AMERICAN SOCIETY OF HEMATOLOGY ANNUAL MEETING 2018

innate pharma

KOL CALL: IPH4102 DATA RESULTS IN SÉZARY SYNDROME

TUESDAY, DECEMBER 4, 2018

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PROF. MARTINE BAGOT – KEY OPINION LEADER

- Current: Professor of Dermatology, Head of the Dermatology Department, Saint Louis Hospital, Inserm U976, Paris, France
- MD, Master in immunology, PhD at Paris 12 University
- Board in dermato-venerology
- Particular interest in cutaneous T cell lymphomas and Sézary syndrome
- Numerous implications in international Scientific Societies (ISCL, EORTC-CLTF…)
- Principal investigator for IPH4102-101 trial
- Past positions
  - > Researcher in Immunology - Inserm U152, Paris Cochin
  - > Assistant Professor then Professor, Department of Dermatology - Inserm U312, Paris 12
  - > Chairperson of Department of Dermatology, Hôpital Henri Mondor

IPH4102, an anti-KIR3DL2 monoclonal antibody in refractory Sézary Syndrome: Results from a multicenter phase 1 trial

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1Hôpital Saint Louis , Paris, France, 2INSERM U976, Hôpital St Louis, Paris, France, 3S. Kimmel Cancer Center, Jefferson, Philadelphia, PA, USA, 4Ohio State University – Columbus, OH, USA, 5LUMC - Leiden, the Netherlands, 6Guy's and St Thomas' Hospital – London, UK, 7Stanford Cancer Institute - Palo Alto, CA, USA, 8INNATE PHARMA, Marseille, France

CONFLICTS OF INTEREST

Consultant: Innate Pharma

Advisory committee: Innate Pharma, Actelion, Takeda, Kyowa Kirin

Equity Ownership: Innate Pharma

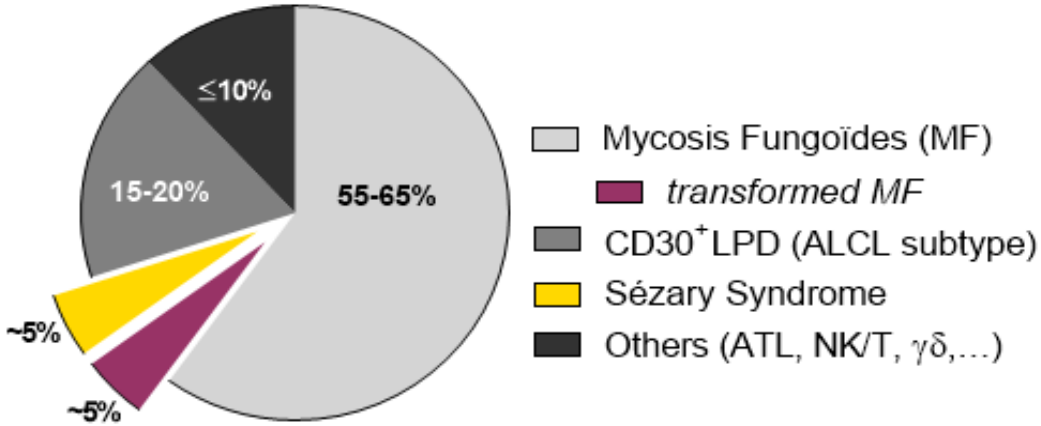
WHAT IS CTCL?

- Non Hodgkin's lymphoma, originating from T cells and with a tropism for the skin
- 4% of Non Hodgkin's Lymphoma
  - > ~ 1 / 100,000 (6,000 new cases for the US + EU)
  - > Rising annual incidence in US - increase by 2.9 per million per decade
- Clinically:
  - > Median age at diagnosis of 55-65 years
  - > Pronounced cutaneous involvement with debilitating pruritus
  - > Lymph nodes, viscera, and blood (Sézary Syndrome) may be involved
  - > Elevated risk of infections

Agar et al, JCO 2010; Kempf et al, Blood 2011; Willemze, Blood 1997; Willemze et al, Annals Oncol 2011; Kim et al, Arch Dermatol 2003; SEER, 2017

EPIDEMIOLOGY OF CTCL (1)

Relative frequency of CTCL subtypes per WHO-EORTC classification



Nr new cases/yr	5-yr overall survival
6,000	
3,300-3,900	20-95%
150-300	≤ 15%
500-1000	76-96%
150-300	~ 10%
600	≤ 20%

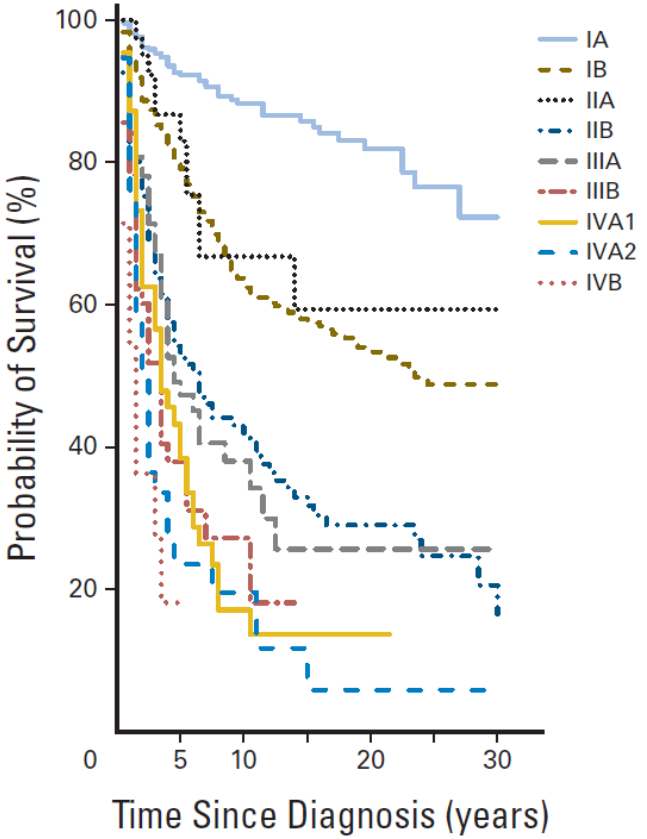
LPD: lymphoproliferative disorder. ALCL: anaplastic large cell lymphoma
ATL: Adult T cell lymphoma

Agar et al, JCO 2010; Kempf et al, Blood 2011; Willemze, Blood 1997; Willemze et al, Annals Oncol 2011; Kim et al, Arch Dermatol 2003

EPIDEMIOLOGY OF CTCL (2)

- Prognosis and survival of Mycosis fungoides and Sezary syndrome are strongly linked to **clinical stage**

