




innate pharma

IPH 1101-202 results
June 2010



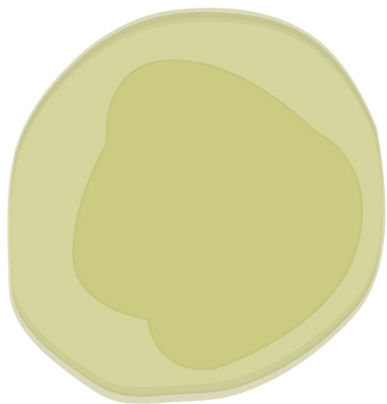
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IPH1101-202

Final results - Response Rate

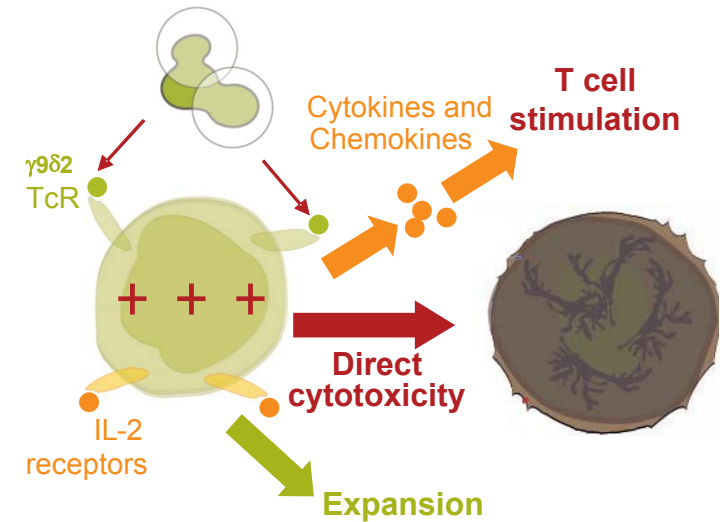


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IPH 1101

Overview

Compound class:	Small molecule (NCE)
Target / Mechanism of action:	Agonist of $\gamma\delta 2$ T-cells
Indications in development:	Follicular Lymphoma and Type C viral Hepatitis
Development status:	Phase II POC data in HCV reported POC data in NHL reported



- Immune modulator, first molecule to specifically target $\gamma\delta$ T-cells
- Long patent life providing market exclusivity
- First drug candidate of the Company
 - 10 years R&D, 200 patients treated, 6 clinical trials

IPH 1101-202

A PHASE I/II STUDY OF IPH 1101, GAMMA DELTA T CELL AGONIST, IN COMBINATION WITH RITUXIMAB RE-TREATMENT, IN PATIENTS WITH LOW GRADE FOLLICULAR LYMPHOMA

EHA, Barcelona, 13th June 2010

Jean-François Rossi MD PhD
INSERM U847 and Haematology Department
University Hospital Montpellier, FRANCE

Disclosures

- Honorarium from Innate Pharma, France

Immune therapy in FL

Vaccination

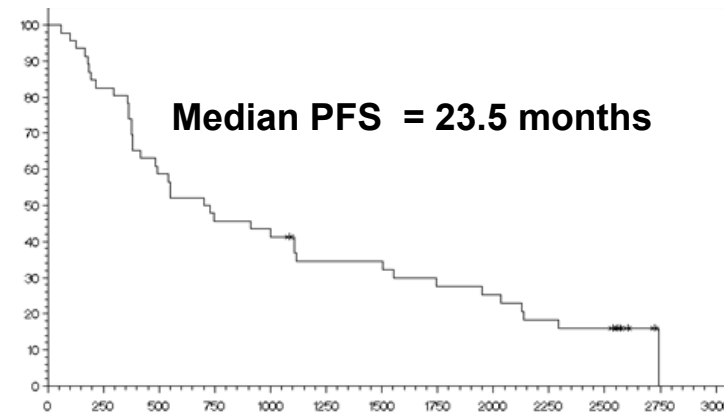
Levy R 1996-2008, Di Nicola 2008, Rossi JF 2007

Anti CD20: Rituximab alone

In relapse (11% CR)

In front-line therapy (28% CR)

GOELAMS study, Colombat Ph, ASH 2006



Need to amplify the activity of rituximab

+ chemo

Amplifying ADCC

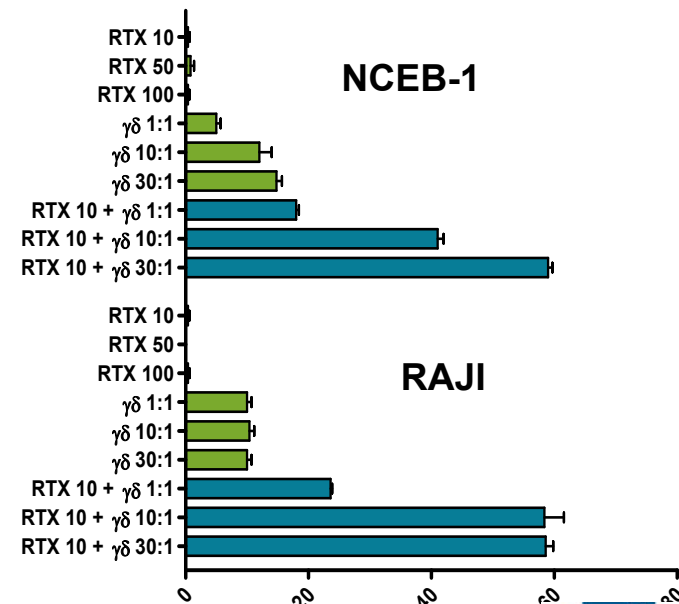
+ GM-CSF *in vivo*

Cartron G, Rossi JF JCO 2008

3rd generation anti-CD20 (GA101, LFB R603)

→ Targeting Tγδ (phosphoAgs *in vitro*)

J. Gertner-Dardenne, 2008, Blood



Why stimulate V γ 9V δ 2 T Cells ?

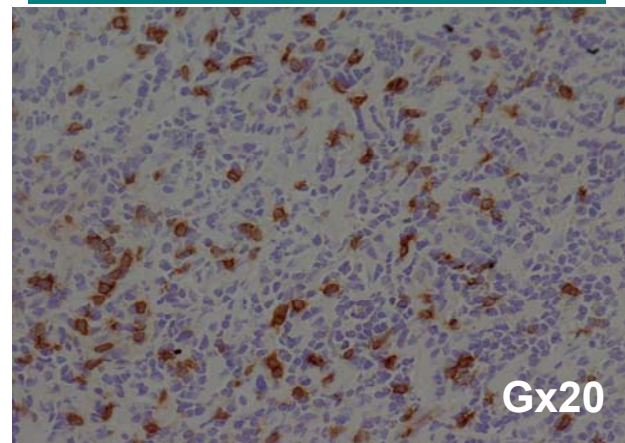
- V γ 9V δ 2 T cells are specialized innate immunity lymphocytes
- V γ 9V δ 2 T cells represent 1 to 5% of circulating mononuclear cells
- V γ 9V δ 2 T cells can be expanded and activated by phosphoantigens (PAG)
 - natural phosphoantigens produced by the cholesterol pathway
 - bi-phosphonates
 - IPH1101 (BrHPP) a synthetic analog of phosphoantigen
- IPH 1101 activated V γ 9 T cells kill potently tumoral B-cells (NHL and MM)
 - including cell lines derived from Follicular lymphoma (FL): e.g. RL or Karpas-222

