



Creating innovative antibodies for cancer & auto-immune diseases

Petercam Benelux Conference, London 23 September 2015

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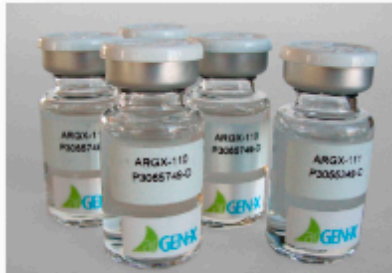
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Creating value from highly differentiated antibodies



Focus on cancer & severe autoimmune diseases

- Highly differentiated products
- Orphan and large indications

Drug	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Current Status
ARGX-110	Her2 malignancies	→	→	→	→	Phase 1/2
ARGX-111	Solid tumors	→	→	→	→	Phase 1
ARGX-113	Autoimmunity	→	→	→	→	Phase 1
ARGX-115	Autoimmunity	→	→	→	→	Phase 1
ARGX-116	Autoimmunity	→	→	→	→	Phase 1
ARGX-117	Autoimmunity	→	→	→	→	Phase 1
ARGX-118	Autoimmunity	→	→	→	→	Phase 1
ARGX-119	Autoimmunity	→	→	→	→	Phase 1
ARGX-120	Autoimmunity	→	→	→	→	Phase 1
ARGX-121	Autoimmunity	→	→	→	→	Phase 1
ARGX-122	Autoimmunity	→	→	→	→	Phase 1
ARGX-123	Autoimmunity	→	→	→	→	Phase 1
ARGX-124	Autoimmunity	→	→	→	→	Phase 1
ARGX-125	Autoimmunity	→	→	→	→	Phase 1
ARGX-126	Autoimmunity	→	→	→	→	Phase 1
ARGX-127	Autoimmunity	→	→	→	→	Phase 1
ARGX-128	Autoimmunity	→	→	→	→	Phase 1
ARGX-129	Autoimmunity	→	→	→	→	Phase 1
ARGX-130	Autoimmunity	→	→	→	→	Phase 1
ARGX-131	Autoimmunity	→	→	→	→	Phase 1
ARGX-132	Autoimmunity	→	→	→	→	Phase 1
ARGX-133	Autoimmunity	→	→	→	→	Phase 1
ARGX-134	Autoimmunity	→	→	→	→	Phase 1
ARGX-135	Autoimmunity	→	→	→	→	Phase 1
ARGX-136	Autoimmunity	→	→	→	→	Phase 1
ARGX-137	Autoimmunity	→	→	→	→	Phase 1
ARGX-138	Autoimmunity	→	→	→	→	Phase 1
ARGX-139	Autoimmunity	→	→	→	→	Phase 1
ARGX-140	Autoimmunity	→	→	→	→	Phase 1

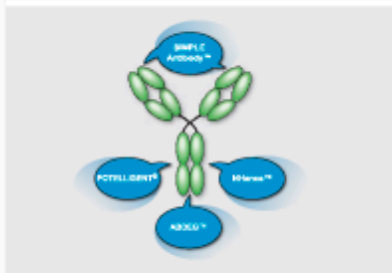
Rich pipeline approaching major value inflection points

- ARGX-110 in Ph1/2 (oncology): first-in-class; clinical activity demonstrated
- ARGX-111 in Ph1 (oncology): best-in-class; clinical activity demonstrated
- ARGX-113 in preclinical (autoimmune): breakthrough concept for crisis management
- ARGX-115 in preclinical (oncology): novel immune checkpoint



Strategic alliances with premier partners

- Strategic partnerships fuelled by consistent success
- Non-dilutive funding and product rights
- Strong cash position (~€50.5m/\$57m June 2015)
- Capital efficient



Powerful technology suite

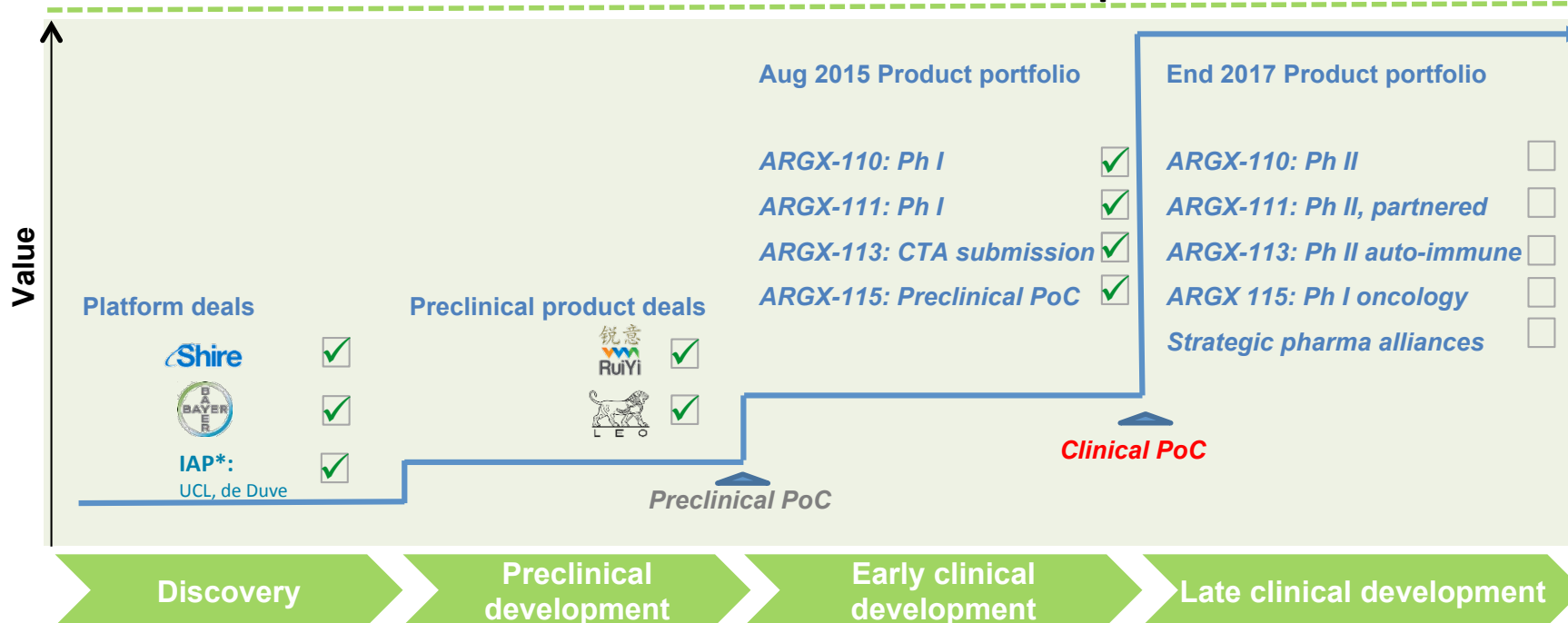
- Highly productive platform generates multiple leads
- SIMPLE Antibody™: llama immune systems cracks complex/novel targets
- NHance®, ABDEG™, POTELLIGENT® Fc engineering enables multiple MoA's
- IP protection until 2028-2032

Business model maximizing shareholder value

Generating differentiated antibody product candidates...