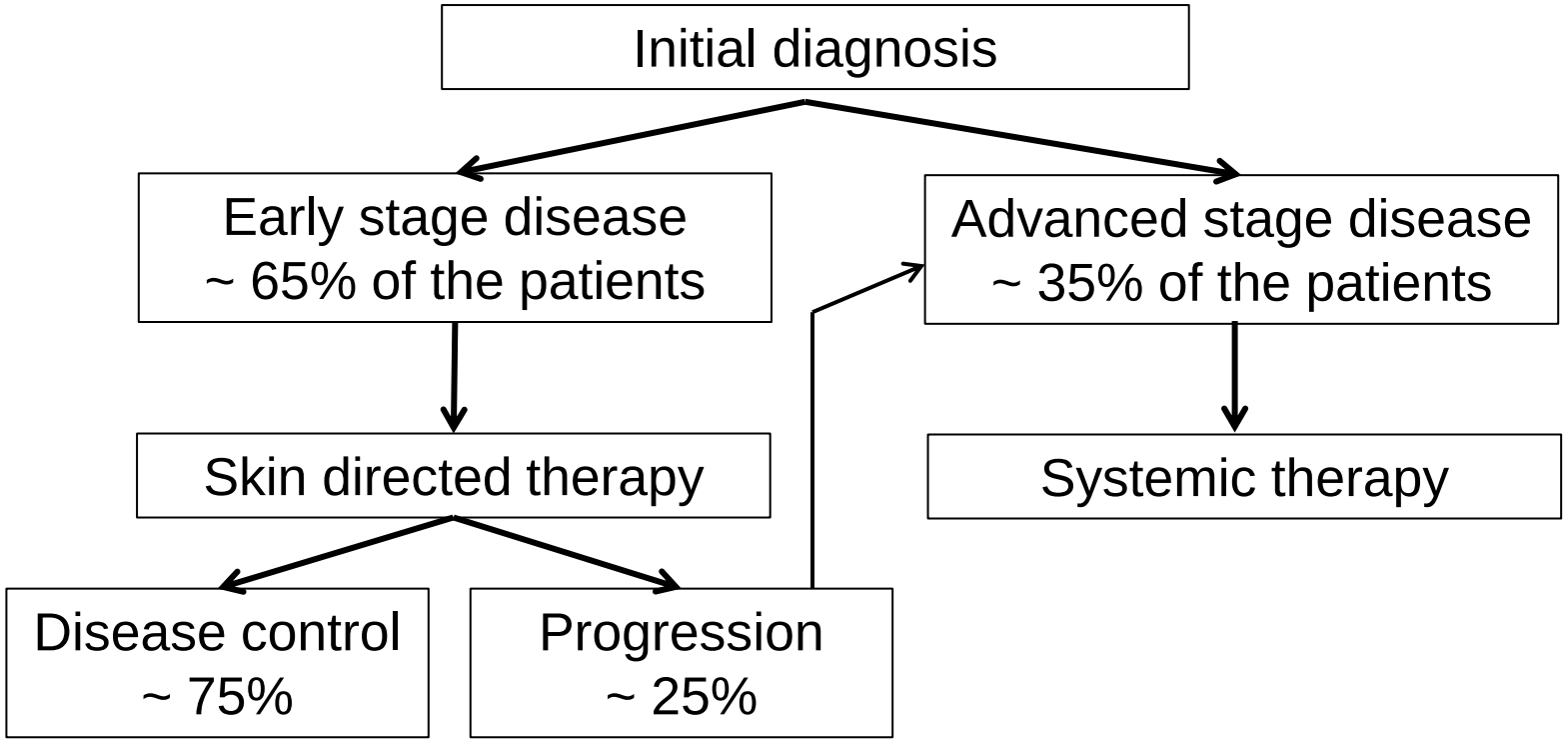
- **Other poor prognostic factors**: age >60 years, large cell transformation (LCT) in skin, increased Lactate Dehydrogenase (LDH) and extracutaneous involvement



Agar et al, JCO 2010. Scarisbrick et al., 2015

TREATMENT OF CTCL

OVERVIEW



STANDARDS OF CARE IN CTCL
TREATMENT OF MYCOSIS FUNGOIDES IN 2018

Bexarotene = primary agent in 1st line (oral)

Strong impact of brentuximab & mogamulizumab in later lines

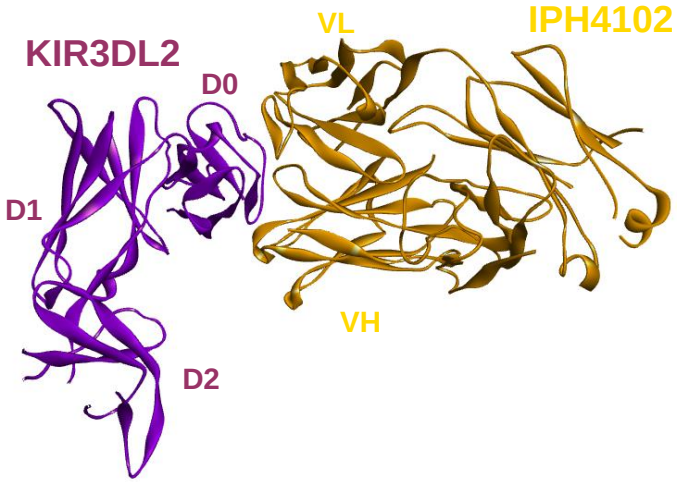
	Preferred therapies
1st line	Bexarotene, bexarotene-based combinations
2nd line	Brentuximab*, mogamulizumab, and older drugs competing in 2nd/3rd line
3rd line	
4th line	**Still remaining a major unmet medical need**

* not approved in Sézary syndrome

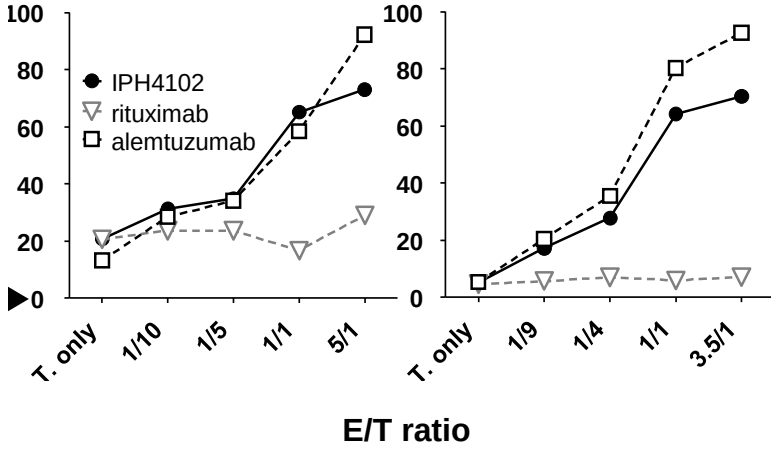
KOL interviews conducted by IPH

IPH4102

FIRST IN CLASS mAb DIRECTED AGAINST KIR3DL2

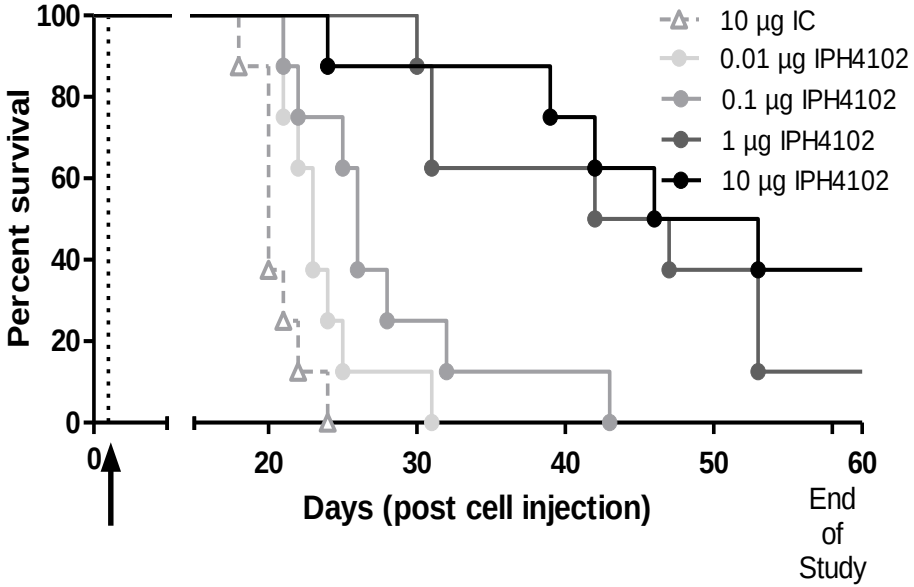


NK cells kill primary Sézary cells in *ex vivo* autologous model through IPH4102-mediated ADCC



