Creating innovative antibodies for cancer & severe autoimmune diseases

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Eric Castaldi, CFO argenx

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Agenda

- Introduction
- Creating innovative antibodies
- Differentiated products
- Collaborations
- Financials
Introduction
Creating value from highly differentiated antibodies

Rich proprietary pipeline
- Oncology & severe autoimmune diseases
- 4 products in clinical phase

Thriving strategic alliances
- Industrial partners
- Innovative Access Program

Competitive technology suite
- Antibodies with differentiated modes of action
- Based on llama immune system and unique Fc engineering

Strong financials
- Strong cash position
  (€ 54Mio March 2016; AbbVie € 35Mio April ‘16, Private Placement € 30Mio June ‘16)
- > € 2B potential future income from partnerships
Business model maximizing shareholder value

Generating differentiated antibody product candidates...

Novel + arGEN-X technology suite = Maximally differentiated mAbs

... towards Phase II value inflection point

Aug 2015 Product portfolio
- ARGX-110: Ph I
- ARGX-111: Ph I
- ARGX-113: CTA submission
- ARGX-115: Preclinical PoC

End 2017 Product portfolio
- ARGX-110: Ph II
- ARGX-111: Ph II, partnered
- ARGX-113: Ph II autoimmune
- ARGX 115: Ph I oncology

Strategic pharma alliances
- Platform deals
- Discovery
- Preclinical development
- Early clinical development
- Late clinical development

Preclinical product deals
- ARGX-115 Preclinical PoC

IAP*: UCL, de Duve

* IAP: Innovative Access Program
### Proprietary pipeline in cancer and severe autoimmunity

<table>
<thead>
<tr>
<th>Drug candidate</th>
<th>Target</th>
<th>Indication</th>
<th>Pre-clinical</th>
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<th>Phase 2</th>
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<tr>
<td>ARGX-113</td>
<td>FcRn</td>
<td>Autoimmunity, ITP, Myasthenia Gravis</td>
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<td>ARGX-110</td>
<td>CD70</td>
<td>Cancer (Blood &amp; Solid), [Autoimmunity]</td>
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<td>ARGX-111</td>
<td>c-MET</td>
<td>Solid tumors Blood cancer</td>
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<td>Discovery</td>
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**Autoimmune diseases**

**Cancer immunotherapy**

**Cancer metastasis**

**Partnered, non-dilutive income**
### Upcoming news flow 2016

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- **Confirmation**
  - Favorable safety profile
  - Signs of anti-tumor activity in MET-amplified patients
Creating innovative antibodies
Unique technology platform: multiple modes of action

- SIMPLE Antibody™: Unlock novel and complex targets
- NHance®, ABDEG™, POTELIGENT®: Enhance SIMPLE Antibody™ leads
- Multiple layers of IP protection in place until 2028-2033 (excluding any PTE)

Leapfrogging transgenics:
- V-regions llama & human antibodies virtually identical
- Unprecedented epitope coverage
Continuous technology innovation: antibody mediated target clearance

- NHance®/ABDEG™ FcRn modulation
- SIMPLE ANTIBODY™ pH-dependent target binding

- Clinical potential for indications:
  - with high circulating target concentrations
  - which require fast target clearance
  - e.g. inflammatory cytokines (receptors)
ARGX-113
What is autoimmune disease?

- Immune system attacks own organs
- Tissue destruction by autoantibodies
- Common diseases include: multiple sclerosis, lupus, rheumatoid arthritis, psoriasis, myasthenia gravis

Why target autoimmune diseases?