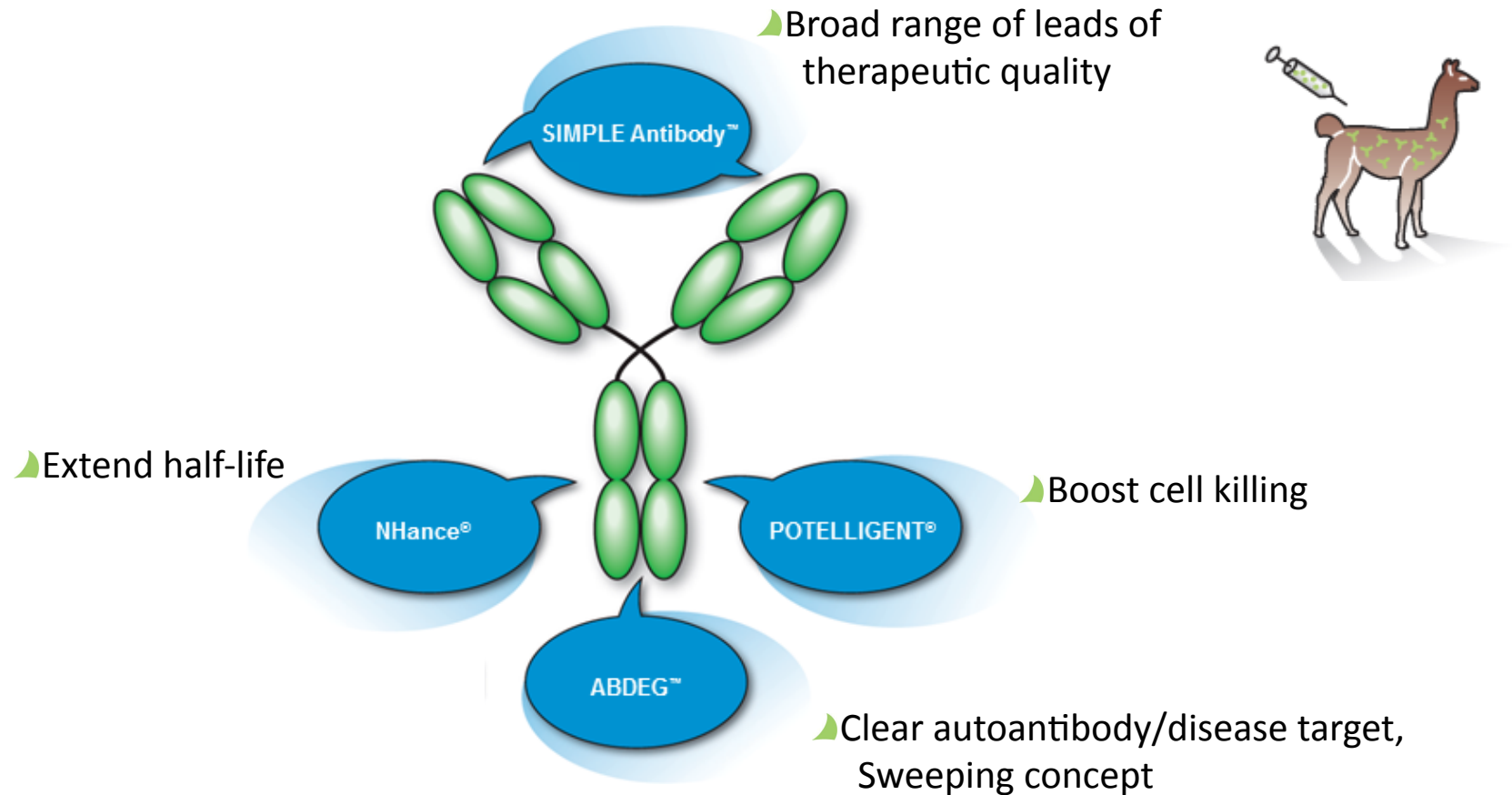
... towards Phase II value inflection point



* IAP: Innovative Access Program

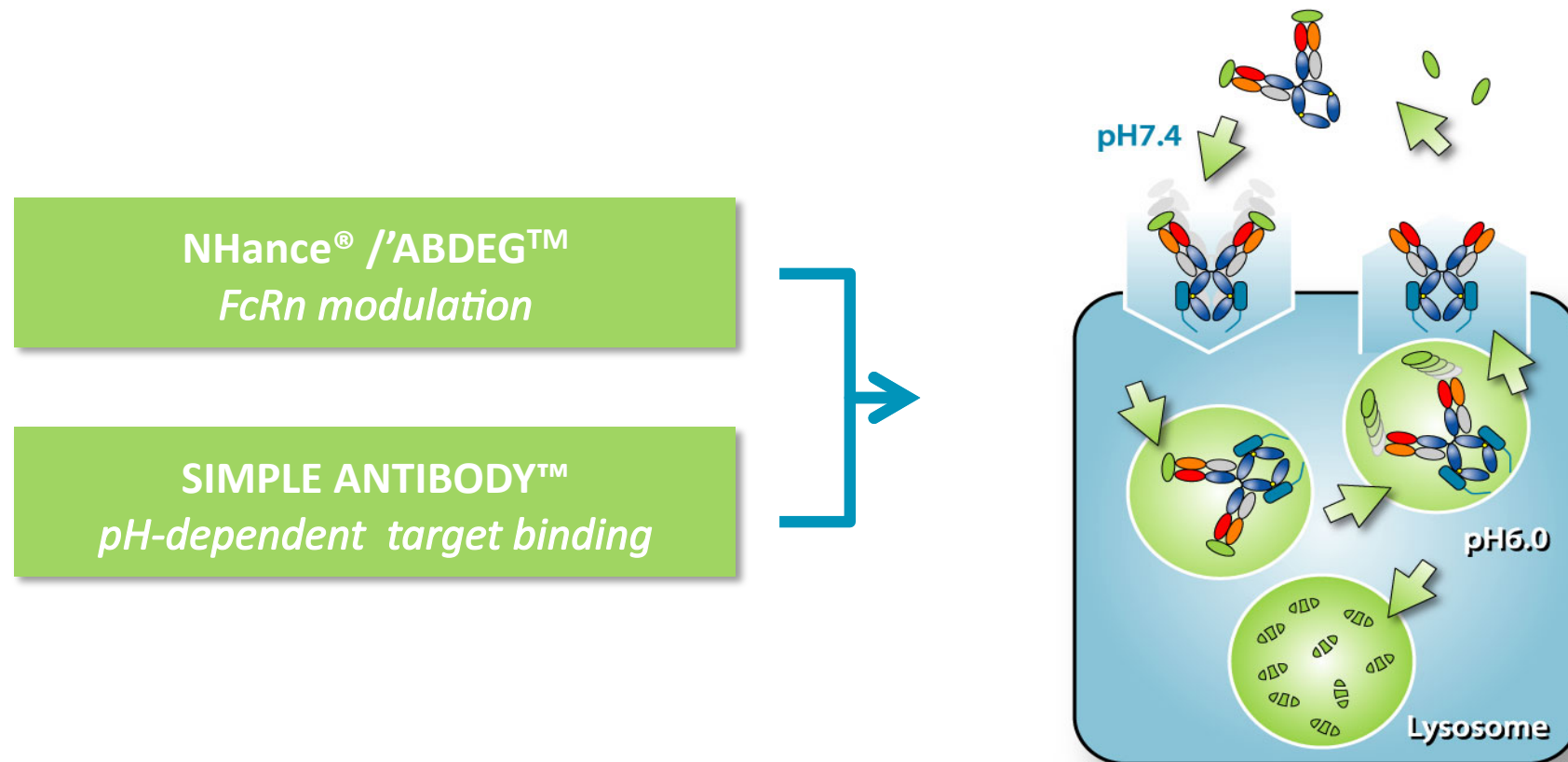
Highly productive discovery engine

Powerful technology suite: multiple modes of actions



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

Continuous technology innovation – antibody mediated target clearance







- Clinical potential for indications:
 - with high circulating target concentrations
 - which require fast target clearance
 - e.g. Inflammatory cytokines (receptors)

Recognized promise of proprietary technology suite

The strength of arGEN-X' technology suite is recognized by its partners



Rich pipeline approaching major value inflection points

Drug Candidate	Indication	Preclinical	Phase 1	Phase 1/2	Owner-ship	Next Milestone
ARGX-110 (CD70)	Heme malignancies <i>TCL</i>				Wholly owned	<input checked="" type="checkbox"/> ICML '15: TCL PhI/ results heme cohort
ARGX-110 (CD70)	Solid tumors					<input checked="" type="checkbox"/> Science Translational Medicine pub.
ARGX-110 (CD70)	Autoimmunity					<input type="checkbox"/> ASH '15: TCL clinical update; leukemia biology update
ARGX-111 (c-MET)	Solid tumors Heme malignancies					<input checked="" type="checkbox"/> ASCO '15: PhI dose escalation results <input checked="" type="checkbox"/> Cancer Research pub. <input type="checkbox"/> ASCO '16: PhI safety expansion update
ARGX-113 (FcRn)	Autoimmunity <i>Myasthenia gravis</i>					<input type="checkbox"/> CTA submission <input type="checkbox"/> Start first HV study
ARGX-115 (GARP)	Cancer immunotherapy					<input checked="" type="checkbox"/> Science Translational Medicine pub. <input type="checkbox"/> IBC '15: preclinical update
Discovery	Autoimmunity Cancer	multiple				
	Autoimmunity Cancer				Partnered	<input checked="" type="checkbox"/> IND submission
	Undisclosed					
	Chronic inflammation					<input type="checkbox"/> Preclinical milestone payments
	Undisclosed					

ARGX-110: Pioneering intervention in CD70 biology



First-in-class human mAb

- Targets CD70 involved in broad range of blood & solid tumors
- 3 modes of action:
 - SIMPLE Antibody™ : blocks tumor proliferation
 - POTELLIGENT®: elimination of tumor cells
 - Prevention of tumor immune escape
- Optionality in niche *and* major indications