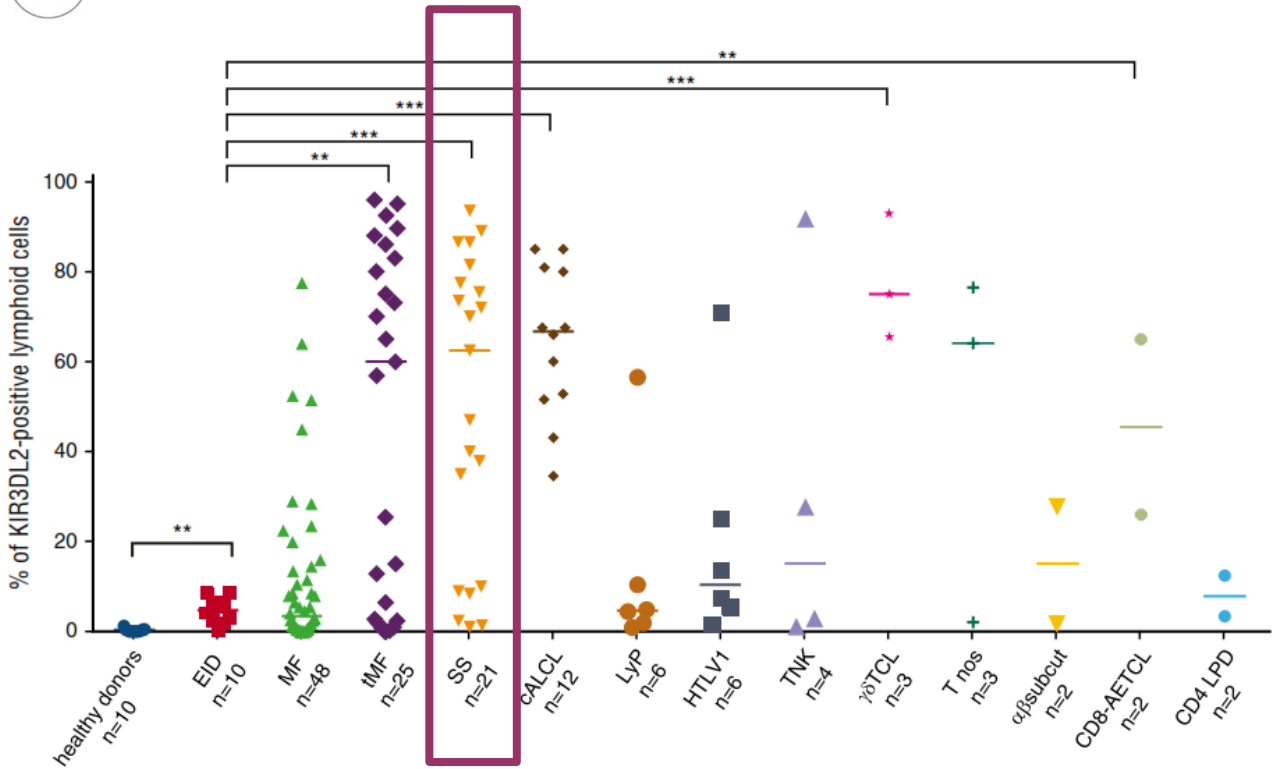
Marie-Cardine et al, Cancer Res 2014, Bagot et al, ASH 2018

IPH4102 IMPROVES SURVIVAL IN MOUSE XENOGRAFT MODELS

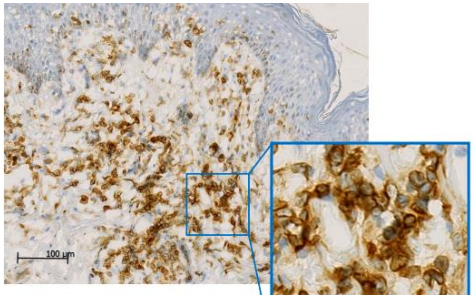


Marie-Cardine et al, Cancer Res 2014, Bagot et al, ASH 2018

KIR3DL2 IS EXPRESSED IN CTCL **PARTICULARLY IN SÉZARY SYNDROME**



KIR3DL2 expression by IHC



EID: erythrodermic inflammatory disease, MF: mycosis fungoides, SS: Sézary syndrome, cALCL: cutaneous anaplastic large cell lymphoma, LyP: lymphoid papylosis, HTLV1 Adult T-cell lymphoma, TNKL nasal-type lymphoma, γ δ T-cell lymphoma, T-nos: T cutaneous peripheral T-cell lymphoma non otherwise specified, αβ T celll lymphoma, CD8-positive aggressive epidermotropic cytotoxic T-cell lymphoma, LPD: lymphoproliferative disorder

Battistella et al; Blood 2017, Bagot et al, ASH 2018

STUDY DESIGN
FIRST IN HUMAN PHASE 1 CLINICAL TRIAL

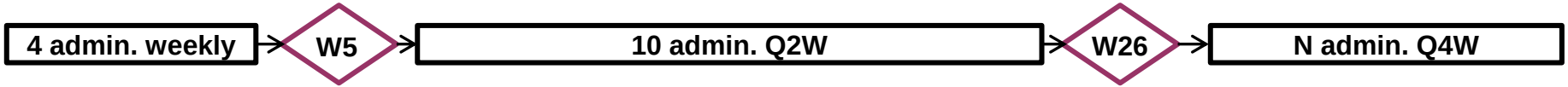
Dose-escalation

- 10 dose levels (up to 10mg/kg) – accelerated 3+3 design
- All CTCL subtypes
- ≥ 2 prior systemic therapies
- KIR3DL2+ ≥ 5% in skin and/or blood (centrally)

Cohort expansion

- Recommended Phase 2 dose (750 mg)
- SS and tMF only
- ≥ 2 prior systemic therapies
- Any KIR3DL2 expression level

- **Dosing regimen**, until progression or unacceptable toxicity



- Intra-patient dose-escalation allowed after Week 5 (W5) in the dose-escalation portion

Bagot et al, ASH 2018

STUDY OBJECTIVES

- **Primary objective**: determination of Maximal Tolerated Dose (MTD) and RP2D, overall safety
- **Secondary objectives**:
  - > Overall Response Rate (ORR, Olsen JCO 2011 criteria), duration of response (DOR) and Progression-Free Survival (PFS)
  - > PK and immunogenicity
- **Quality of Life**
  - > Pruritus (Visual Analogue Scale)
  - > SkinDex29
- **Exploratory objectives**:
  - > Early changes (at week 5) in KIR3DL2-positive cells* and molecular residual disease (MRD)** in skin and blood and ORR

THIS PRESENTATION FOCUSES ON SS PATIENTS

* By Immunohistochemitstry (IHC); ** By TCR deep sequencing

Bagot et al, ASH 2018

BASELINE DISEASE CHARACTERISTICS
SÉZARY SYNDROME (N=35)

	Total N = 35
Median age in years (range)	70 (37 – 90)
Evidence of LCT*, n (%)	7 (20%)
KIR3DL2 expression, n (%) - Skin - Blood - Skin and/or blood	 27 (77%) 33 (94%) 33 (94%)
Median time from diagnosis in months (range)	23 (6 – 268)
Median N. of prior systemic therapy (range)	2 (1 – 9)^
Prior treatment with HDAC inhibitors, n (%)	13 (37%)
Prior treatment with Mogamulizumab, n (%)	7 (20%)

* LCT: large cell transformation based on central testing on frozen tissue
^ One patient had a protocol violation, treated with only one prior line of systemic therapy

Bagot et al, ASH 2018

SAFETY PROFILE

IPH4102 DISPLAYS A FAVORABLE SAFETY PROFILE

Dose escalation: no DLT / MTD not reached / RP2D = 10 mg/kg - 750 mg flat dose

Common AEs	All AEs		Related AEs*	
	All grades	Grade 3-4	All grades	Grade 3-4
Peripheral edema	10 (29%)	0	0	0
Asthenia	9 (26%)	0	5 (14%)	0
Fatigue	8 (23%)	0	3 (9%)	0
Cough	7 (20%)	0	0	0
Pyrexia	7 (20%)	0	3 (9%)	0
Arthralgia	6 (17%)	0	2 (6%)	0
Lymphopenia	5 (14%)	2 (6%)	5 (14%)	2 (6%)
Diarrhea	5 (14%)	0	1 (3%)	0

Only 3 patients (9%) stopped treatment for an AE

Four patients developed 5 possibly related grade ≥ 3 AEs

- grade 5 hepatitis (n=1)**, grade 4 sepsis (n=1), grade 3 lymphopenia (n=3), grade 3 hypotension (n=1).