Fournié JJ 2009 and Lu ZY, 2008

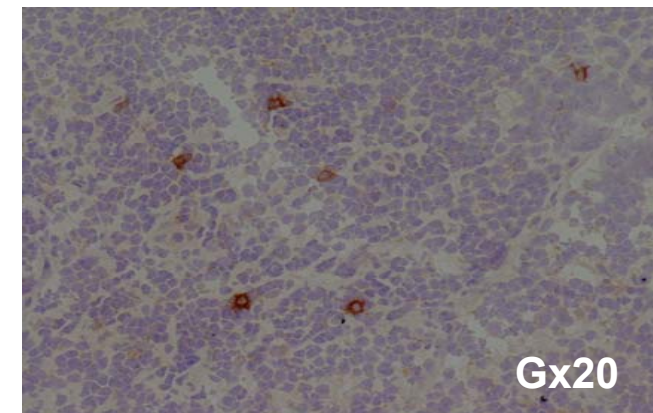
$\gamma\delta$ are rare cells in FL but present in inflammatory LN and chemokines modulate their trafficking

$T\gamma\delta$ (CCR7+)

Inflammatory Lymph Node



Follicular lymphoma



Chemokines

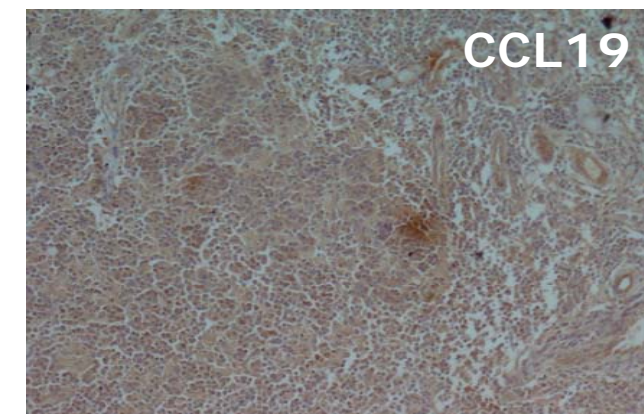
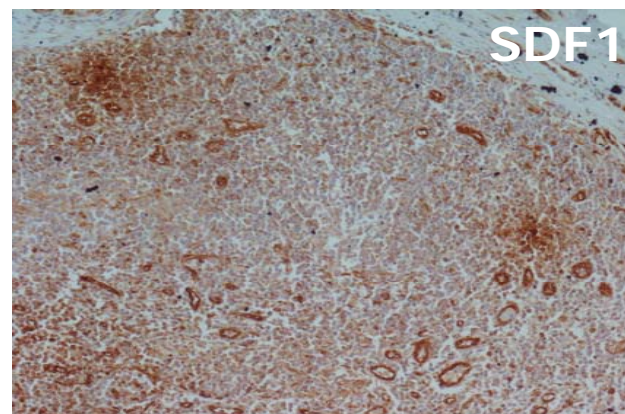
T-cell homeostasia

SLC/CCL21

ELC/CCL19

Inflammatory

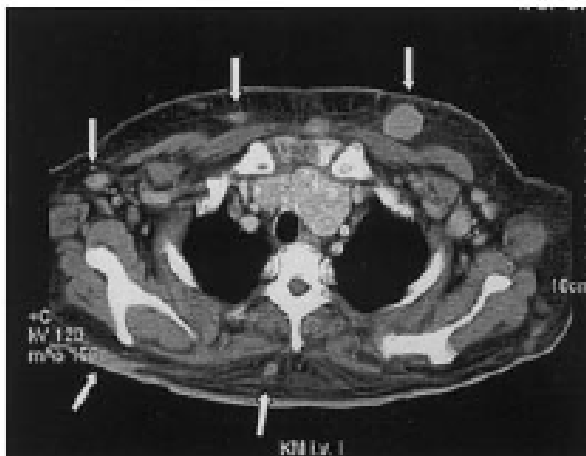
BCA/CXCL13



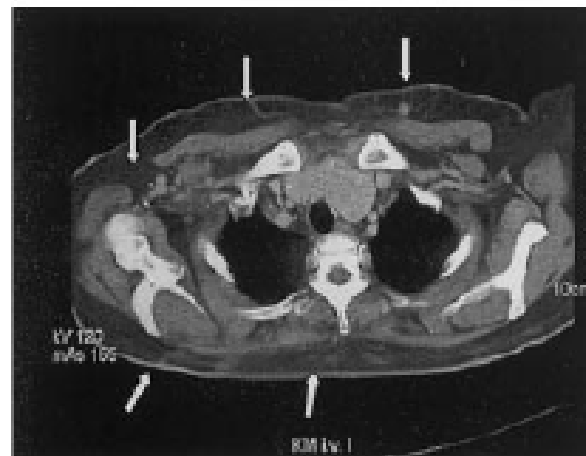
M Braza, JF Rossi, *ASH 2008 and J Immunol 2009*

Results of the 1st Phase I immunotherapy targeting $\gamma\delta$ cells with pamidronate + IL-2 in FL and MM

Before treatment



After 2 months



Correlation between $\gamma\delta$ *in vivo* Proliferation and clinical response

Objective response	In vivo $\gamma\delta$ T-cell proliferation		Σ
	+	-	
+	3	0	3
-	2	13	15
Σ	5	13	18

Wilhelm et al. , *Blood*, 2003

IPH1101 combined with rituximab Phase IIa study in relapsing Follicular Lymphoma

- **Main inclusion criteria**

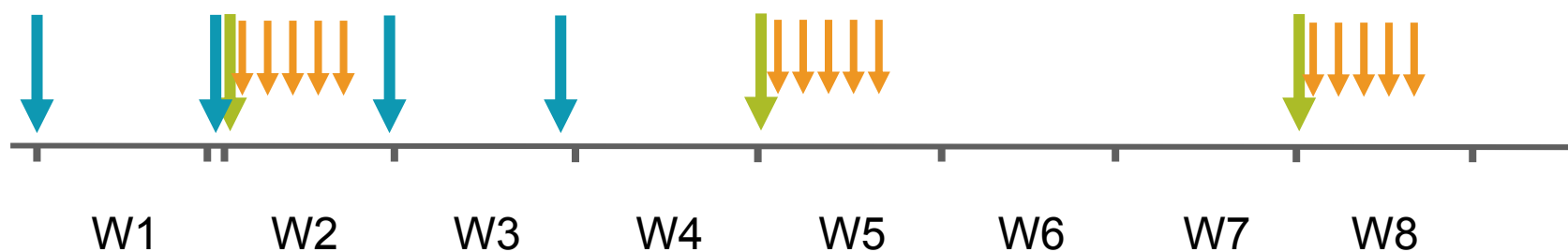
- Age > 18 and ≤ 75 years
- FL of histological grade 1 or 2 WHO
- Progressing after 1 to 4 previous lines of treatment
- Including at least one line of rituximab-based treatment
- Low tumor burden
 - ECOG should be ≤ 1
 - Tumor should be ≤ 7 cm
 - LDH should be ≤ ULN (or 2 ULN if absence of transformation documented)
 - Pleural or mesenteric effusions were excluded