Clinical activity & safety demonstrated

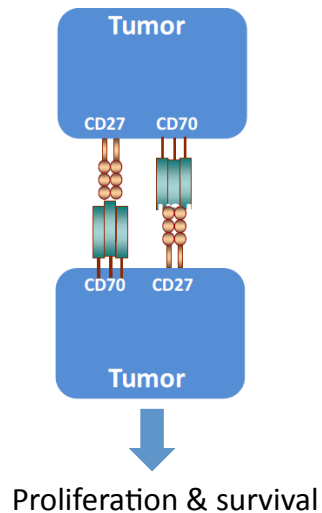
- Biological activity in 3/4 TCL patients in Ph 1
- PFS benefit in RCC, ovarian cancer, mesothelioma,...
- Outstanding safety profile
 - No dose-limiting tox, no auto-immune AE's
 - No impact on total B- and T-cells, IgG, IgM

Clinical development status

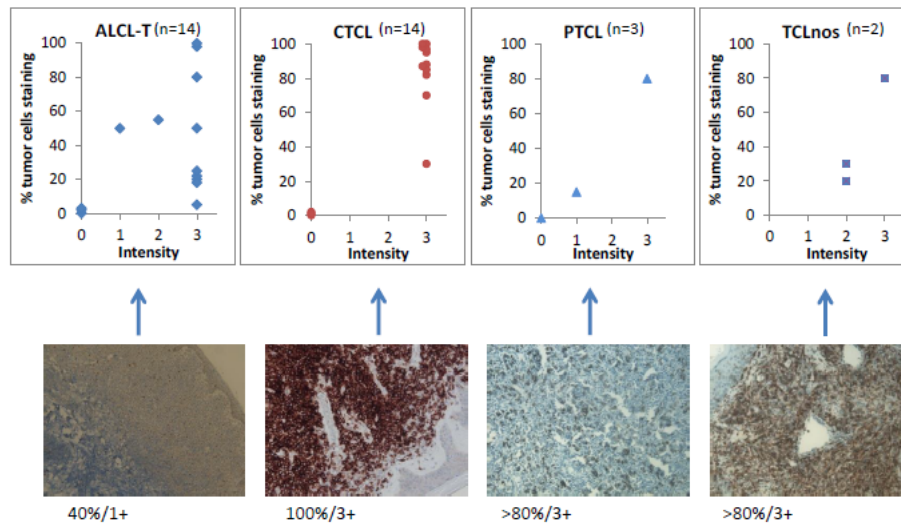
- Hematological tumors
 - T-Cell Lymphoma (TCL): Ph Ib safety expansion cohort - 4 clinics open
 - Leukemia (CML & AML): Preclinical PoC
- Solid tumors:
 - Nasopharyngeal Carcinoma (NPC) (cfr. EBV): Ph Ib safety expansion cohort – 4 patients enrolled

ARGX-110: CD70/sCD27 pathway highly relevant in TCL

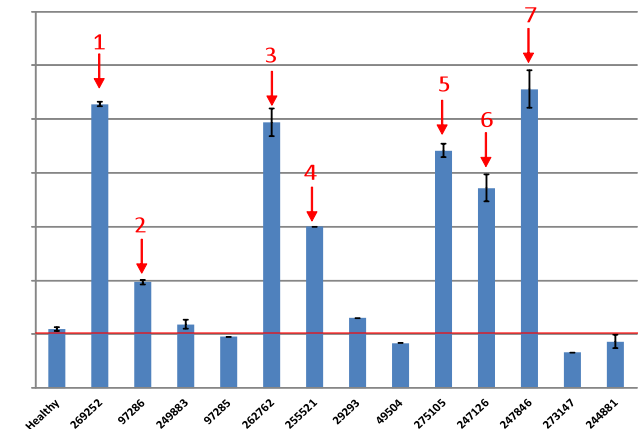
CD70/CD27 on tumor cells



IHC of CD70 expression in TCL biopsies



sCD27 levels in TCL patient sera

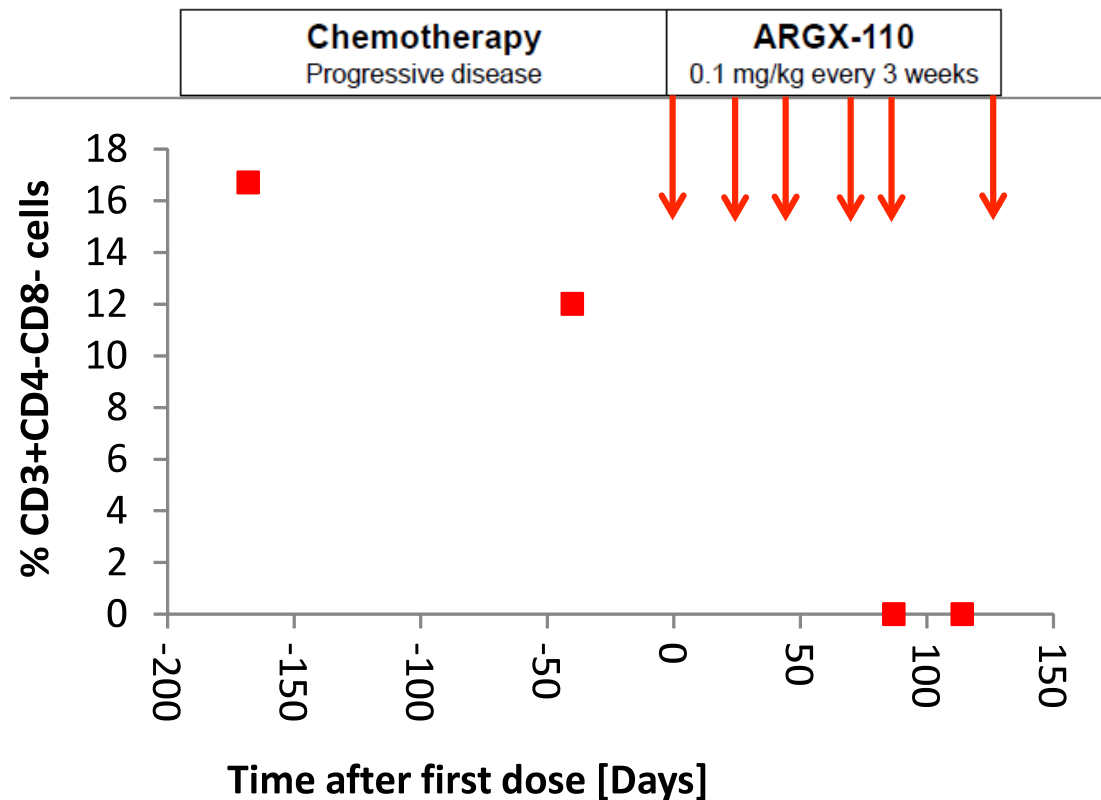


- CD70 strongly overexpressed across different TCL types
- Elevated sCD27 levels suggest strong pathway activity in TCL

ARGX-110: Proof of biological activity in 2 patients with CTCL Sézary-Syndrome (SS)

Blood compartment cleared from malignant cells (■)