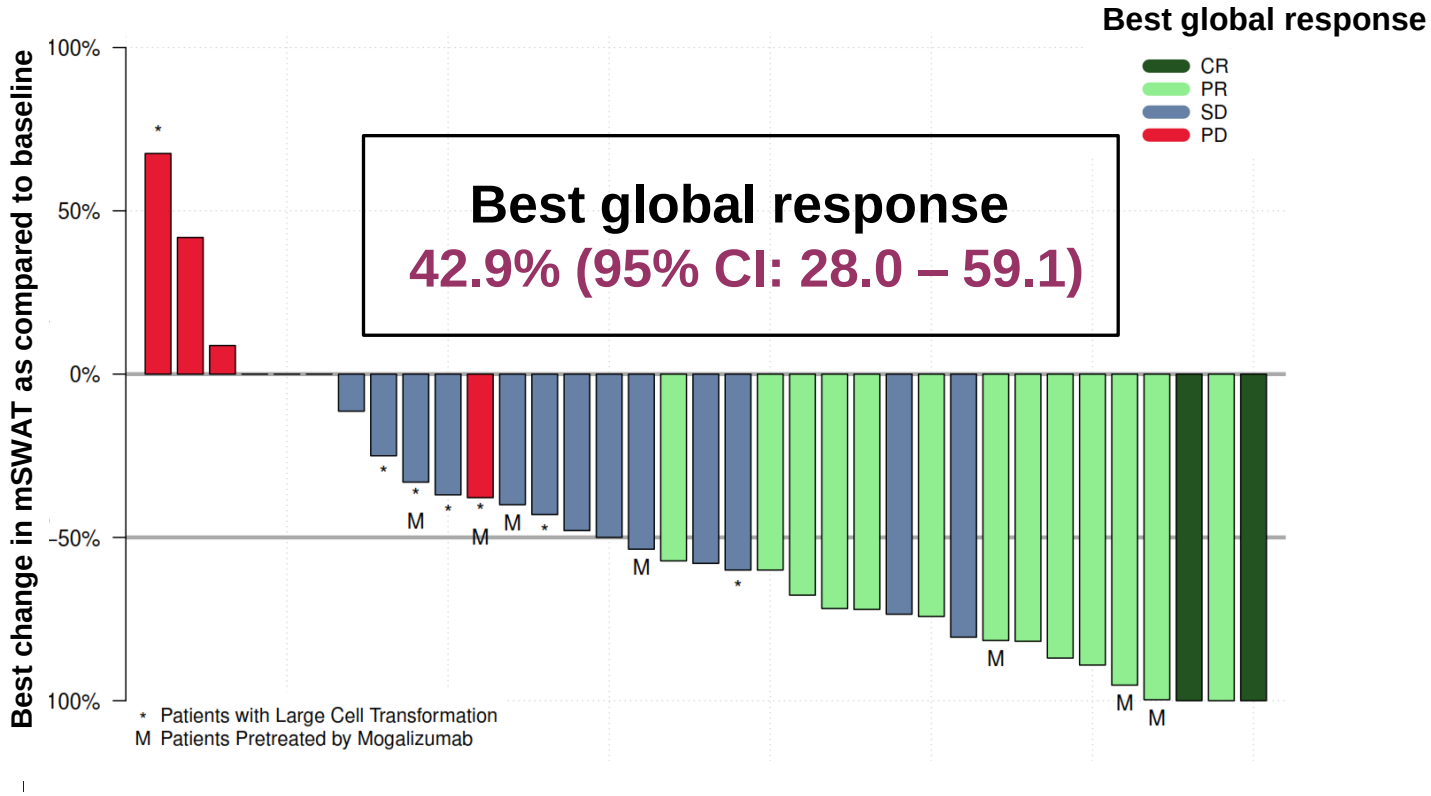
* According to investigator assessment

** 6 weeks after stopping IPH4102, evidence of HHV-6B infection

Data Cut-off: October 15, 2018

Bagot et al, ASH 2018

CLINICAL EFFICACY RESULTS
HIGH OVERALL RESPONSE RATE

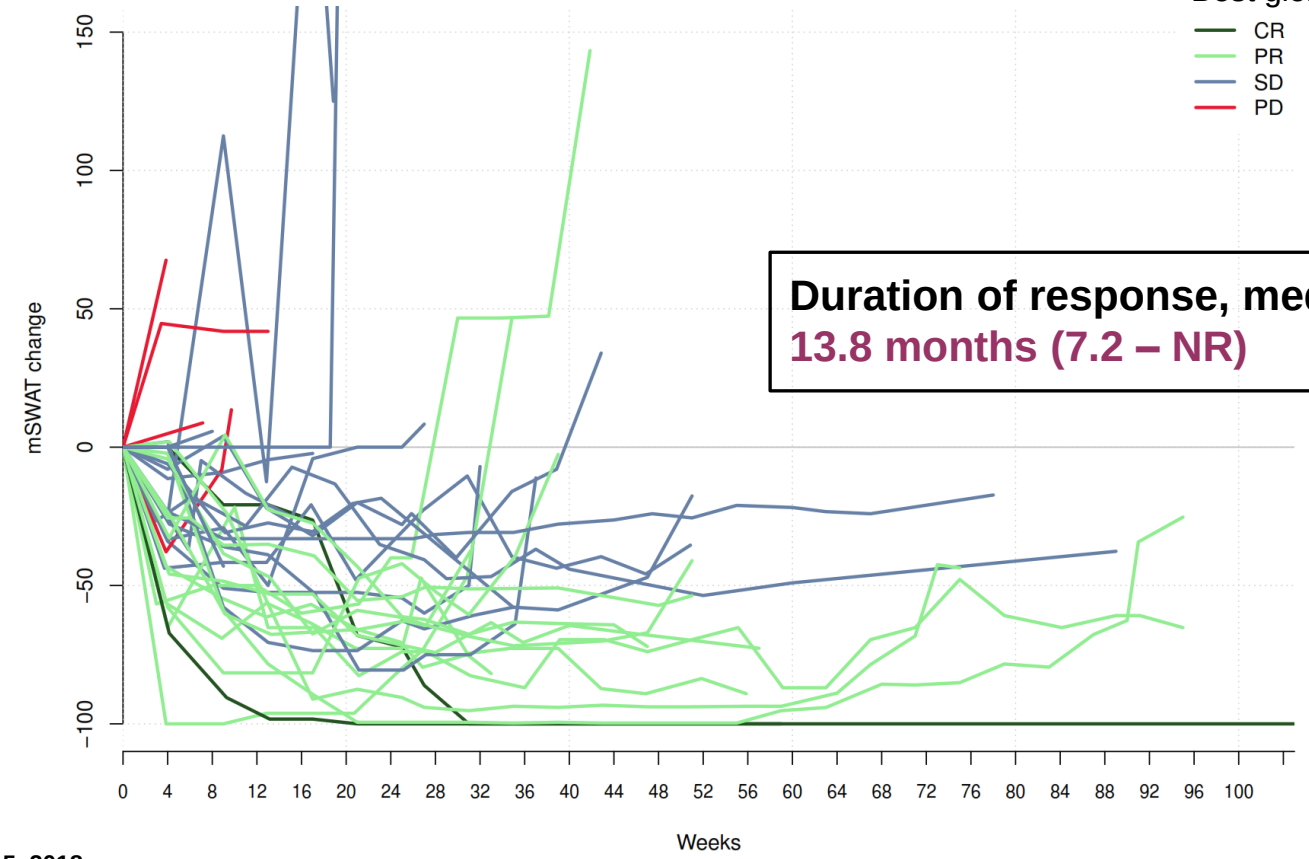


Data Cut-off: October 15, 2018

Bagot et al, ASH 2018

CLINICAL EFFICACY RESULTS

DURABLE RESPONSES



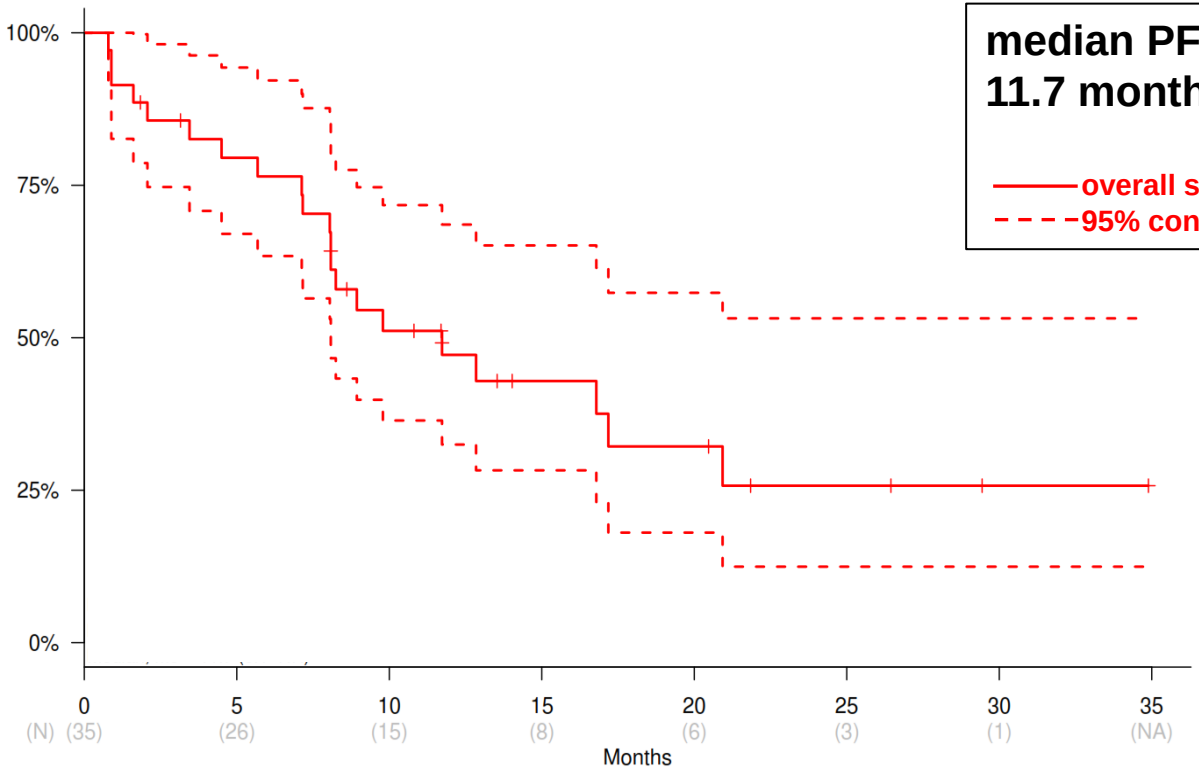
Duration of response, median (95% CI)
13.8 months (7.2 – NR)

NR: Not Reached

Data Cut-off: October 15, 2018

Bagot et al, ASH 2018

CLINICAL EFFICACY RESULTS
LONG PROGRESSION FREE SURVIVAL



median PFS (95% CI):
11.7 months (8.1 – NR)

overall survival
95% confidence interval

Median follow-up:
14.2 months (95% Ci: 11.8 – 20.5)