- **Primary objective**

- Objective Response Rate (ORR) during the 6 months of the treatment

Treatment Schedule

- **Rituximab: 375 mg/m² (4 times, weekly)**
- **IPH1101: 750 mg/m² (3 times, every 3 weeks)**
- **IL-2: 8 M IU (daily for 5 days, every 3 weeks)**



Study Population

- 45 patients treated
- 45 patients analysed for demography, safety and biological activity
- 38 patients evaluable for overall response efficacy, with disease status confirmed by **independent central review** at 6 months
- 7 non evaluable patients

Study Population, Characteristics (1)

On 45 patients

Age	Median Range > 50 years old	59 39-74 78%
Sex (M/F)	20/25	
ECOG* * Scale of disease severity. The higher the ECOG, the poorer the prognosis	0 1 to 4	91% 9%
FLIPI* * Follicular Lymphoma International Prognostic Index, correlated with tumor burden. The higher, the poorer	Low Intermediate High (Poor)	47% 27% 27%
Prior lines of treatment	One line Two to four lines	53% 47%
Mediastinal or intra abdominal involvement* * Deep ganglions involvement: marker of severity of the disease	Yes No	69% 31%
Median time since last treatment	19 months	

Efficacy evaluation – Final data

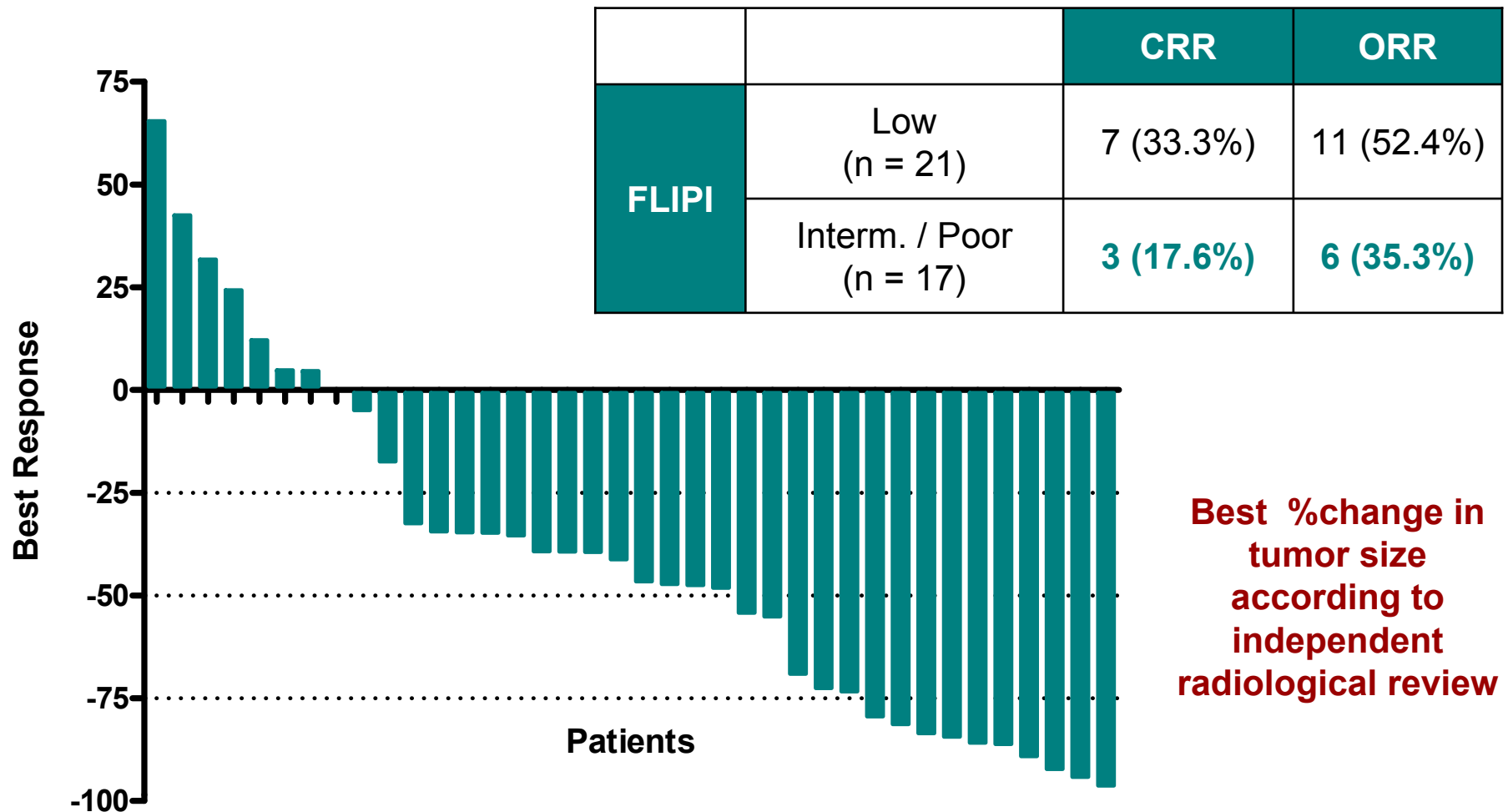
On 38 patients evaluable for clinical efficacy, best response at 3 or 6 months

	Local Investigator N (%)	Independent Medical Review N (%)
CR/CRu	7 (3/4) (18.4%)	10 (8/2) (26.3%)
PR	13 (34.2%)	7 (18.4%)
SD	15 (39.4%)	18 (47.4%)
PD	3 (7.9%)	3 (2.9%)
ORR	20 (52.6%)	17 (44.7%)

Work in progress on:

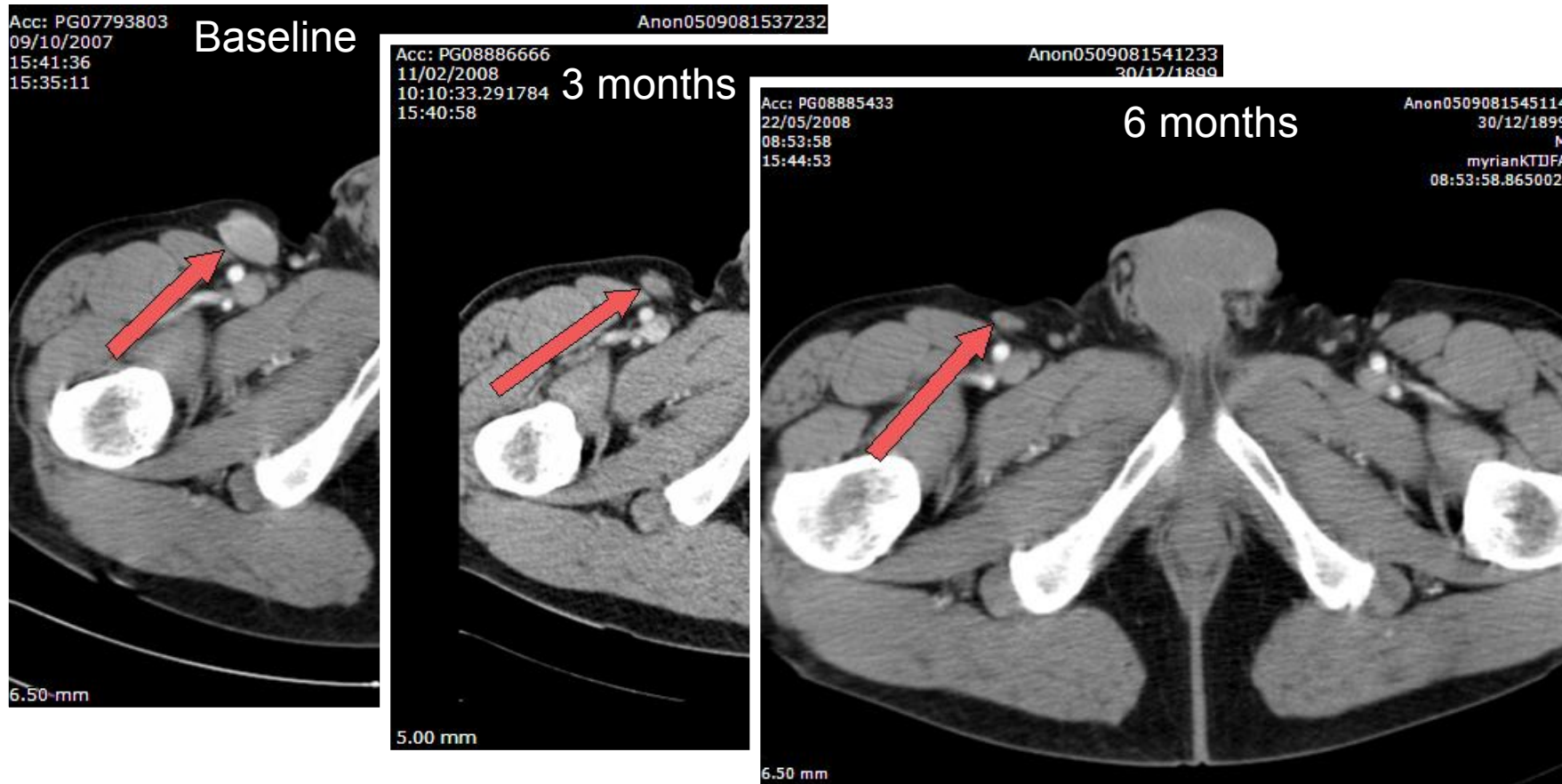
- Calculation of duration of response;
- Comparable efficacy on historical data from a matched cohort

Response by FLIPI and Representation of Quantitative Efficacy Data



Efficacy, Example

Patient 010701JMB, Complete Response



Age 55, High LDH, Low FLIPI,
treated with R 20 months before (best response PR).

Safety - Related Adverse Events

Most frequent AEs: Constitutional and Gastro-Intestinal symptoms

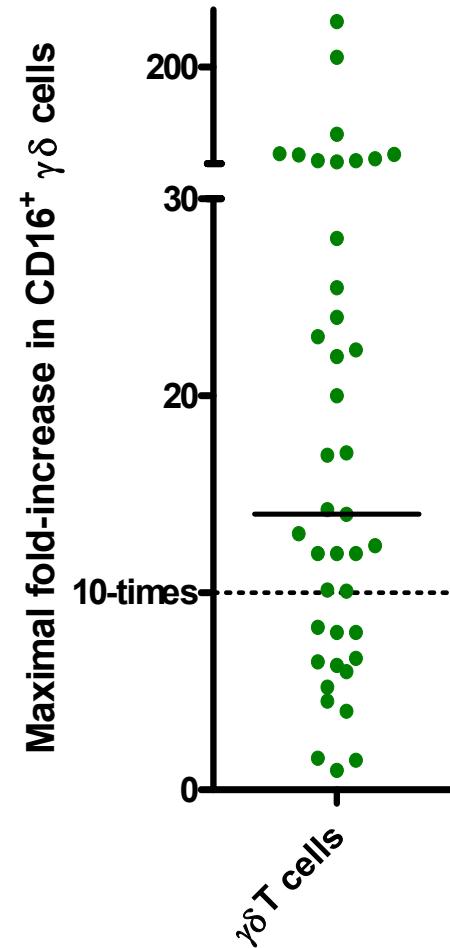
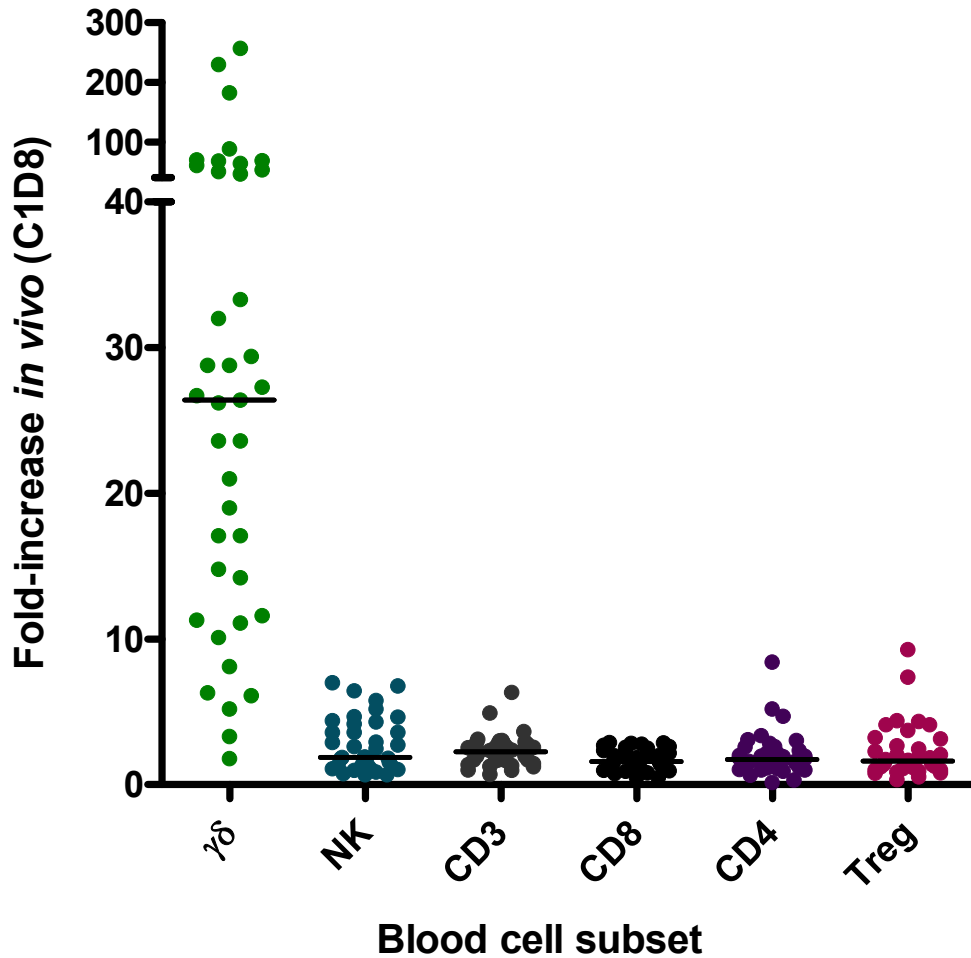
AE term	Grades 1 & 2	3 & 4
	per patient	per patient
	N=45	N=45
Pyrexia	33 (75.6%)	3 (6.7%)
Nausea	28 (62.2%)	-
Injection site reaction	26 (57.8%)	-
Vomiting	24 (53.3%)	1 (2.2%)
Chills	22 (48.9%)	1 (2.2%)
Fatigue	19 (42.2%)	2 (4.4%)
Diarrhea	16 (35.6%)	1 (2.2%)
Hypotension	14 (31.1%)	3 (6.7%)
Headache	13 (28.9%)	-