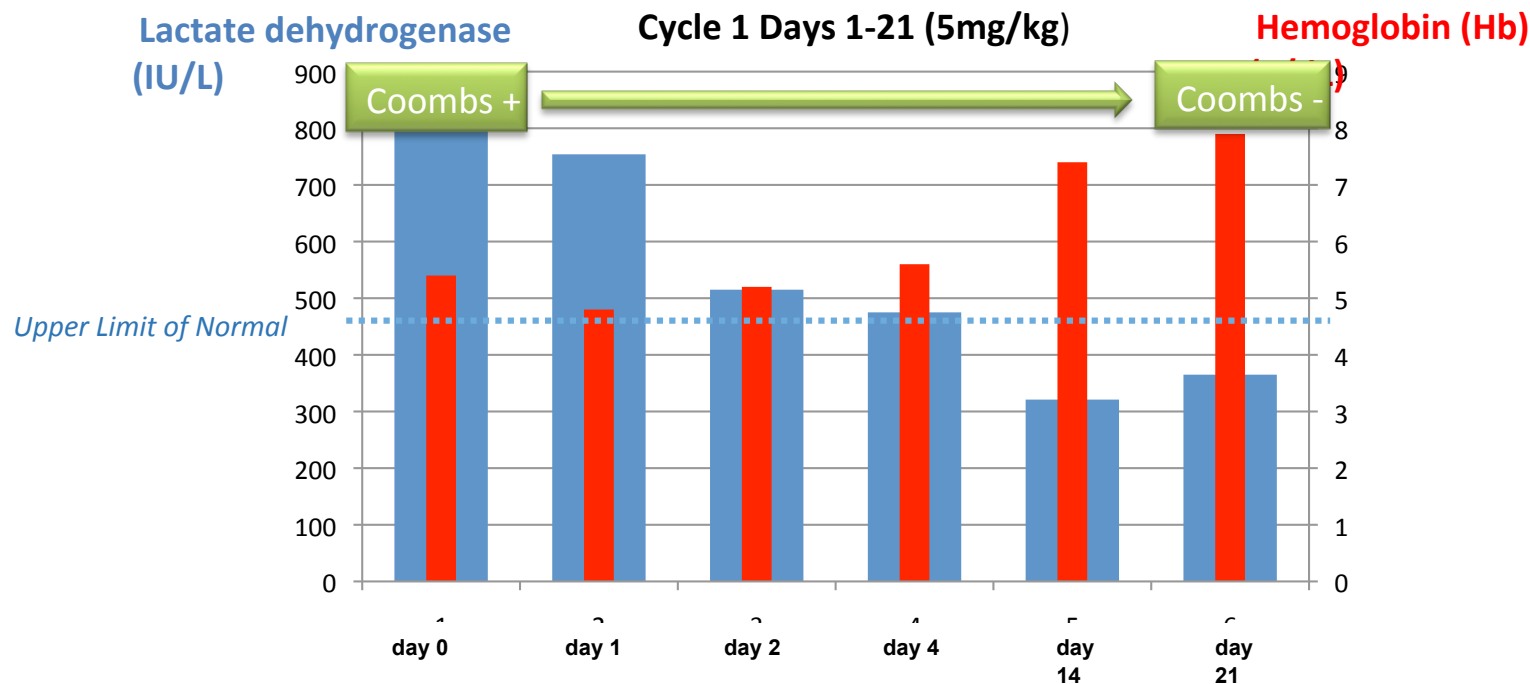
Stable disease in skin lesions



- 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 & lymph nodes
- Elimination of CD70 positive Sezary cells in 2nd CTCL-SS patient

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

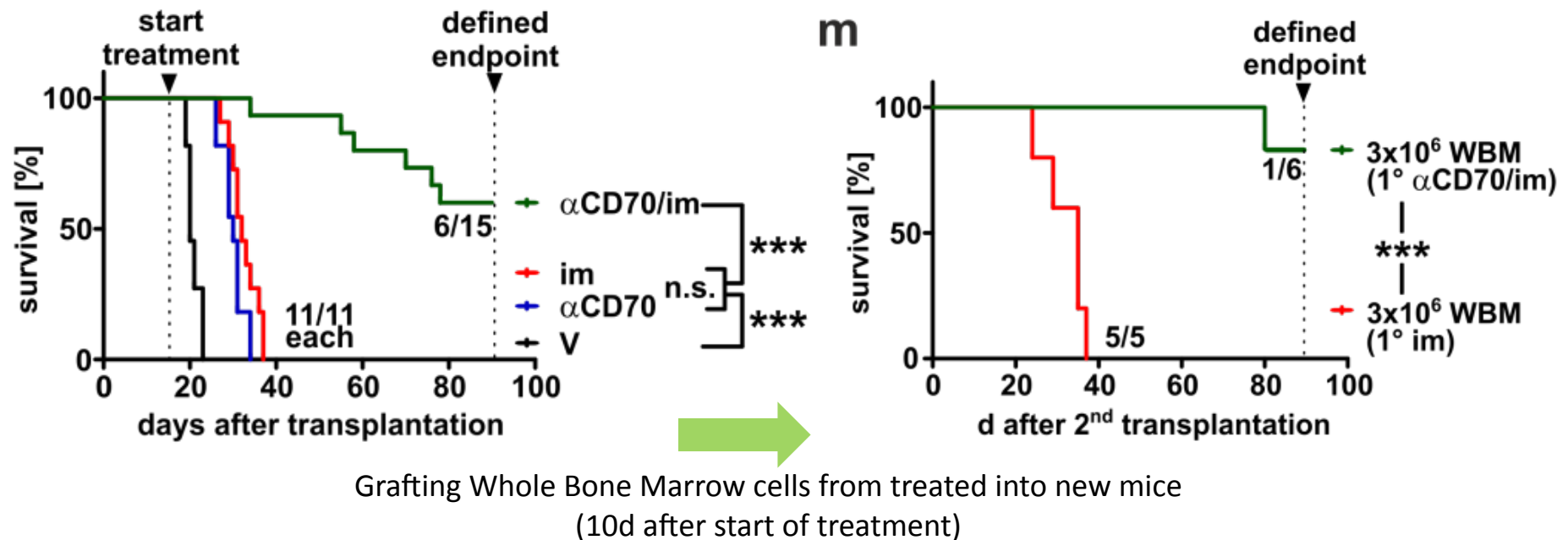
Normalized LDH and increased Hb



- 61 year-old male AITL patient showing elevated LDH and reduced Hb levels
- Refractory to chemotherapy (CHOP + Etoposide /Cyclosporine /Bendamustine - Transplant)
- After 2 doses of ARGX-110
 - LDH normalized to 365 & Hb increase to 7.9 without transfusion support
 - 16% reduction in tumor size by CT scan

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

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



- 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

ARGX-111: Superior intervention in c-Met biology



Best-in-class therapeutic antibody

- Targets c-Met driven metastasis
- 3 modes of action
 - SIMPLE Antibody™: blocks tumor proliferation
 - POTELLIGENT®: elimination of tumor cells
 - NHance® : increased tissue penetration
- Potential in major c-Met+ cancer indications
- Superior performance to MetMab in preclinical models
- Eliminating circulating tumor cells and blocking metastasis

Proof of biological activity

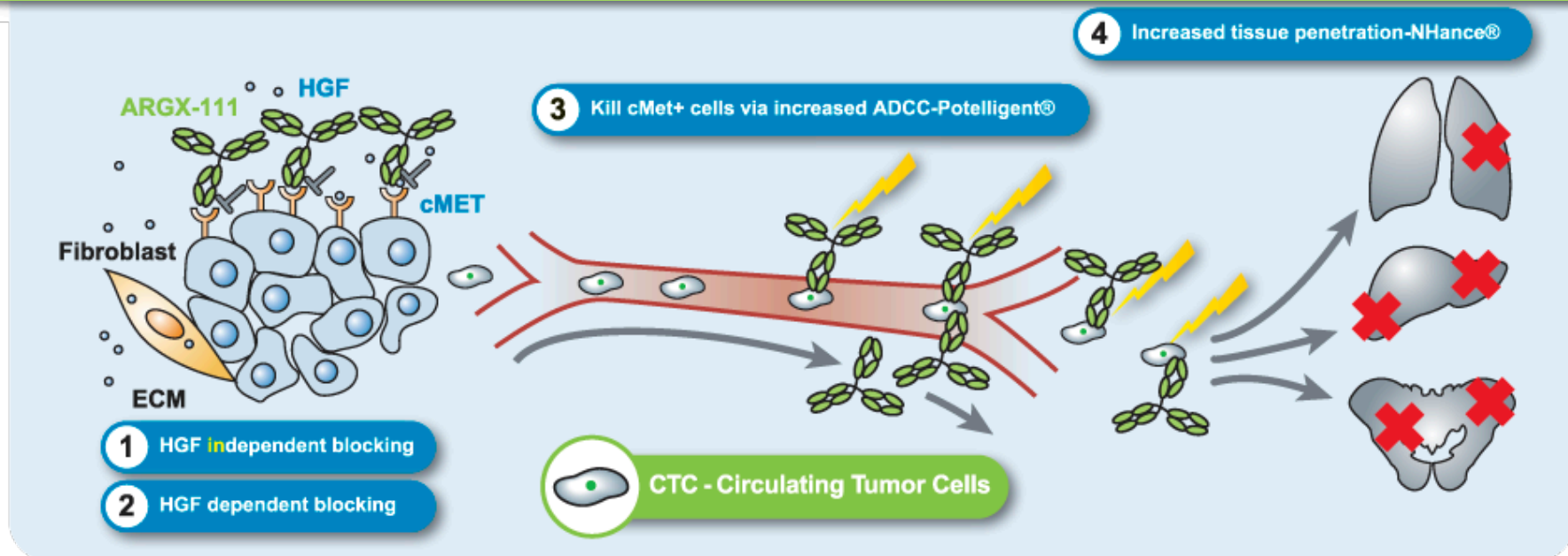
- Metabolic response (FDG-PET) in Met amplified, end-stage gastric cancer patient in Ph1
- Biological activity on bone metastasis and CTCs correlates with preclinical data

