIC-014</td>
<td>2-3+ (50-100%)</td>
<td>2-3+ (100%)</td>
<td>2-3+ (30-100%)</td>
</tr>
<tr>
<td>CR-IGR-034P</td>
<td>2-3+ (100%)</td>
<td>2-3+ (30-100%)</td>
<td>3+ (20-50%)</td>
</tr>
<tr>
<td>CR-IGR-002M</td>
<td>2-3+ (50-100%)</td>
<td>3+ (50-100%)</td>
<td></td>
</tr>
<tr>
<td>SA-STO-014</td>
<td>3+ (20-50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STO-IND-007</td>
<td>3+ (50-100%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CEA expression**

<table>
<thead>
<tr>
<th></th>
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<th>Stomach</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEA expression</td>
<td>1-3+ (50-90%)</td>
<td>2-3+ (50-100%)</td>
<td>2-3+ (100%)</td>
</tr>
<tr>
<td>Sensitivity to conjugated DM4</td>
<td>-/+</td>
<td>+++</td>
<td>+++-</td>
</tr>
<tr>
<td>SAR408701 (mg/k)</td>
<td>2.5</td>
<td>+/++</td>
<td>+/++</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>++</td>
<td>+++</td>
</tr>
</tbody>
</table>

; -: ΔT/ΔC>40 inactive; +: 10<ΔT/ΔC<40 active or obvious tumor growth delay; ++: 0<ΔT/ΔC<10 very active or tumor stasis; +++: 1ΔT/ΔC<0 highly active or tumor regression
TED13751: SAR408701 FIH Study
A Phase I/II Design

- Study populations

  **Enriched for**
  - Tumors expressing or likely to be expressing CEACAM5
  - or Shed CEA levels > 5 ng/mL

  **Restricted to**
  - CRC, lung adenocarcinoma, gastric cancer (including signet ring cell subtype & EGJ type II & III)
  - CEACAM5 positive (Local IHC – Archival tissue)
    - >2+ intensity
    - ≥50% tumor cell population

* CEACAM5 expression documented retrospectively and centrally on archival tissue
Acknowledgements

SAR566658 Team
Sylvie Assadourian
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Patrick Cohen
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Eric Lacoste
Anne-Marie Lefebvre
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Jie Zhang

Sanofi Oncology
Jo Lager
Vicky Richon

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