- 10% of population suffers from autoimmune diseases
- Antibody therapy used for rheumatoid arthritis, multiple sclerosis & psoriasis
- ARGX-113 targets severe autoimmune diseases

Current treatment

- High dose corticosteroids and broad immunosuppressive agents: severe side effects
- IVIg or Plasmapheresis: incomplete effect, slow onset of action
ARGX-113: Potential breakthrough in autoimmune disease

ARGX-113 addresses acute autoimmune flares more effectively

Mode of action

- Targeting auto-immune diseases driven by pathogen autoantibodies (IgG’s)
- Fast & deep reduction of pathogenic IgG’s
- Prevention & control of disease flares/exacerbation
ARGX-113: How it works - Antibody clearance capability

- Proprietary Fc mutations
- Block IgG recycling
- Resulting in rapid autoantibody clearance

Repeat dose ARGX-113

- Saturation of PD effect at doses ≥ 20 mg/kg
- Repeat dosing > single dose

Vaccaro et al., 2005, Nature Biotechnology
# Clinical rationale for targeting autoantibody clearance

## Myasthenia gravis autoantibody levels and disease score following therapy

<table>
<thead>
<tr>
<th>Treatment*</th>
<th>Plasmapheresis</th>
<th>Immunoadsorption</th>
<th>IVIg</th>
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<tr>
<td>Decrease in antibody levels (%) after treatment</td>
<td>62.2 ± 6.3</td>
<td>55.1 ± 3.2</td>
<td>28.9 ± 3.8</td>
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<tr>
<td>Decrease in disease score (%) after treatment</td>
<td>60.8 ± 3.5</td>
<td>42.4 ± 4.2</td>
<td>23.8 ± 3.7</td>
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<td>Clinical efficacy rate after 14 days**</td>
<td>12/15</td>
<td>7/10</td>
<td>6/15</td>
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<td>Duration of hospital stay (days)</td>
<td>12.80 ± 0.28</td>
<td>13.50 ± 0.50</td>
<td>16.00 ± 0.50</td>
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* Comparison between 3 cycles of Plasmapheresis/Immunoadsorption every 24h-48h and 5 cycles of IVIG every 24h
** Clinically effective if disease score has improved by >50% 14 days after treatment

- Degree of autoantibody reduction: correlates with clinical improvement & reduced hospital stay
- Similar observations reported for other autoimmune disorders

Liu et al., 2009
ARGX-113: In vivo PoC
MuSK-MG transfer model – therapeutic setting

- Daily injection of MuSK-MG patient IgG causes Myasthenia gravis in NOD/SCID mice
- ARGX-113 (1mg) administration:
  - reduces autoantibody levels (anti-MuSK Ab-levels)
  - stabilizes disease: measured by inverted mesh (see graph) and grip strength (not shown)
ARGX-113: Phase 1 study design & interim safety read out
Double-blinded, placebo-controlled study in healthy volunteers

Single ascending dose (SAD)  
Multiple ascending dose (MAD)  
Data analysis

(mg/kg)

4:2 → active:placebo  
6:2 → active:placebo  
Up to 6 doses

End SAD in-life phase  
End MAD in-life phase

4 months  
4 months  
2 months

• SAD completed according to plan (38 healthy volunteers in total)  
• Favourable safety and tolerability profile observed (no serious adverse events reported)
ARGX-113: PD marker readout for SAD
Double-blind, placebo-controlled study in healthy volunteers

Rapid, deep and specific IgG reduction

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<th>ARGX-113 vs. IVIg*</th>
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<td>Speed of IgG reduction</td>
<td>&gt;&gt;&gt;</td>
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<tr>
<td>Level of IgG reduction</td>
<td>&gt;&gt;</td>
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<tr>
<td>Duration of PD effect</td>
<td>&gt;</td>
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* Extrapolated based on literature data

- Initial Phase 1 data -

- Single 2h infusion: rapid reduction of IgG, not affecting IgM/IgA and albumin levels
- Maximal PD effect (~50% IgG reduction) as of 6 days after infusion
- Low IgG levels maintained for >1 week
ARGX-113 vs. IVIg/PLEX: Key differentiators for MG

- Rapid speed of onset
  - "Demonstrating that its onset of action is faster than IVIg would be fantastic," MG KOL