Clinical development status

- Ph Ib safety expansion cohort in Met amplified patients
- 4 clinics open

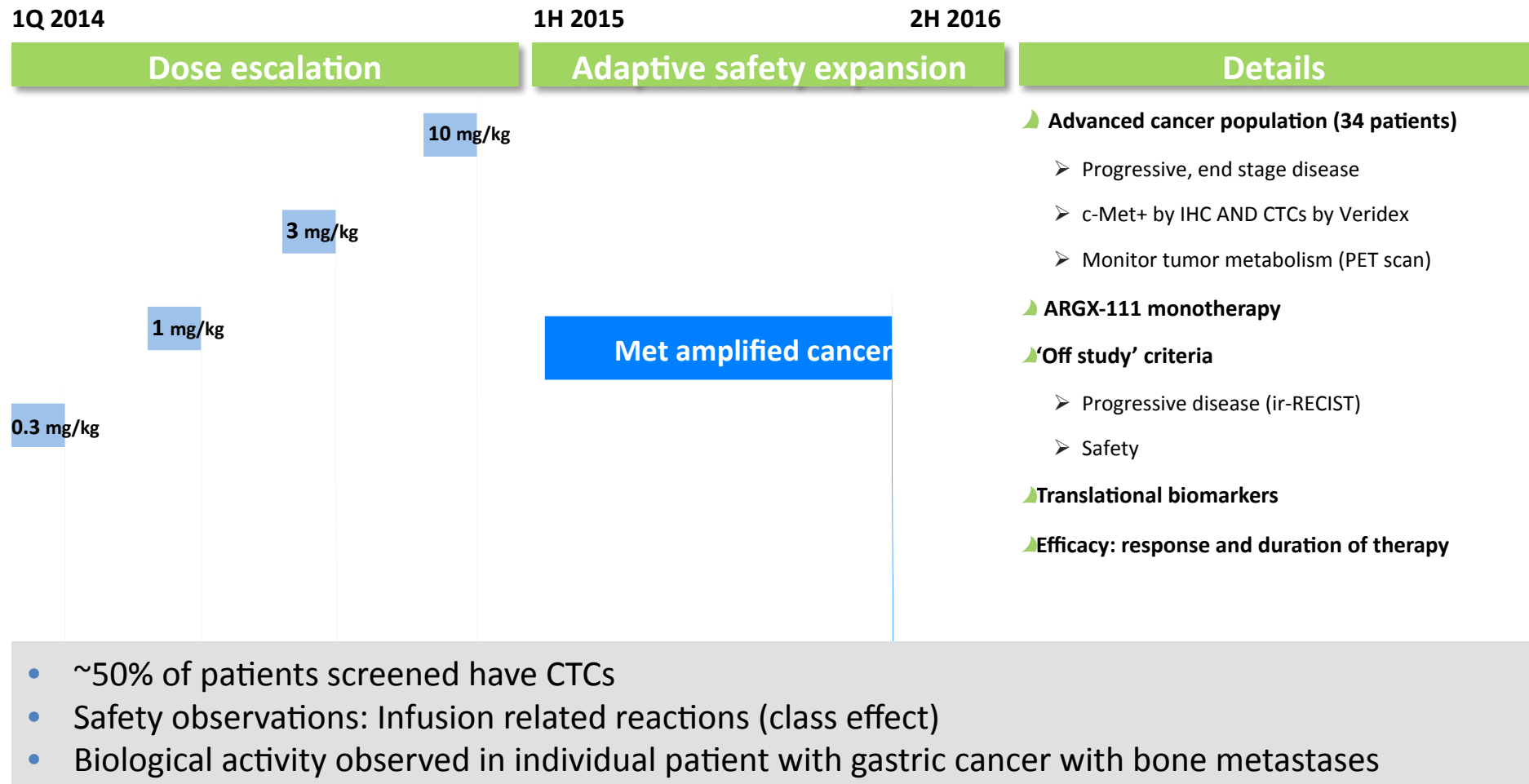
ARGX-111: Targeting MET positive tumors and CTC's

Different view on c-Met biology



- ARGX-111 has several distinct modes of action
 - HGF-dependent blocking
 - HGF-independent blocking
 - Killing MET expressing cells

ARGX-111: Phase 1 trial overview



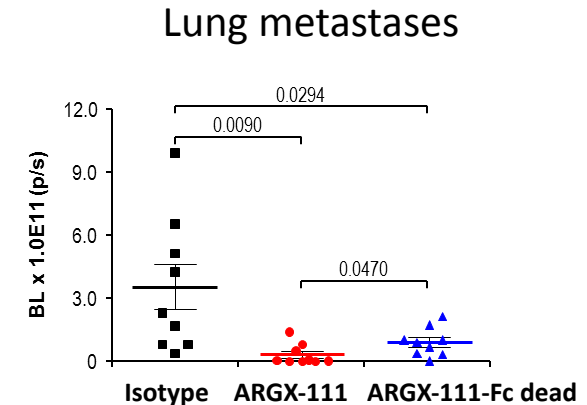
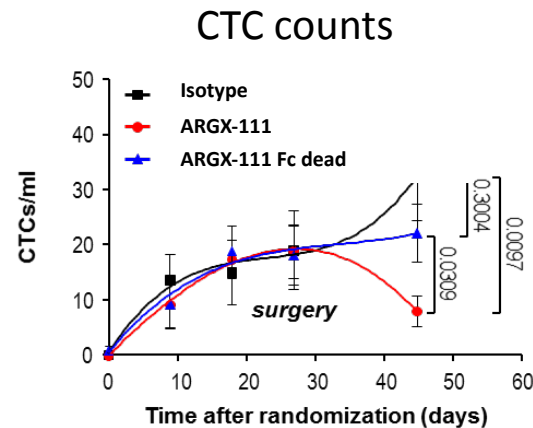
ARGX-111: Highly effective in preclinical models

neoadjuvant animal model

Treatment
(4 weeks, twice weekly, 5mg/kg)

Surgery

Autopsy

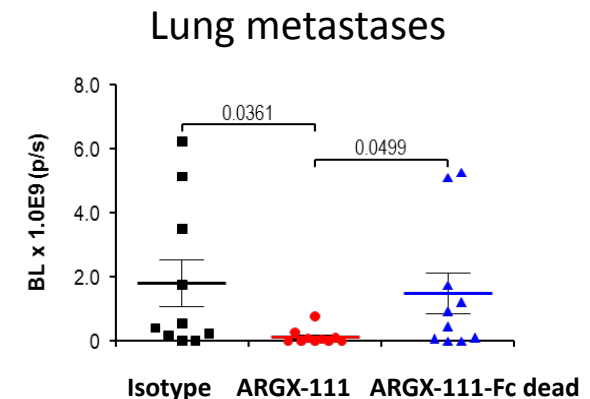
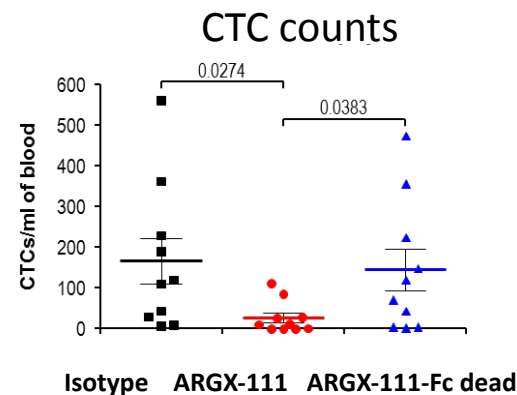


adjuvant animal model

Surgery

Treatment
(4 weeks, twice weekly, 5mg/kg)

Autopsy



- Blocks tumor spread and eliminates CTCs in metastatic breast cancer model

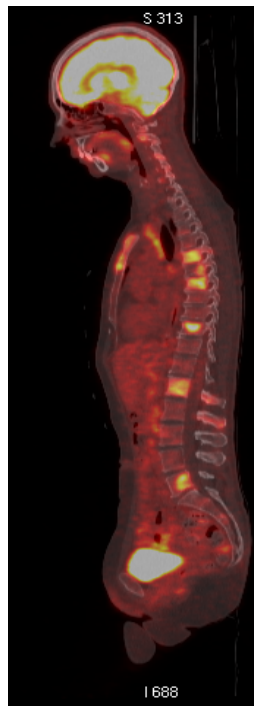
ARGX-111: Proof of biological activity in patient with gastric cancer

Background

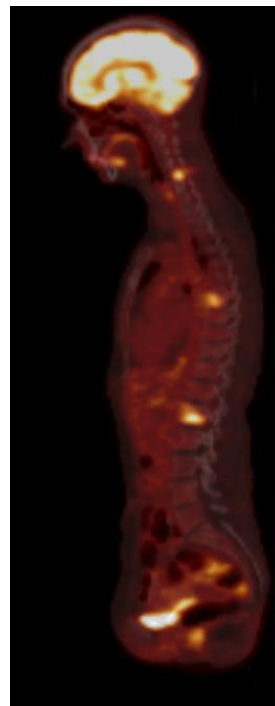
- 50 year old gastric cancer patient with bone metastases; Met amplified
- Multiple lines of previous treatment; including surgery and 2 lines of triplet chemotherapy
- FDG-PET scan observation of biological activity (see right) confirmed on repeat imaging; CTCs reduced by 75%
- Good performance (clinical) status maintained throughout treatment period