Data Cut-off: October 15, 2018

Bagot et al, ASH 2018

CLINICAL EFFICACY RESULTS
SUBGROUP ANALYSIS

	All SS N=35	**SS without LCT N=28**	**Prior treatment with mogamulizumab N=7**
Best global response - CR - PR - SD - PD	**42.9% (28.0 – 59.1)** 2 (5.7%) 13 (37.2%) 16 (45.7%) 4 (11.4%)	**53.6% (35.8 – 70.5)** 2 (7.1%) 13 (46.5%) 11 (39.3%) 2 (7.1%)	**42.9% (15.8 – 75.0)** 0 3 (42.9%) 3 (42.9%) 1 (14.2%)
Duration of Response*	13.8 (7.2 – NR)	13.8 (7.2 – NR)	13.8 (7.2 – NR)
Progression Free Survival*	11.7 (8.1 – NR)	12.8 (8.2 – NR)	16.8 (8.1 – NR)

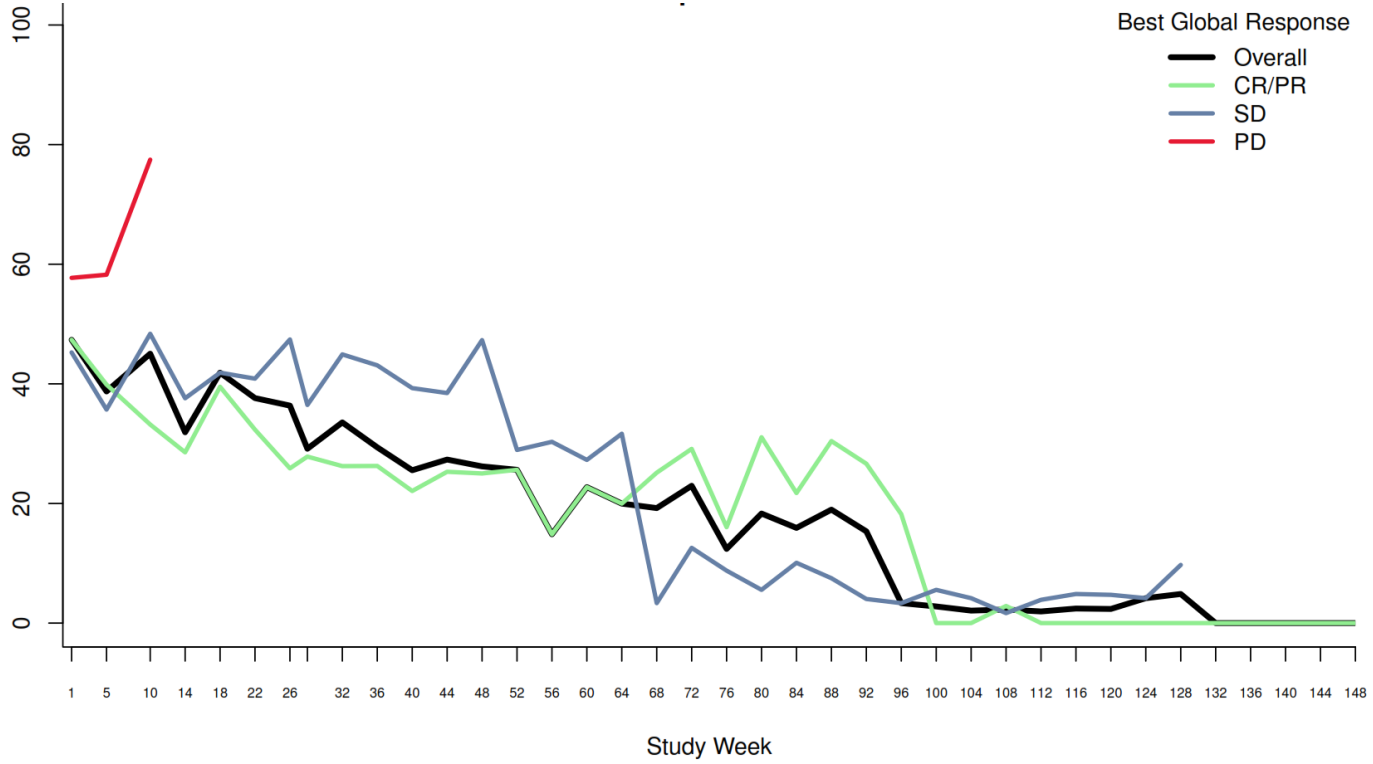
* Median (95% CI)
NR: Not Reached
LCT: Large Cell Transformation tested centrally on frozen tissue

Data Cut-off: October 15, 2018

Bagot et al, ASH 2018

QUALITY OF LIFE

SKINDEX29 (N = 35)