- More convenient administration
  - "Getting an infusion done within 2 hours, that is an attractive piece" MG KOL

- Superior efficacy
  - "Acute MG crisis, I don't think it responds all that well to IVIg," MG KOL

- Better tolerated, shorter procedure with limited follow-up
ARGX-113 vs. IVIg/PLEX: Key differentiators for ABD

- **Rapid speed of onset**
  - “If you can control the disease within a week or two, that would be great,” ABD KOL

- **More convenient administration**
  - “PLEX is a nightmare to apply,” ABD KOL

- **Superior efficacy**
  - “IVIg just doesn’t work that great,” ABD KOL

- Better tolerated, shorter procedure with limited follow-up
ARGX-113: What next?

Next steps

Clinical Status
- Multiple Ascending Dose study (MAD)
- Start of Phase 2 in first indication

Market potential

Benchmark therapeutic treatments
- IVIg: annually > $4B (autoimmune diseases approx. 50%)
- IVIg: $79K/cycle
- Benlysta®: $35K/year
- Plasmapheresis: $101K/cycle
- Xolair® annual sales exceed $800M
ARGX-110
ARGX-110: 3 distinct modes of action

1. Block tumor growth signal
2. Kill tumor
3. Restore immune surveillance

Silence et al., 2014, mAbs
Why T Cell Lymphoma?

T Cell Lymphoma: rare and heterogeneous disease

- Elderly (> 60y)
- Rare (1/100,000) but underdiagnosed
- Treatment: first by dermatologist, then by oncologist
- Present in skin, blood and lymph compartments; susceptible to infections

Very high unmet medical need

- Unfit for chemo or stem cell transplantation
- Current therapies: only moderately effective, not curative
  - Retinoids; HDAC inhibitors
  - Antifolates; chemo

ARGX-110 potential

- Ph I results demonstrate biological activity in skin, blood, lymph compartment
- Favorable safety profile enables mono and combo therapy

“...We haven’t made much progress in TCL survival in the last decades. With PFS getting worse after each relapse, we are desperate for the next Rituxan for TCL. This would be a real game changer.”

Dr. O’Connor,
Columbia University Medical Center
ARGX-110: CD70/CD27 pathway highly relevant in TCL

CD70 strongly overexpressed across different TCL types
• Elevated sCD27 levels suggest strong pathway activity in TCL
ARGX-110: Proof of biological activity in 2 patients with Cutaneous T-Cell Lymphoma (Sézary-Syndrome)

- 78 year old woman with CTCL-SS; refractory to multiple lines of chemotherapy
- ARGX-110 treatment (0.1 mg/kg every 3 weeks)
  - Complete response in blood compartment
  - Stabilized disease in skin lesions (see image a. & c.) & lymph nodes
- Elimination of CD70 positive Sézary cells from blood in 2nd CTCL-SS patient

Blood compartment cleared from malignant cells (■)

Stabilized skin lesions

Chemotherapy
Progressive disease
ARGX-110
0.1 mg/kg every 3 weeks

% CD3+CD4-CD8- cells

Time after first dose [Days]
ARGX-110: **Proof of biological activity in patient with Cutaneous Follicular Helper T Cell Lymphoma**

- **55 year old male with cutaneous T_{FH} lymphoma**
- **Disease in skin**
- **Treated with Interferon and PUVA**

- **ARGX-110 treatment (5 mg/kg)**
  - Stabilized disease up to cycle 3
  - After 3 cycles: skin lesions decreased in number and size
  - Patient already 19 cycles on study (15 months)

**Stable disease in skin lesions**

*Illustration CTCL patient*
ARGX-110: Proof of biological activity in patient with Angioimmunoblastic T-Cell lymphoma (AITL)

- 61 year-old male AITL patient with severe Hemolytic Anemia
- Refractory to chemotherapy: CHOP + Etoposide/Cyclosporine /Bendamustine - Transplant