Biological activity

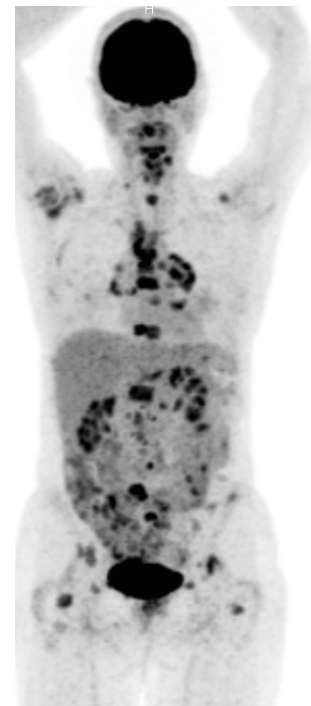
Baseline PET scan



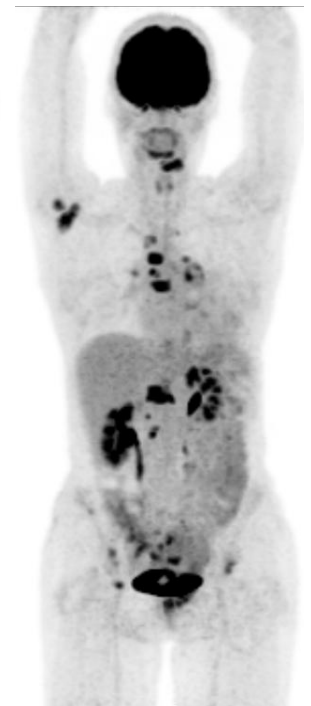
Improvement after 4 doses



Baseline PET scan

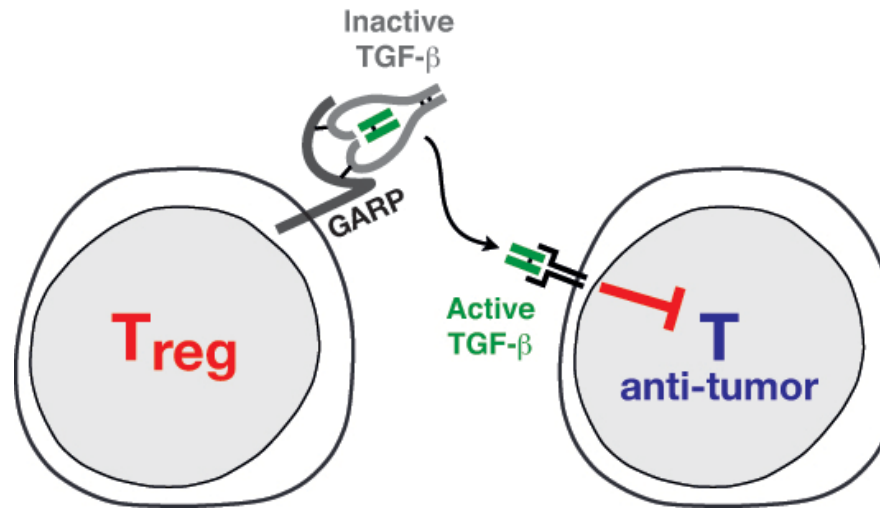


Improvement after 4 doses



ARGX-115: Towards a next generation Yervoy®

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 model delivered convincing PoC



Cuende et al., 2015, Science Translational Medicine

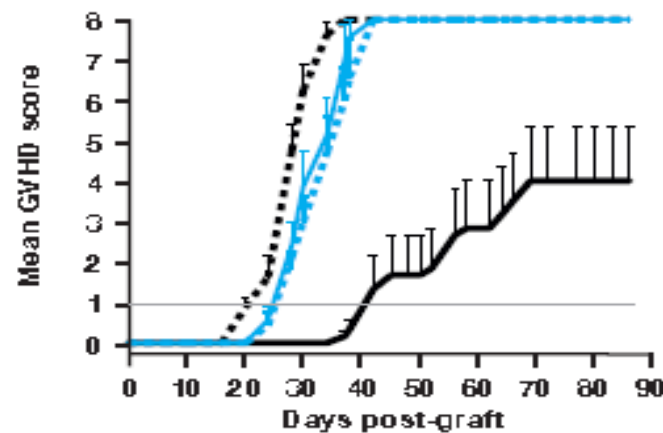
ARGX-115: Towards a next generation Yervoy®

In vivo efficacy of anti-GARP-TGF β 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



- PBMCs
- PBMCs + Tregs
- PBMCs + Tregs + LHG-10.6
- PBMCs + Tregs + LHG-10.6_{N297Q}



Cuende et al., 2015, Science Translational Medicine

ARGX-113: Generic therapeutic for auto-immune flares



First-in-class therapeutic antibody fragment

- Breakthrough management of autoantibody-induced flares
- Targets FcRn involved in IgG recycling
- Uses ABDEG™ technology to rapidly clear pathogenic autoantibodies
- Applicable to niche *and* major indications

Preclinical proof of concept & safety

- Highly effective in preclinical models of RA, MS, MG, Pemphigus,...
- Safe profile expected (individuals with loss-of-function mutations in FcRn)
- Pharmacology study shows IgM and IgA levels unaffected

Clinical development – upcoming milestones

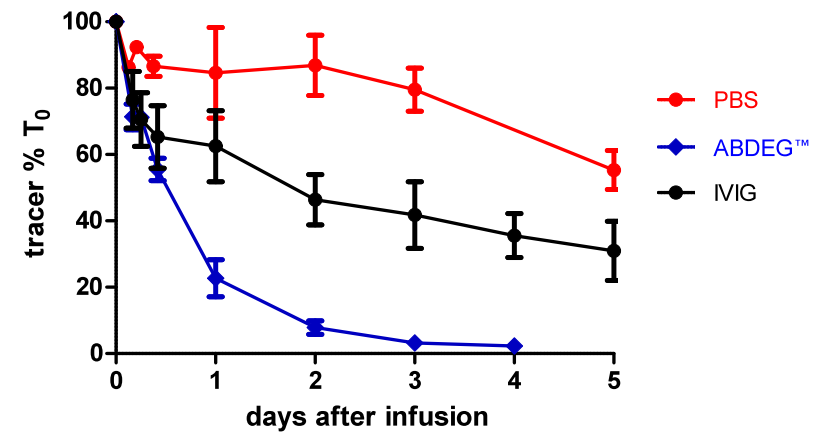
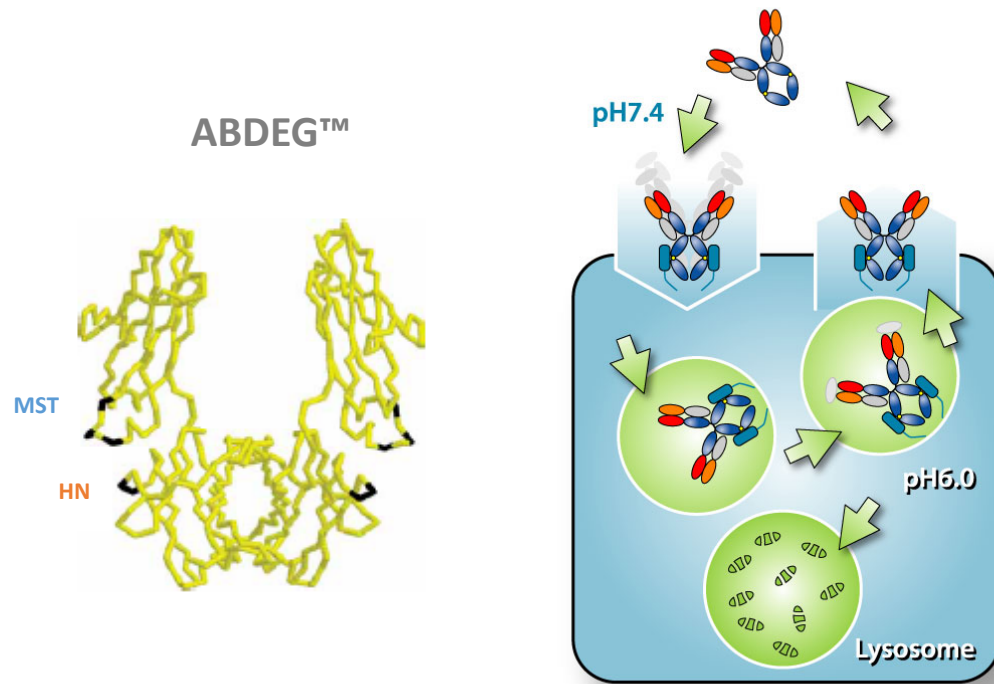
- CTA submitted
- Start first healthy volunteer study
- Single Ascending Dose and Multiple Ascending Dose study