Data Cut-off: October 15, 2018

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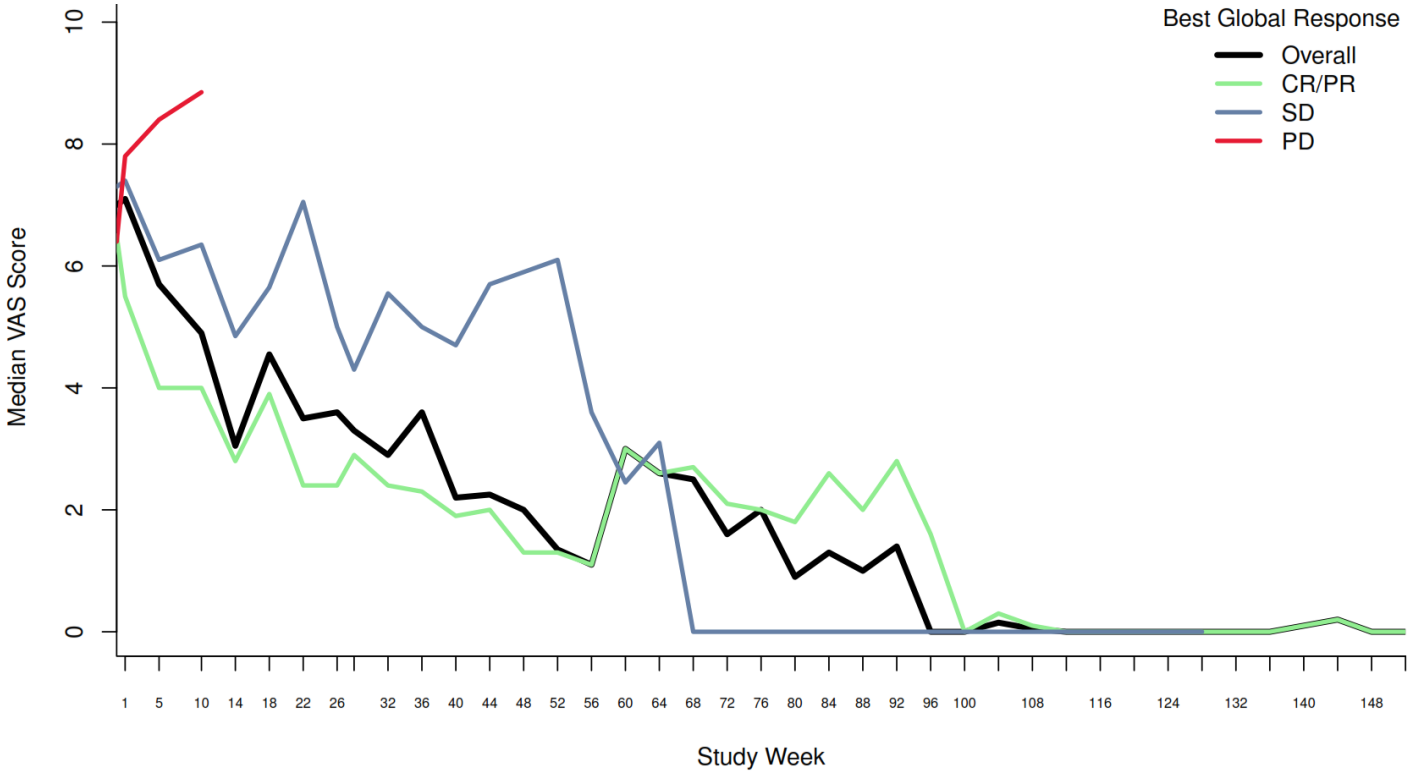
QUALITY OF LIFE

PRURITUS VISUAL ANALOGUE SCALE SCORE (N = 35)



Data Cut-off: October 15, 2018

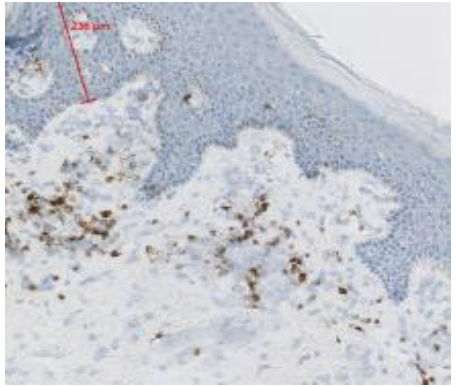
Bagot et al, ASH 2018

EXPLORATORY BIOMARKERS

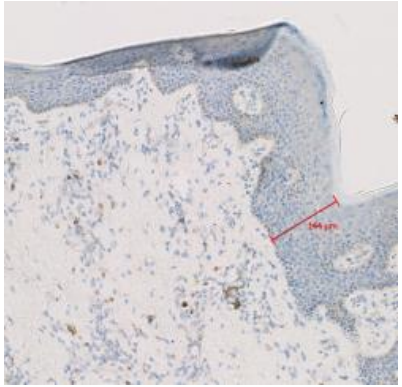
CHANGES IN KIR3DL2 EXPRESSING CELLS IN SKIN

Patient 11-005, global partial response since W10 lasting 1 year and 8 months

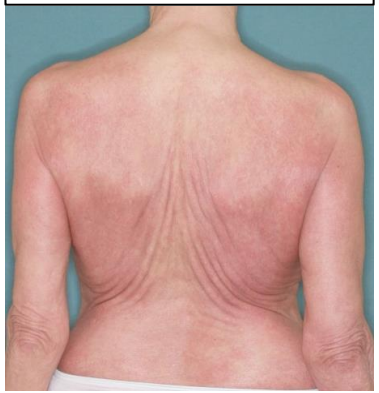
Baseline
KIR3DL2: 52%



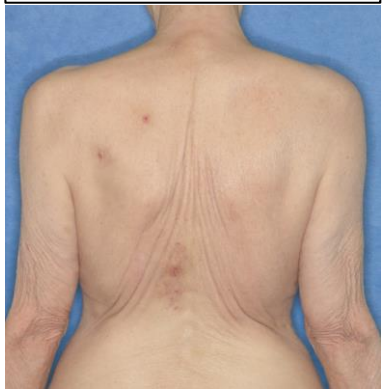
Week 5
KIR3DL2: 4.4%



Baseline
mSWAT: 80.5/1/0



Week 64
mSWAT = 5.2/0/0



^ 77 y old woman, received 6 prior lines of systemic therapies including Bex, IFN, HDAC and Mogamulizumab
Global PR since week 10 (starting dose : 0.05 mg/kg)

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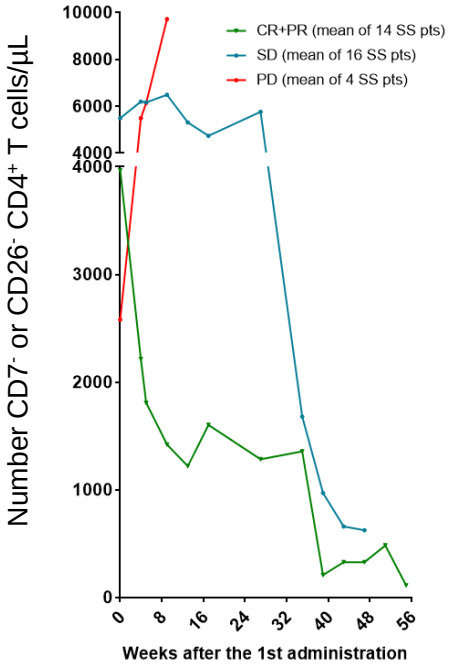
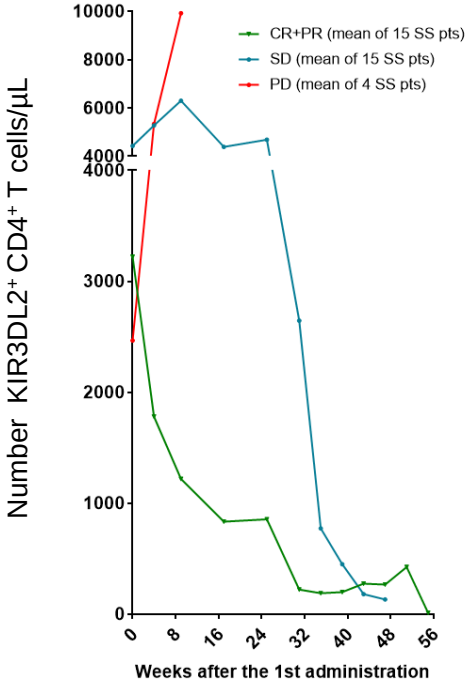
EXPLORATORY BIOMARKERS