Safety - Related SAEs

On 45 patients

	N	Recovered ?	Evaluable for efficacy ?
G4 Back Pain	1	Yes	Yes
G4 Diarrhoea	1	Yes	Yes
G4 Hypotension	1	Yes	Yes
G3 Hypotension	1	Yes	Yes
G3 ALAT elevation	1	Yes	Yes
G3 Pyrexia	1	Yes	Yes
G3 Asthenia	1	Yes	Yes
G3 Bronchospasm	1	Yes	Yes
G2 Glomerular filtration decrease	1	No	Yes

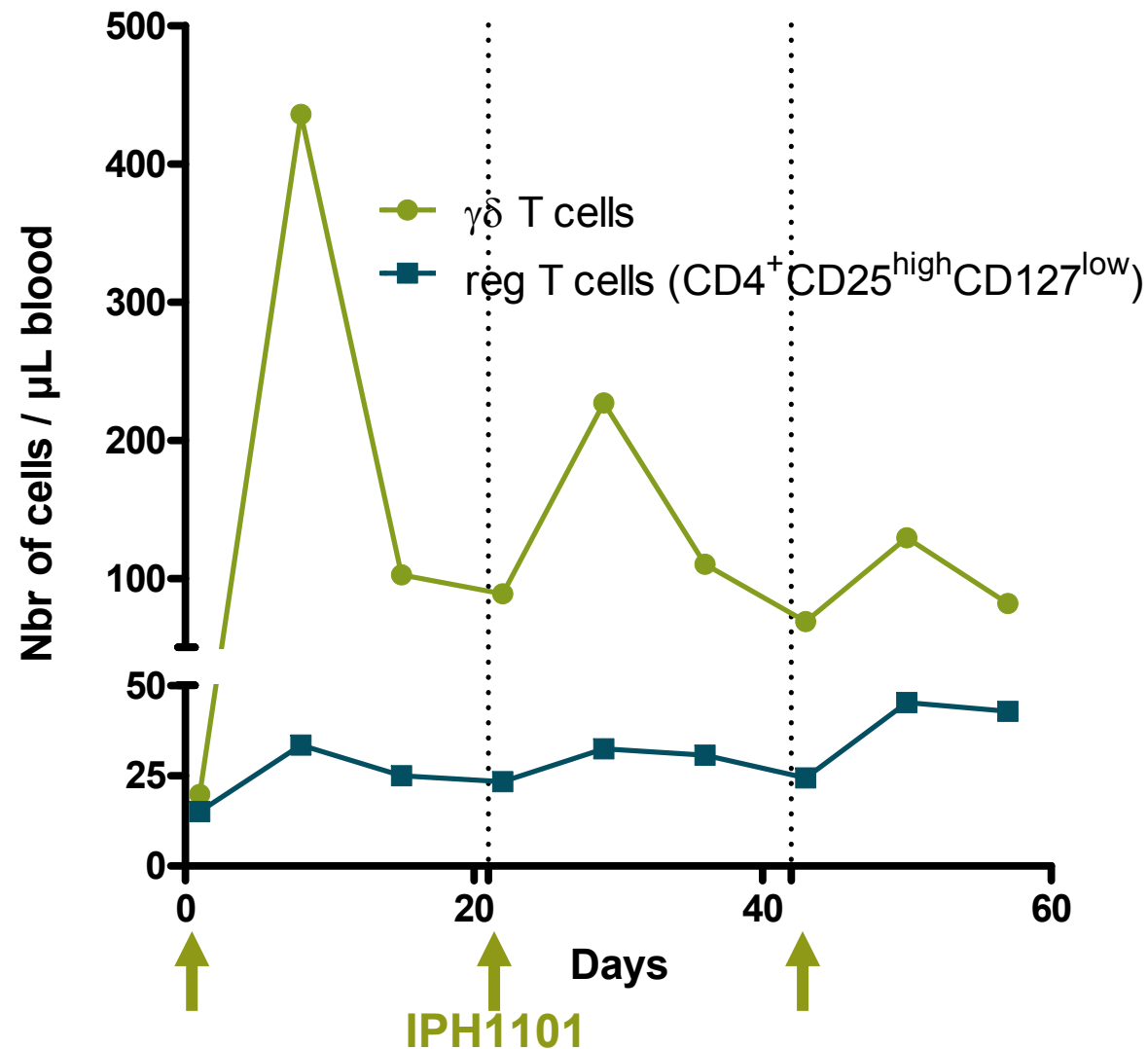
Selective amplification of targeted CD16+ $\gamma\delta$ T cells