- After 2 doses of ARGX-110 (5 mg/kg)
  - Clinical response in lymph nodes
    - Reference lesions shrink between 4-40 %
    - Clear tendency for all other lesions to shrink
  - Clinical response in blood
    - Transfusion independent
    - Coomb positive → Coomb negative after 1 cycle

- Patient anecdote -
ARGX-110/BCR-ABL1 inhibitor eliminates leukemic stem cells in CML model

Curative potential of combo treatment ARGX-110/BCR-ABL1 inhibitor

Leukemic stem cells (LSCs) resistant to BCR-ABL1 inhibitors via CD70 overexpression

Combo treatment with CD70 blocking mAb eliminates LSCs by synergistic blockade of Wnt signalling pathway

Im: imatinib; V: vehicle; WBM: whole bone marrow

Riether and Schürch et al., 2015, Science Translational Medicine
Next steps

Ongoing clinical studies

- Hematological tumors
  - T-Cell Lymphoma (TCL): Phase 1b ➔ 6 sites (BE, FR, IT)
  - Recruiting up to 10 CTCL (min 5 Sz) - 10 PTCL (min 5 AITL) patients
  - 10 patients enrolled; on track to complete enrollment by end July

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<tr>
<th>Site</th>
<th>Investigator</th>
<th>Status</th>
<th>Patients (pre)screening</th>
<th>On treatment/treated</th>
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<td>Dr. Offner</td>
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<td>Jules Bordet Institute (BE)</td>
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<td>Gustav Roussy (FR)</td>
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- Solid tumors
  - Nasopharyngeal carcinoma (NPC): Phase 1b (UZ Gent)
ARGX-111: Addressing the end game of cancer

Hultberg et al., 2014, Cancer Research – Gherardi et al., 2013, Nature Reviews Cancer

• ARGX-111 has several distinct modes of action
  • HGF-dependent blocking
  • HGF-independent blocking
  • Killing MET-expressing cells
  • Specific targeting of tumor tissue

Targeting MET, receptor responsible for tumor growth and metastasis

1. HGF independent blocking
2. HGF dependent blocking
3. Kill cMet+ cells via increased ADCC-Potelligent®
4. Increased tissue penetration-NHance®

ARGX-111

HGF

MET

Fibroblast

ECM
ARGX-111: Phase 1 trial design

1Q 2014
Dose escalation

1H 2015
Adaptive safety expansion

2H 2016
Details

- Advanced cancer population (34 patients)
- Progressive, end stage disease
- MET+ by IHC and CTCs by Veridex
- Monitor tumor metabolism (PET scan)
- ARGX-111 monotherapy
- ‘Off study’ criteria
  - Progressive disease (ir-RECIST)
  - Safety
  - Translational biomarkers
  - Efficacy: response and duration of therapy

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Ph1 safety expansion update (ASCO) NCT02055066

- Favorable safety profile
- Biological activity (SD, PR)
  - Gastric* (2), Renal* (2), Cholangio, Lung*
- Preclinical PoC:
  - ARGX-111 impacts MDSC’s in tumor environment

* MET-amplified

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- ~50% of patients screened have CTCs
- Safety observations: Infusion related reactions (class effect)
- Biological activity observed in individual patient with gastric cancer with bone metastases

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ClinicalTrials.gov Identifier: NCT02055066
ARGX-111: Proof of biological activity in MET-amplified cancer patients

**Gastric cancer patient**
- 50 year old gastric cancer patient with bone metastases; MET-amplified
- Multiple lines of previous treatment
- PET/CT scan: biological activity
- CTCs reduced by 75%
- Good clinical performance

**Renal cancer patient**
- 57 year old renal cancer patient; MET-amplified
- 11 cycles on study; progressive disease stabilized after 2 cycles
- PET/CT scan: biological activity
- 30% reduction of lesion in lymph node

**Renal cancer patient**
- 58 year old renal cancer patient; MET-amplified
- 4 cycles on study

**Patient anecdotes**

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*Patient anecdotes* - 35
ARGX-111: What next?