CHANGES IN TUMOR CELLS AND KIR3DL2 IN BLOOD

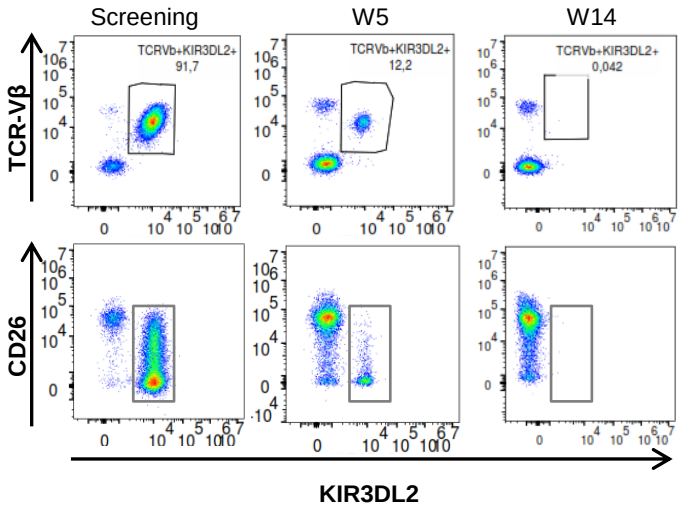
Aberrant cells



KIR3DL2+ CD4+ T cells



Patient 01-036, ongoing complete response > 1 year



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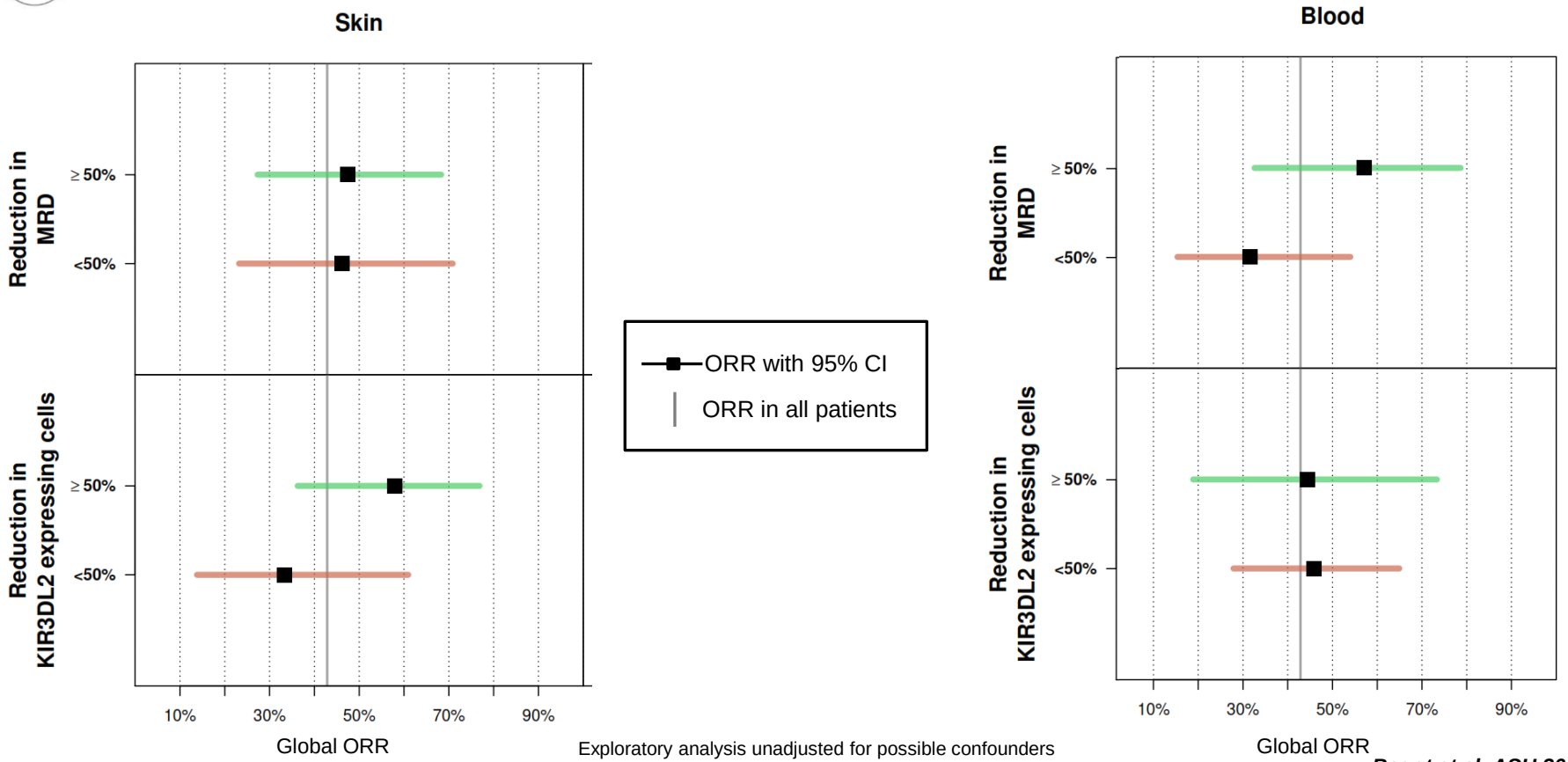
EXPLORATORY BIOMARKERS

REDUCTION IN KIR3DL2 / MRD AT WEEK 5 AND GLOBAL RESPONSE



Exploratory analysis unadjusted for possible confounders

Bagot et al, ASH 2018

CONCLUSIONS

- IPH4102 is **safe and well tolerated** in heavily pretreated relapsed/refractory SS.
- IPH4102 shows impressive clinical activity, demonstrated by **high and durable response** rate and **long PFS.**
- IPH4102 **substantially improved QOL** even in patients with stable disease.
- Exploratory biomarker analyses show **relevant pharmacodynamics effects of IPH4102 in skin and in blood**. These results will be further validated in future studies.
- These data support further investigations of IPH4102 in T cell lymphomas in general and in SS in particular

Bagot et al, ASH 2018

PHASE 2 STUDY (N≈250)

TELLOMAK : T-CELL LYMPHOMA ANTI-KIR3DL2 THERAPY

TELLOMAK

Sézary Syndrome
≥ 2 prior systemic therapies that must include mogamulizumab

Mycosis Fungoides
≥ 2 prior systemic therapies including biological agents

IPH4102 single agent

Peripheral T Cell Lymphoma
≥ 1 prior systemic therapy including anthracycline-based chemo

IPH4102 + GEMOX

Bagot et al, ASH 2018

ACKNOWLEDGEMENTS

Dpts of Dermatology & Pathology
St Louis Hospital (Paris, France)
Martine Bagot
Caroline Ram-Wolff
Steve Mathieu
Maxime Battistella

INSERM Unit 976 (Paris, France)
Anne Marie-Cardine
Nicolas Thonnart
Armand Bensussan

Histalim (Montpellier, France)
Laurence Maunier

Leiden University Medical Center
(Leiden, Netherlands)
Maarten Vermeer

Stanford Cancer Institute (CA, USA)
Youn Kim
Michael Khodadoust

Ohio State University (OH, USA)
Basem William
Pierluigi Porcu

Guy's and St Thomas' Hospital
(London, UK)
Sean Whittaker

Innate Pharma (Marseille, France)
Christine Paiva
Cécile Bonnafous
Frédérique Moriette
Federico Rotolo
Hélène Sicard
Carine Paturel
Agnès Widemann
Anne T. Martin
Ariane Morel
Hatem Azim