CD16+ $\gamma\delta$ T cells

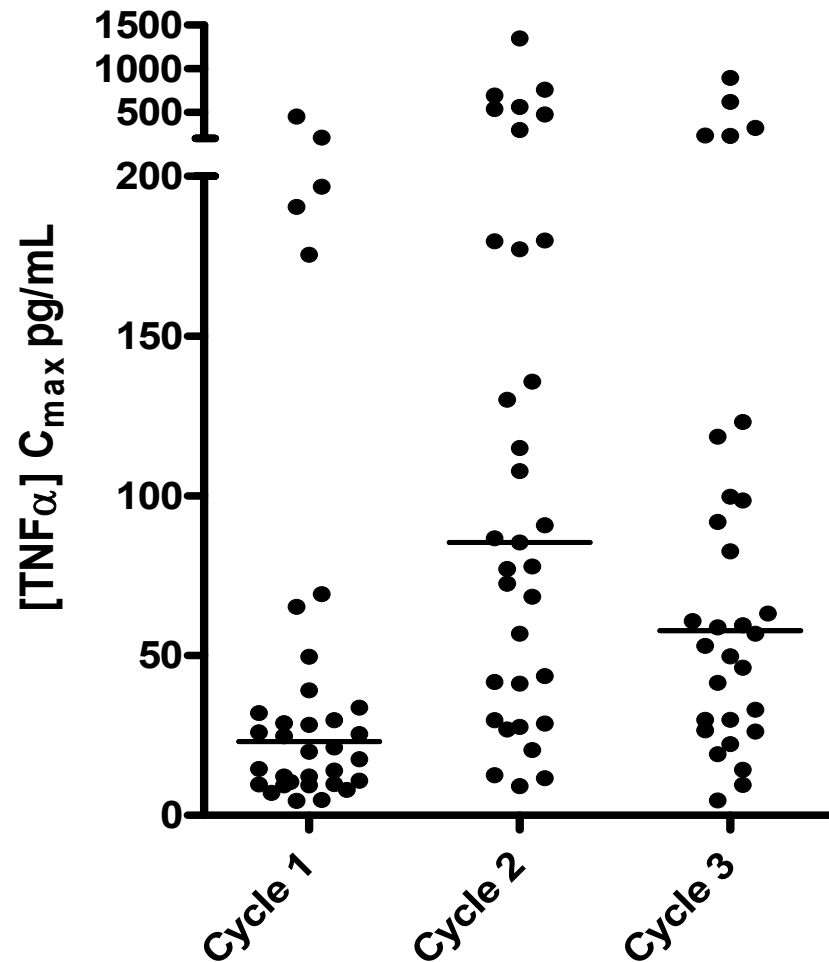
On 39 patients

Mean curves of $\gamma\delta$ T cells *versus* Tregs

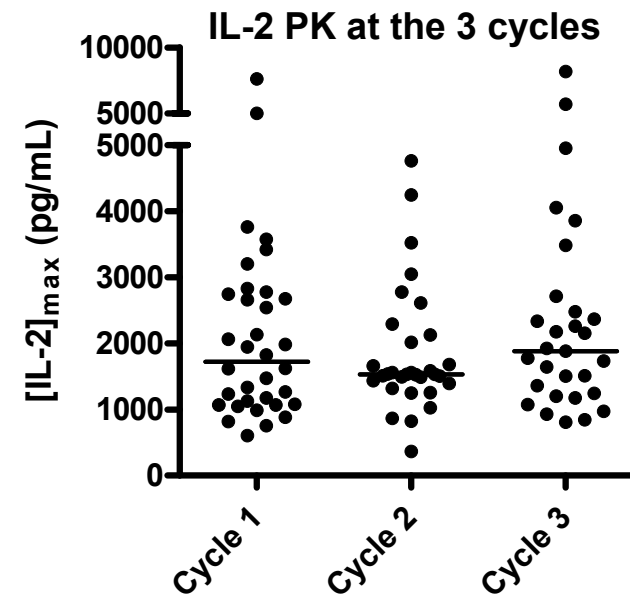


Pharmacodynamics - Features of cytokine release

TNF- α as representative example



**In vivo release of cytokines is maximal
after the 2nd and the third
administrations of IPH1101**



Response according to FcRγIIIa genotype

- FcRγIIIa Polymorphism, on 36 patients:

FcRγ3a Polymorphism * "F-carriers" are less likely to respond to rituximab alone	V/V	2 (5.6%)
	V/F and F/F	34 (94.4%, ow 19 F/F)

- On 32 patients evaluable for both Genotyping and Efficacy:

	CR/CRu	PR	SD	PD
F/F	6 (33.3%)	2 (11.1%)	9 (50%)	1 (5.6%)
V/F	4 (33.3%)	2 (16.7%)	4 (33.3%)	2 (16.7%)
V/V	0	2	0	0

33.3% CR and 46.7% ORR in F-carriers

Conclusions (1)

- The observed ORR is 45% (26% CR), suggesting a benefit for the combination of IPH1101 and rituximab as compared to rituximab alone
- This benefit is observed in a population with unfavorable FcRγIIIa gene polymorphism (94.4% F-carriers)
- Side effects are generally easily manageable in a majority of patients
- Only a randomized trial would confirm this efficacy
- Analysis of duration of response is ongoing and some patients still have not progressed

Conclusions (2)

This $\gamma\delta$ immunotherapy approach could be beneficial to other anti-CD20 antibody efficacy

$\gamma\delta$ T cells + autologous
primary FL cells



+ nothing



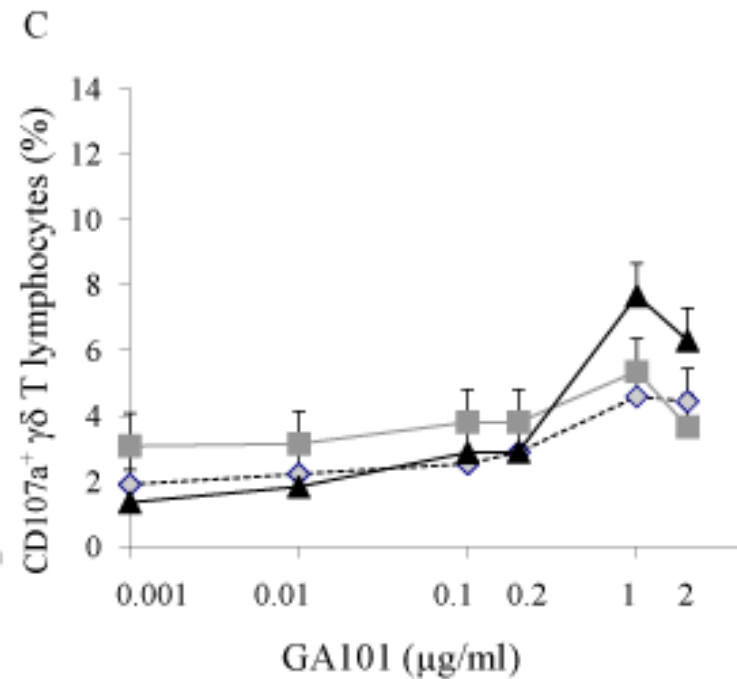
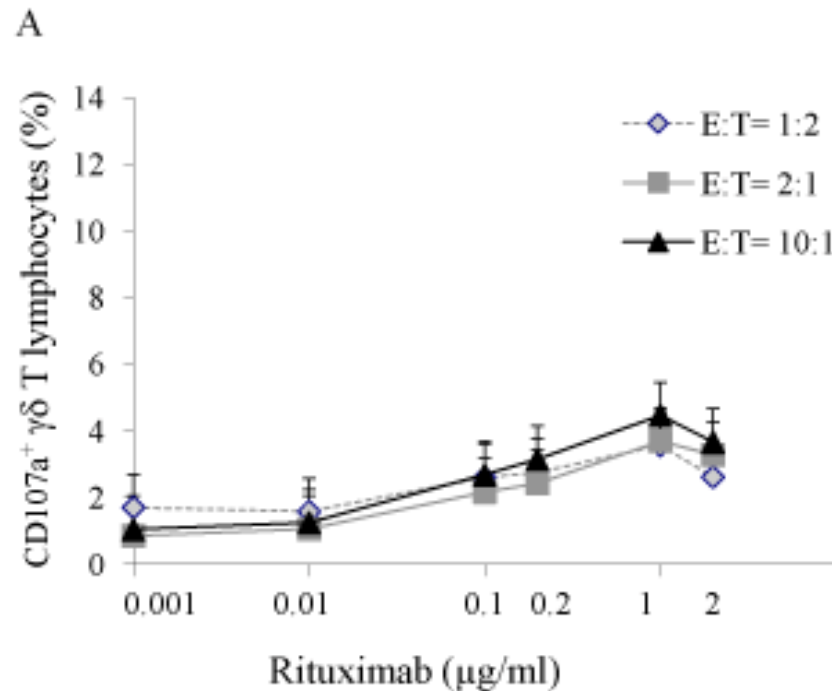
+ Rituximab