ARGX-113: How it works

Proprietary Fc mutations

Block IgG recycling

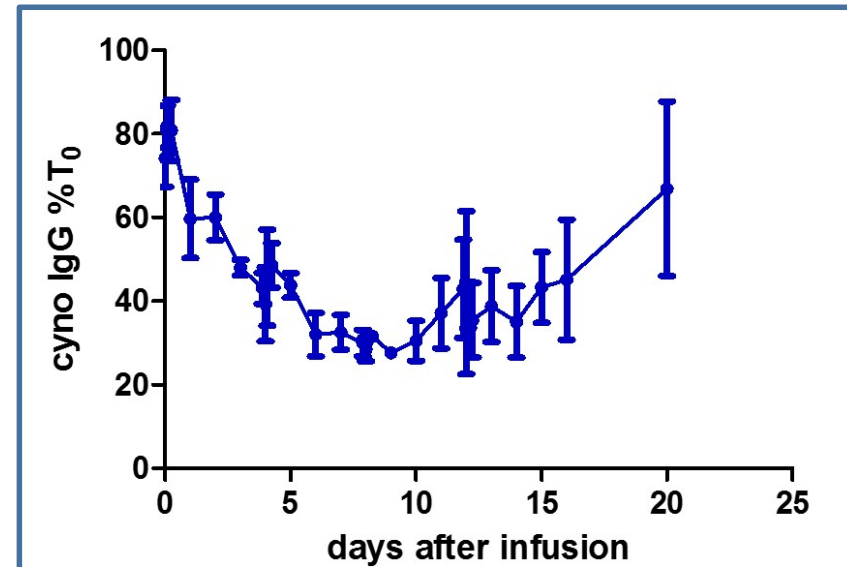
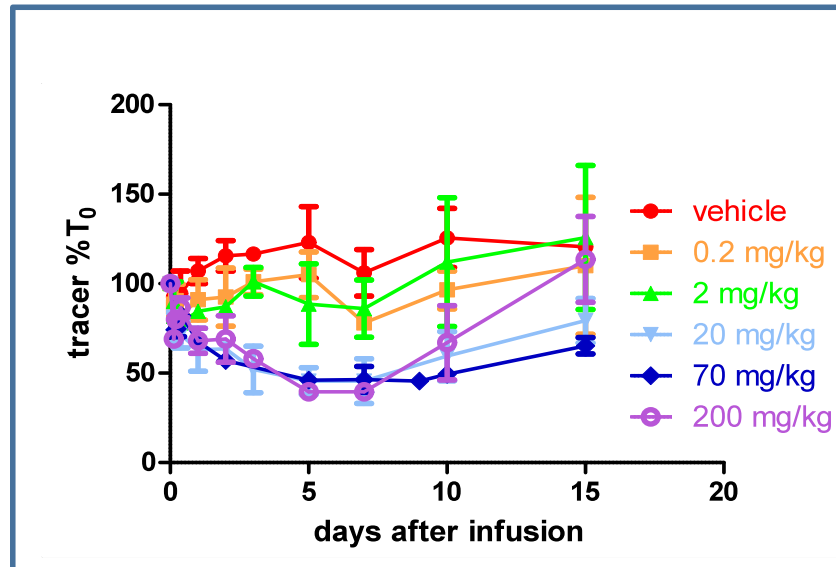
Resulting in rapid auto-antibody clearance



Vacaro and Ward, 2005, Nature Biotech

ARGX-113: Antibody clearance capacity

Therapeutic effect – Cynomolgus monkey model



- Treatments: 0.2 mg/kg ; 2 mg/kg; 20 mg/kg and 200 mg/kg
- Saturation of PD effect on endogenous IgG levels at doses ≤ 20 mg/kg
- Repeated dose ARGX-113 > single dose

Clinical rationale for targeting autoantibody clearance

Myasthenia gravis autoantibody levels and disease score following therapy

Treatment*	Plasmapheresis	Immunoadsorption	IVIG
Decrease in antibody levels (%) after treatment	62.2 ± 6.3	55.1 ± 3.2	28.9 ± 3.8
Decrease in disease score (%) after treatment	60.8 ± 3.5	42.4 ± 4.2	23.8 ± 3.7
Clinical efficacy rate after 14 days**	12/15	7/10	6/15
Duration of hospital stay (days)	12.8 ± 0.28	13.5 ± 0.50	16.0 ± 0.50

* Comparison between 3 cycles of Plasmapheresis/Immunoadsorption every 24h-48h and 5 cycles of IVIG every 24h

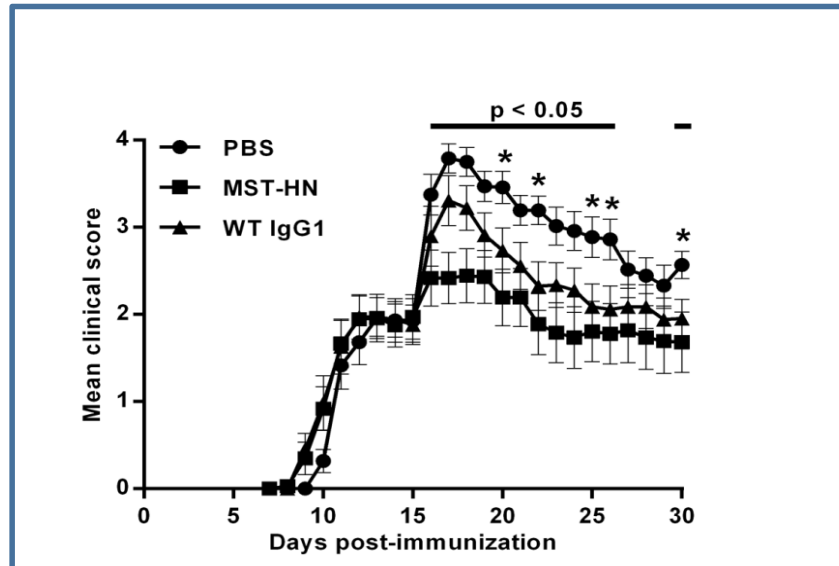
(Liu et al, 2009)

** Clinical effective if disease score has improved by >50% 14 days after treatment

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

ARGX-113: ABDEG™ in vivo PoC

EAE model



Challa et al. mAbs 2013

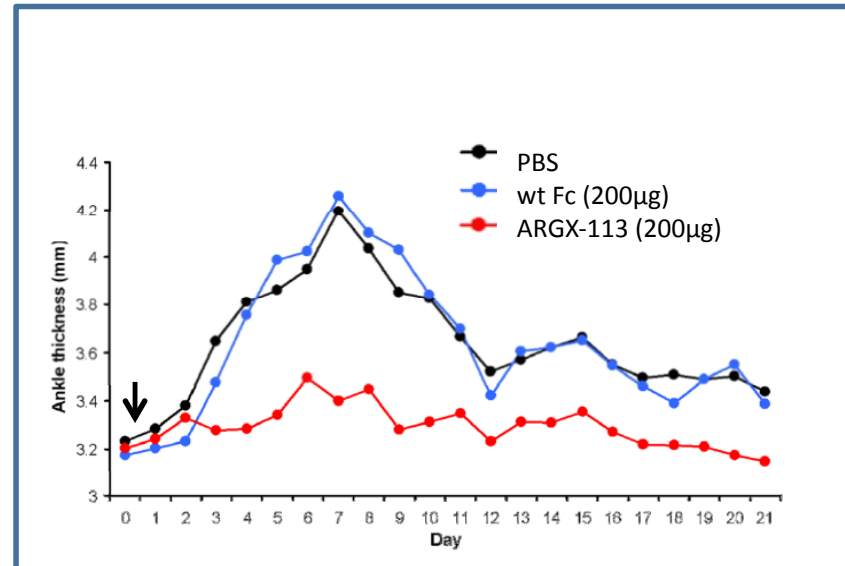
- Injection of encephalitogenic peptide followed by demyelinating mAb (8–18C5) at day 15 induces EAE
- ABDEG™ administration leads to a rapid amelioration of EAE and inhibits autoantibody accumulation in CNS (data not shown)