All our patients and their families…

STRATEGIC PERSPECTIVES

INNATE PHARMA

PIERRE DODION, MD, CMO

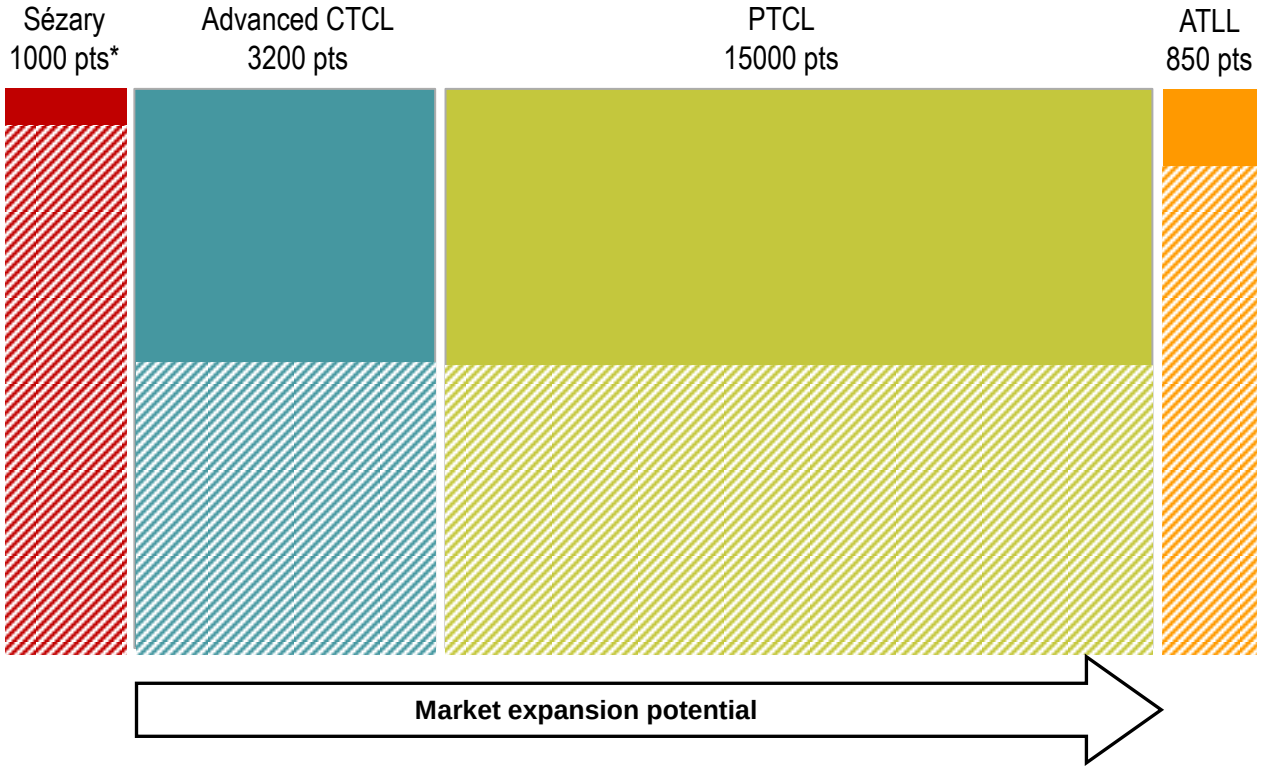
OVERVIEW OF THE IPH4102 PROGRAM

- Strong preclinical rationale supporting IPH4102 in CTCL, SS and PTCL
- Very encouraging clinical data in SS
- Support from FDA:
  - > Safety and efficacy data
  - > Key elements of study design: single arm phase 2 design, primary endpoint, sample size
  - > Potential Indication: *IPH4102 could be indicated in SS patients without histologic transformation and who have received at least two prior systemic therapies that must include mogamulizumab*
- Decision to start a pivotal phase 2 study in 1H19
- Leads to a potential BLA submission in 2022
- Fits very well with Innate Pharma's focus on commercializing therapies for rare oncohematology diseases

IPH4102 HAS A SIGNIFICANT POTENTIAL BEYOND SEZARY SYNDROME OPPORTUNITY

- 15% of all NHL
- Highly heterogeneous
- Medical need in late lines

- Differentiated profile
- Biomarker driven therapy
- Premium pricing strategy
- LCM options



KIR3DL2+

* Prevalence

Epidemiology data : Internal best current estimates of patient numbers based on external research

STANDARDS OF CARE IN CTCL
TREATMENT OF MYCOSIS FUNGOIDES IN 2018

	Preferred therapies
1st line	Bexarotene, bexarotene-based combinations
2nd line	Older drugs, brentuximab, and mogamulizumab competing in 2nd/3rd line
3rd line	
4th line	**Still remaining a major unmet medical need**

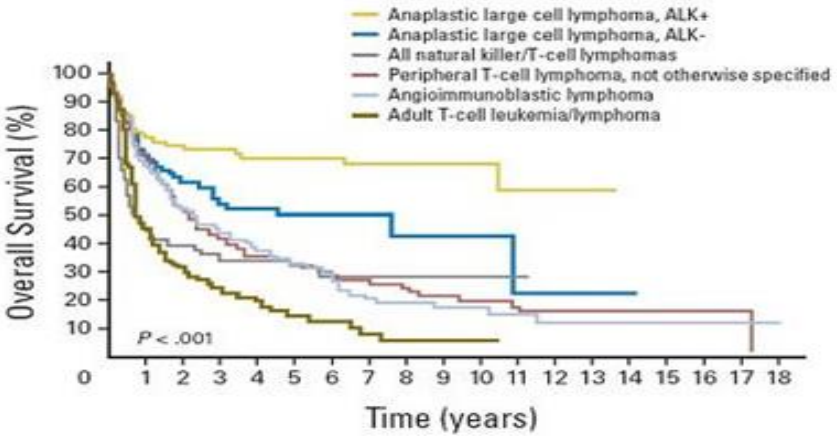
~ 65% of CTCL patients are KIR3DL2+

Rationale for a phase 2 study in CTCL, post 2 prior lines of systemic therapy, KIR3DL2 pos and neg (2 cohorts)

KOL interviews conducted by IPH

POTENTIAL DEVELOPMENT IN PERIPHERAL T CELL LYMPHOMAS

- PTCL represent ~10% of all NHL WW
- Several subtypes with variable response to
- ~ 50% express KIR3DL2



Standard of care

	PTCL	Incl. ALCL
1st line	Chemo (CHOP-like) at times followed by transplantation if possible; recent approval of brentuximab	
2nd line*, Salvage options	Gemcitabine, oxaliplatin, palatrexate§, combination chemo (DHAP, GEMOX) romidepsin§, belinostat§	

*In Japan, mogamulizumab is approved in r/r CCR4-positive PTCL. § approved in the US only

High failure rate and frequent KIR3DL2 positivity provide the rationale to explore IPH4102 in PTCL

International TCL Project JCO 2008

IN SUM: TELLOMAK PHASE 2 STUDY (N≈250)

TELLOMAK : T-CELL LYMPHOMA ANTI-KIR3DL2 THERAPY

TELLOMAK

N≈60	**Sézary Syndrome** ≥ 2 prior systemic therapies that must include mogamulizumab	**IPH4102 single agent**
Cohort # 1		
N≈90	**Mycosis Fungoides** ≥ 2 prior systemic therapies including biological agents	
Cohort # 2	KIR3DL2 expressing	
Cohort # 3	KIR3DL2 non-expressing	
N≈100	**Peripheral T Cell Lymphoma** ≥ 1 prior systemic therapy including anthracycline-based chemo	**IPH4102 + GEMOX**
Cohort # 4	KIR3DL2 expressing	
Cohort # 5	KIR3DL2 non-expressing	

QUESTIONS AND ANSWERS

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