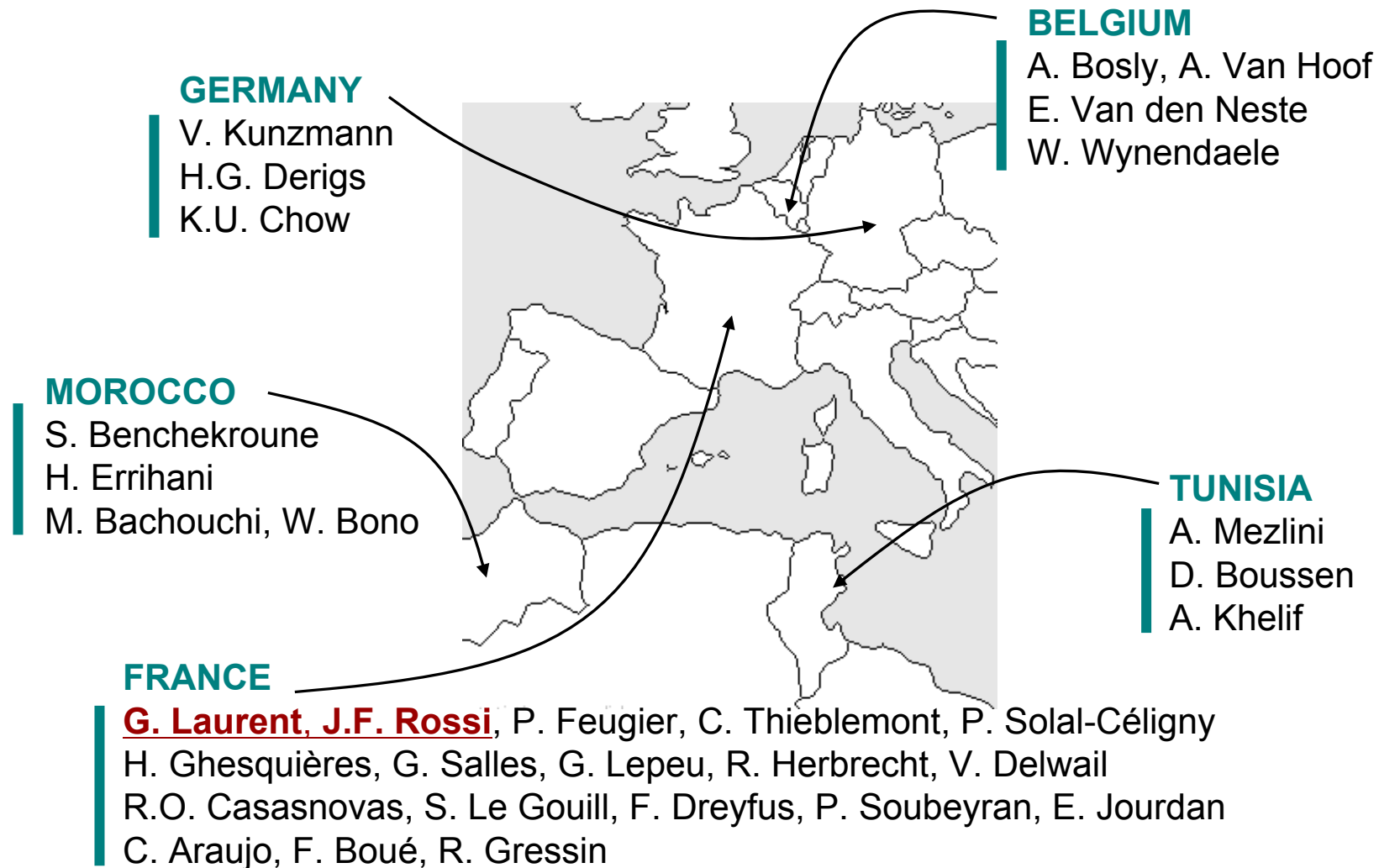
+ Ofatumumab

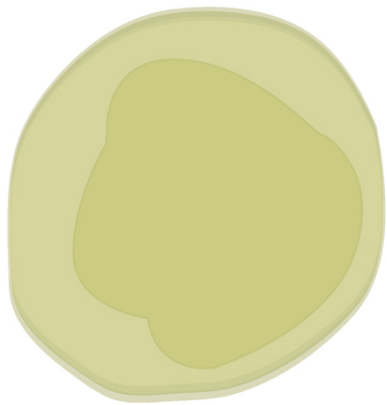


+ GA101



The IPH1101-202 Study Group





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Perspective

Hervé Brailly, CEO of Innate Pharma



IPH 1101 – Phase II program

Oncology

Monotherapy	2 nd line, metastatic	mRCC	No efficacy signal (data published in 2Q08)
Combination	Relapse	fNHL, combination with rituximab	Efficacy signal
	Residual disease	CML, Combination with imatinib	No efficacy signal (data published in 3Q09)

Infectious diseases

Monotherapy	1st line	HCV	Efficacy signal (data published in 2Q09)
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- Good pharmacodynamics and tolerance
- Early efficacy signals in FL in combination with IL-2 and rituximab and in HCV as a single agent



IPH 1101-202 – Follicular non Hodgkin's Lymphoma

Perspective

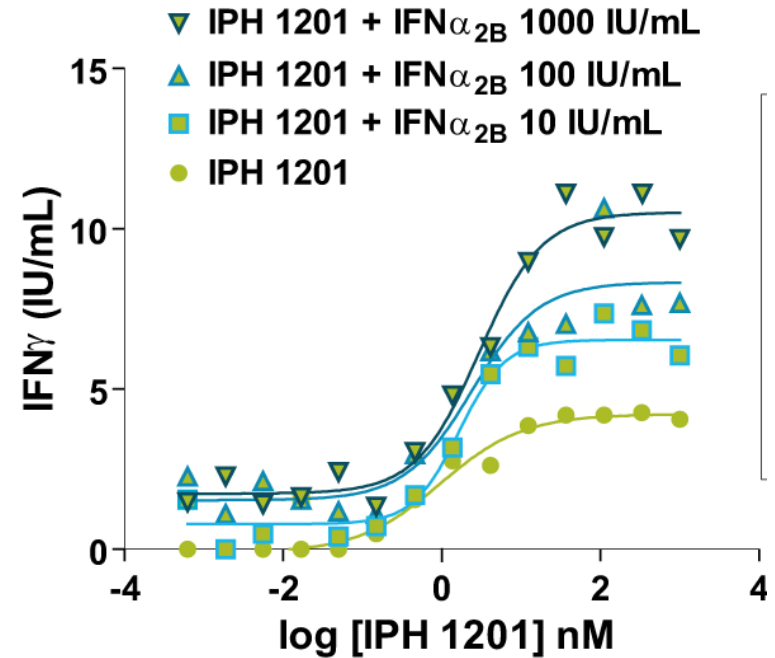
- IPH 1101 has a new mechanism of action that might have a significant impact in cancer treatment in combination with cytotoxic antibodies (ADCC)
- Strong medical need in NHL to improve quality of response, duration of response and to treat relapsing / refractory patients
 - Rituxan to remain a core component of disease management
 - IPH 1101 could be combined with other cytotoxic MAb
- Future envisaged positioning for IPH 1101 could be in combination with rituximab in first line patients with indolent, small mass fNHL eligible to rituximab-alone therapy



Phase IIa in HCV patient (IPH 1101-203)