EAE: Experimental Autoimmune Encephalomyelitis



Challa et al., 2013, mAbs

RA model

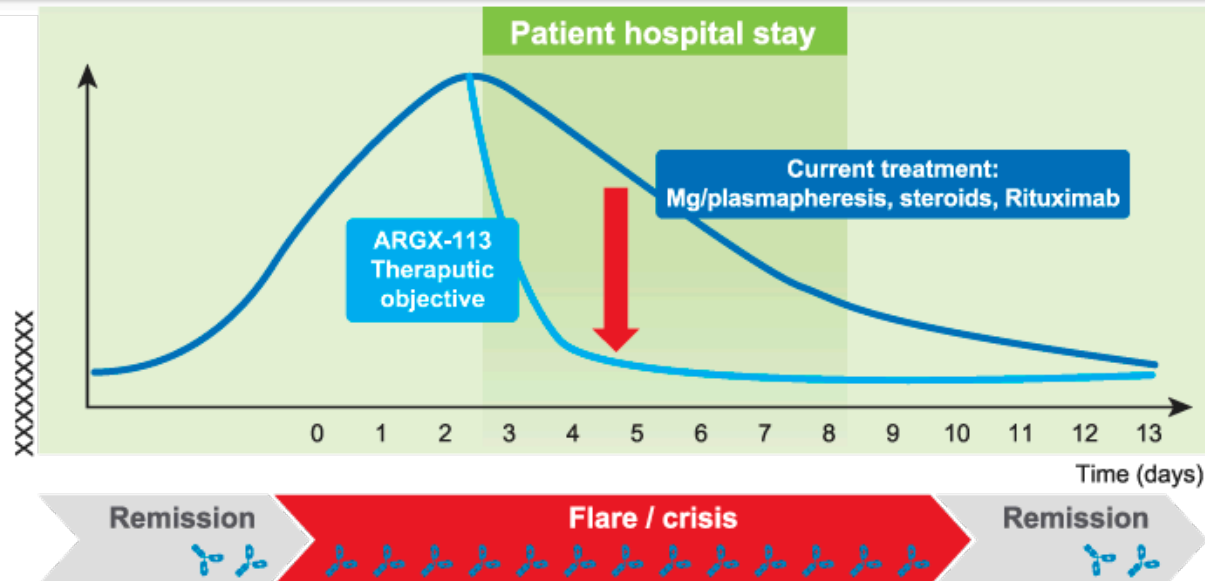


Ward et al. unpublished data

- Injection of arthritogenic serum causes ankle swelling in BALB/c mice
- Single injection of ABDEG™ (whole IgG1 or Fc-fragment) effective in preventing disease progression

ARGX-113: Optionality in niche and major indications

ARGX-113 can address acute autoimmune flares more effectively than IVIG or Plasmapheresis



Indications		Market potential
	Prevalence (per 100,000 US)	
Orphan indications		<ul style="list-style-type: none"> • IVIG annual sales exceed \$4B (autoimmune diseases approximately 50%) • Benlysta® sells for \$35K per year, IVIg and plasmapheresis are \$79K and \$ 101K per cycle • Xolair® annual sales exceed \$800 mio
• <i>Skin blistering diseases</i>	18	
• <i>Myastenia gravis</i>	20-50	
Large indications		
• <i>Lupus</i>	80-100	
• <i>Multiple sclerosis</i>	~90	

Products protected by multiple layers of IP

Technology Platforms: **SIMPLE Antibody™ platform + one or more Fc engineering platform**

- Broad composition of matter and process claims
- Granted claims in US, UK and Israel
- Pending claims in US, EU, other major territories

Product and methods of use patents: **ARGX-110, ARGX-111, ARGX-113, ARGX-109 specific**

- Both specific and broad composition of matter claims and method of use claims
- Granted US claims for ARGX-110, ARGX-111, ARGX-113
- Pending claims in EU, other major territories

Patents currently expected to expire in **2028-2033 window**

- ARGX-110 and ARGX-111 core patents eligible for up to five years of Patent Term Extension

Under our industrial partnerships, **only non-exclusive licenses have been granted to our technology platforms**

Building partnerships for the long term

► Strategic Alliances



- Non-exclusive product discovery and development, leveraging entire technology suite
- Upfront funding, R&D support, development milestones, royalties, product reversion rights

► Collaboration Agreements



- Non-exclusive discovery collaborations, applying SIMPLE Antibody™ to complex targets
- Technology access fees, R&D support, milestones, royalties

► Innovative Access Program



Unnamed Biotech

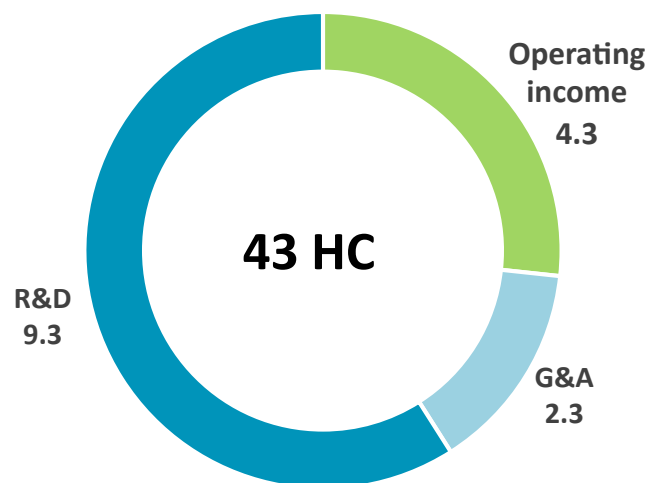
- Non-exclusive access to antibody technologies for academic and biotech centers of excellence
- Creative deal structures including option to acquire asset, golden share,...

- €19.3 million in cumulative revenue (2Q15)
- >€1.4B* potential cumulative revenues from existing partnerships

* Assuming specific development and sales milestones are met for all potential discovery targets

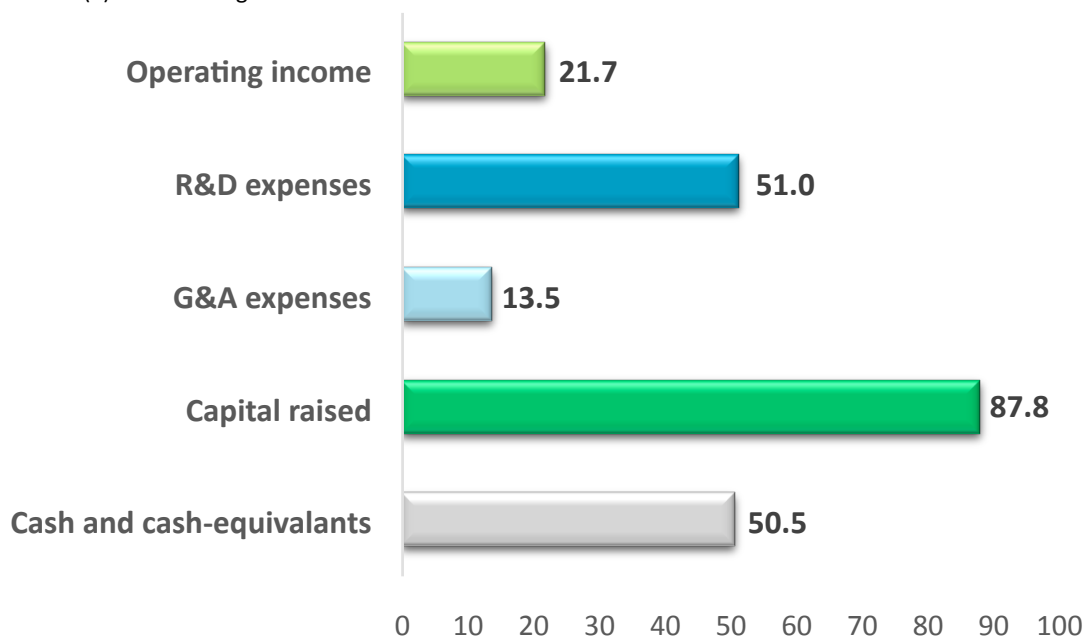
Well capitalized to execute strategic plan

Operating income and expenses (MEUR) 2Q15



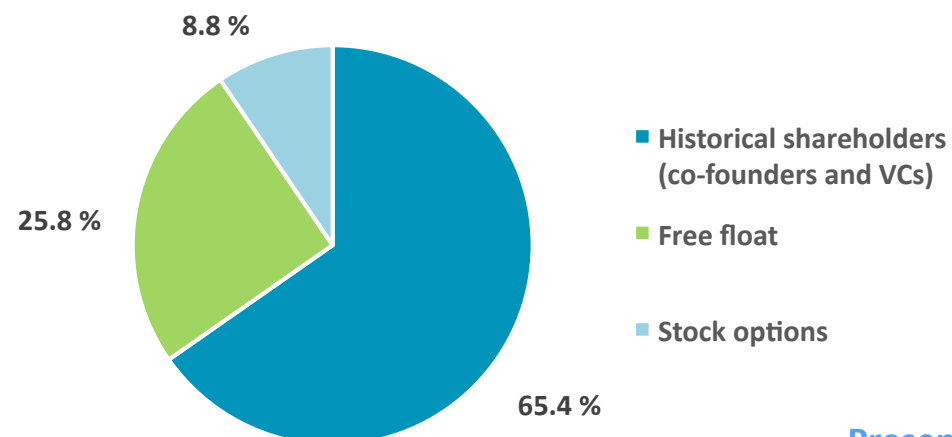
Operating income, expenses and capital raised since inception (MEUR) 2Q15 (*)

(*) not including deferred revenue and accruals



Shareholder structure

Fully diluted





Creating innovative antibodies for cancer & auto-immune diseases

Petercam Benelux Conference, London
23 September 2015