Next steps

Clinical Status

• Phase 1b in MET-amplified patients ongoing
• 5 clinics open EU (BE, FR)
• 3 clinics open in Asia
• Recruiting up to 15 MET-amplified patients

Market potential

Benchmark cancer treatments

• Herceptin®: $ 54K/y
• Avastin®: $ 42.8K– 55K/y
• Erbitux®: $ 80K/y
• Crizotinib: $ 1B/y sales based on 3% of ALK-positive NSCLC patients
ARGX-115
GARP: a novel immune checkpoint

- GARP upregulated specifically on surface of Tregs only
- GARP presents and activates latent TGF-β1, activating Tregs and suppressing Teff cells
- SIMPLE Antibody™ hitting unique, patented epitope on GARP
- GARP blockade sufficient for MoA – no Treg depletion
- Graft-versus-host-disease model delivered convincing PoC

Cuende et al., 2015, Science Translational Medicine
ARGX-115: Towards a next generation Yervoy®

In vivo efficacy of anti-GARP-TGFβ SIMPLE Antibody™ in GVHD Model

NSG mice injected with:

- hPBMC → hPBMC (i.e. CTLs) attack host cells (GVHD)
- +/- hTregs → hTregs delay GVHD
- +/- anti GARP → LHG-10.6 blocks Treg-mediated protective activity

Cuende et al., 2015, Science Translational Medicine
AbbVie Option Deal for ARGX-115: Key Elements

- **Financial terms**
  - $40MM upfront
  - Preclinical milestones 2x $10MM
  - Up to $625MM development, regulatory and commercial milestones
  - Tiered, up to double-digit royalty payments on net sales

- **Deal Structure**
  - Responsible for delivering IND data package
  - May combine ARGX-115 with its own pipeline mAbs
  - Co-promotion right to GARP-targeted products (EU/Swiss Economic Area)
  - Option to exclusive development and commercialization license
  - Will fund further GARP-related research for initial period of 2 years, subject to argenx reaching pre-determined preclinical stage milestone
  - Right to license additional therapeutic programs resulting from this research in return for additional milestone and royalty payments
Partnerships
Building partnerships for the long term

• **Alliances with premier pharma partners**
  - Exclusive product partnership
  - Non-exclusive discovery collaborations leveraging entire technology suite
  - Upfront payments, R&D funding, development milestones, royalties, product reversion rights

• **Innovative Access Program**
  - Non-exclusive access to antibody technologies for academic and biotech centers of excellence
  - Creative deal structures including option to acquire asset, golden share,...

• € 31Mio in cumulative revenue (1Q16) (AbbVie € 35Mio April 2016)
• >€ 2B* potential cumulative revenues from existing partnerships

* Assuming specific development and sales milestones are met for all potential discovery targets
Financials
Well capitalized to execute strategic plan

Operating income & expenses
1Q16 (MEUR)

- Operating income: 2.8
- R&D: 4.4
- G&A: 1.4

Shareholder structure (fully diluted)
June 16

- 51%: Aquilo, Federated investors, JP Morgan, MPM, Perceptive, RTW, Van Herk...
- 40%: Forbion, LSP, Orbimed...
- 9%

Operating income, expenses & capital raised since inception (*)
1Q16 (MEUR)

- Operating income: 31.1
- R&D expenses: 66.9
- G&A expenses: 18.2
- Capital raised: 103.8
- Cash and cash-equivalents: 53.8

(*) not including deferred revenue and accruals

Capital raised & cash
June 16 (MEUR)

- Private placement: +30
- AbbVie: +35.1
- AstraZeneca: +30
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<td>110 ASH: TCL results</td>
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- **Confirmation**
  - Favorable safety profile
  - Signs of anti-tumor activity in MET-amplified patients