Perspectives

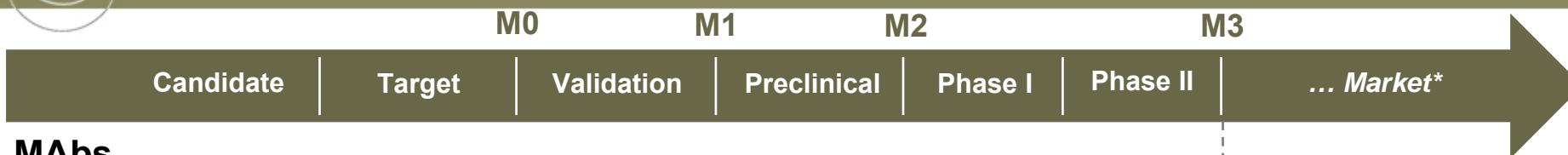
- Novel mechanism of action with demonstrated antiviral effect
- First proof of concept in man for $\gamma\delta$ T cell agonist IPH 1101
- Strong pre-clinical rationale for combining with current SOC
- Persistent need for additional drugs in future combination regimen to treat HCV
- Opens the way for development of $\gamma\delta$ T cell agonists in combination settings






Portfolio of core drug candidates

From novel target to clinical proof-of-concept



MAbs

	Candidate	Target	Validation	Preclinical	Phase I	Phase II	... Market*	
Oncology	IPH 2101	KIR2DL1,2,3	Multiple myeloma / MM					2009: >\$3Bn G7 incidence: 40,000 pts Few treatment options, G7 incidence: 27,000 pts
			Acute myeloid leukemia / AML					
	IPH 4101	KIR3DL2	CTCL				Few treatment options, G7 incidence: 5,000 pts	
Inflammation	IPH 2201 (NN8765)	undisclosed	Inflammation, autoimmunity				2007: >\$15Bn to 2017: \$25Bn	
	IPH 24	undisclosed	Inflammation, autoimmunity					

■ mAbs targeting NK cells
 ■ Cytotoxic antibodies

Small molecule immune modulator

	Candidate	Target	Validation	Preclinical	Phase I	Phase II	... Market*	
Oncology	IPH 1101/ IPH 1201	$\gamma\delta$ TCR	Follicular lymphoma / fNHL					2008: >\$5Bn G7 incidence: 122,000 pts
			Type C hepatitis / HCV					

Clinical proof-of-concept

Discovery assets are not discussed in this presentation



- **A key immuno-pharmacology expertise...**
 - > New mechanisms of action – first-in-class targeted immunomodulators in cancer and chronic inflammation
 - > New tumor antigens - first-in-class cytotoxic antibodies
- **... to address significant opportunities**
 - > Cancer immunotherapy could yield breakthrough in cancer treatment (ipilimumab, anti-PD1, therapeutic vaccines such as Provenge)
 - > Tumor antigen targeting is a validated pathway (>\$10Bn market), still at the beginning of its expansion



- **Track record of 2 Phase II drugs, including one with proof-of-concept data**
- **Key clinical news-flow in the 2010-2013 period with IPH 2101**
 - > EOY 2011: Phase II results in MM (maintenance) and AML Phase I extension results
 - > EOY 2012 : MM Phase II results (relapse in combination with revlimid / smoldering myeloma)
- **Strong cash position to achieve objectives**
 - > As at March 2010: € 44.8m



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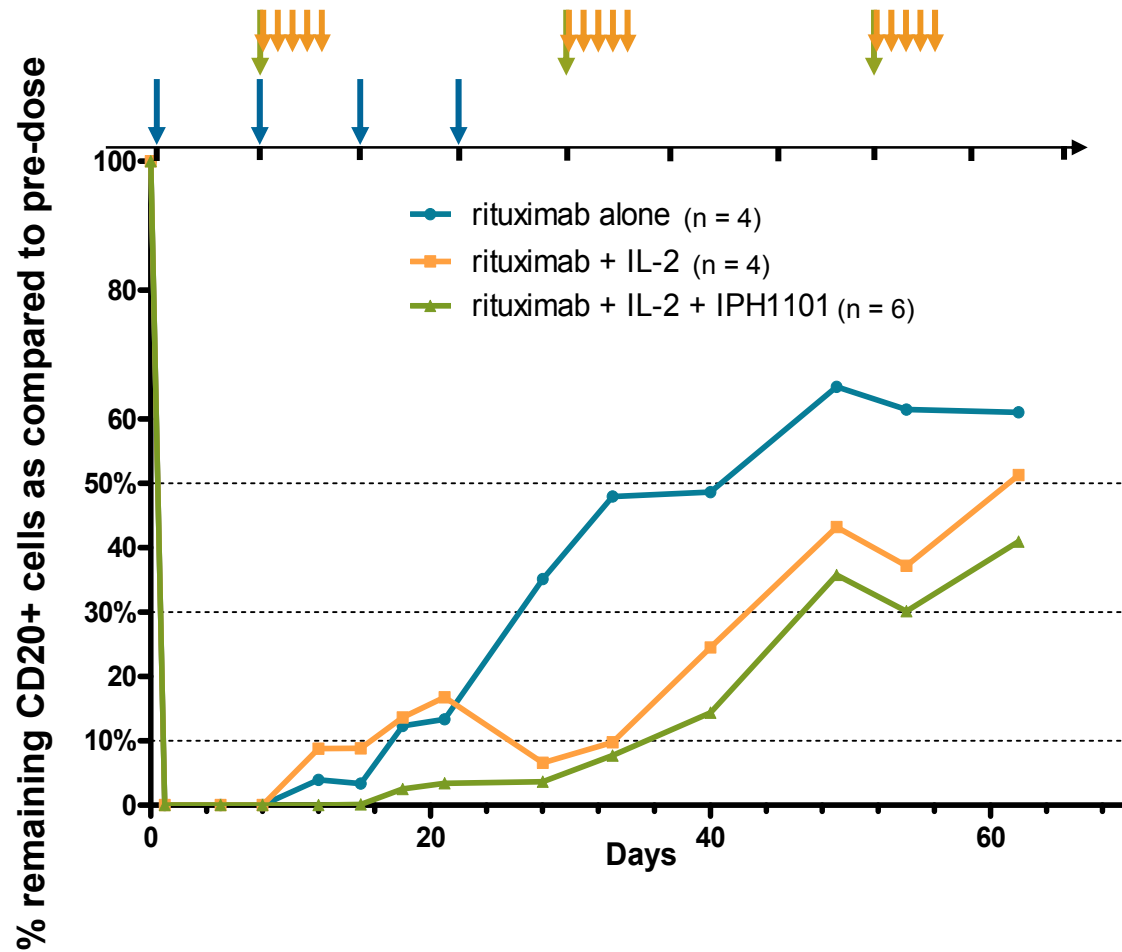
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Appendix:

In vivo (NHP) efficacy of rituximab combined with IPH1101



Time to reconstitution of initial blood B-cells (in days, after 1st rituximab administration)

	10% of initial B-cells	30% of initial B-cells	50% of initial B-cells
RTX alone	18	26	40
RTX + IL-2	16	42	60
RTX + IL-2 + IPH1101	34	47	> 62

J. Gertner-Dardenne, *Blood*, 2008,