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Innate Pharma S.A.

IPH 1101 mRCC Phase IIa results

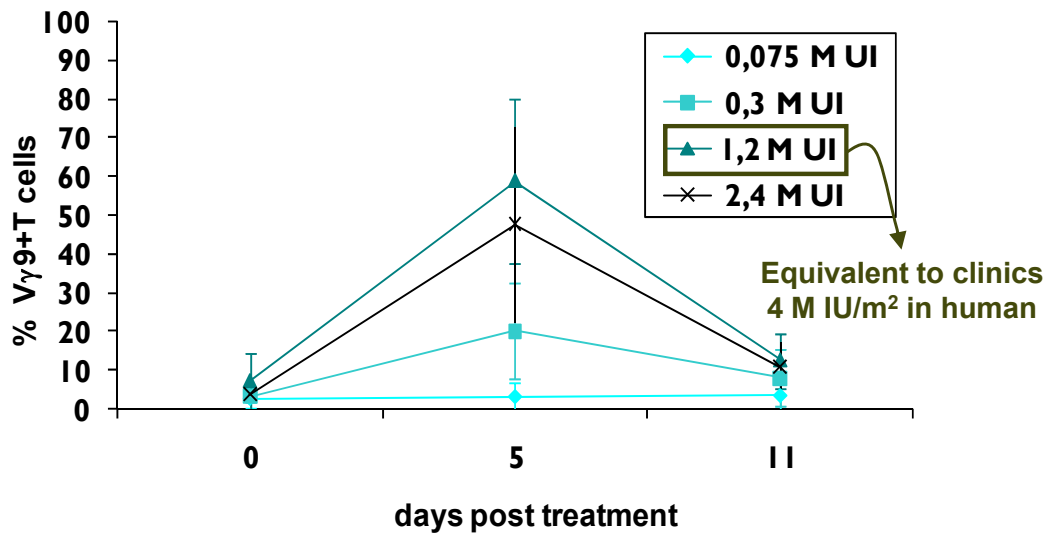
May 23, 2008

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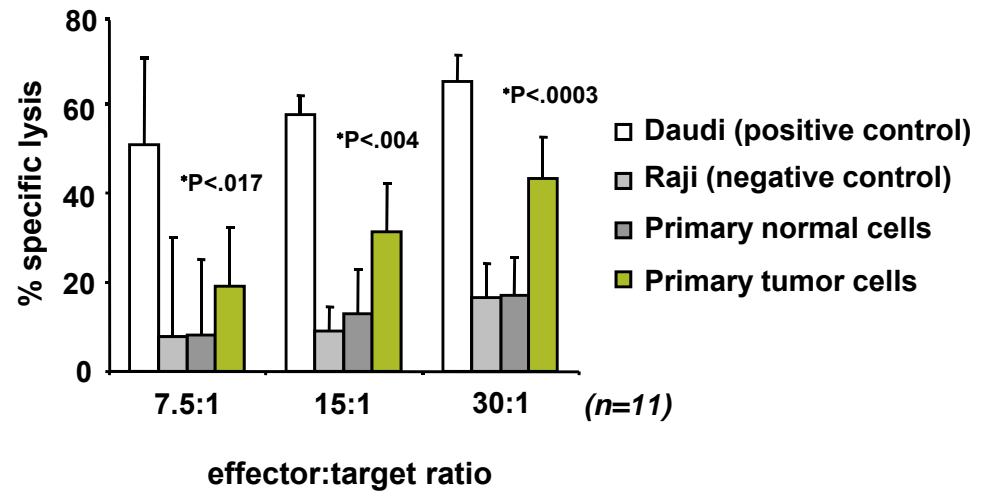
Selection of Renal Cell Carcinoma Indication

Pre-clinical rationale

- IL-2 enables the expansion of $\gamma\delta$ T cells
- $\gamma\delta$ T cells are cytotoxic against autologous RCC tumor cells



Dose-effect of IL-2 on $\gamma\delta$ expansion in the primate



IPH 1101-expanded $\gamma\delta$ T cells lyse efficiently and specifically autologous primary renal cell tumors

- **3 phase I studies:**

- Cell therapy based trial Phase I study in patients with mRCC (Innacell 101 trial)
- Phase I dose escalation study in patients with solid tumors (IPH 1101-101 trial)
- Phase I dose escalation study in patients with NHL (IPH 1101-102 trial)

⇒ **Good tolerance in combination with IL-2 at 1 MIU/m²**

⇒ **Dose dependent $\gamma\delta$ T cells amplification**


⇒ **Interesting activity data in mRCC patients:**

- 5 patients out of 10 with disease stabilization > 24 weeks (Innacell 101 trial)
- 8 patients out of 15 with disease stabilization > 35 weeks (IPH 1101-101 trial)

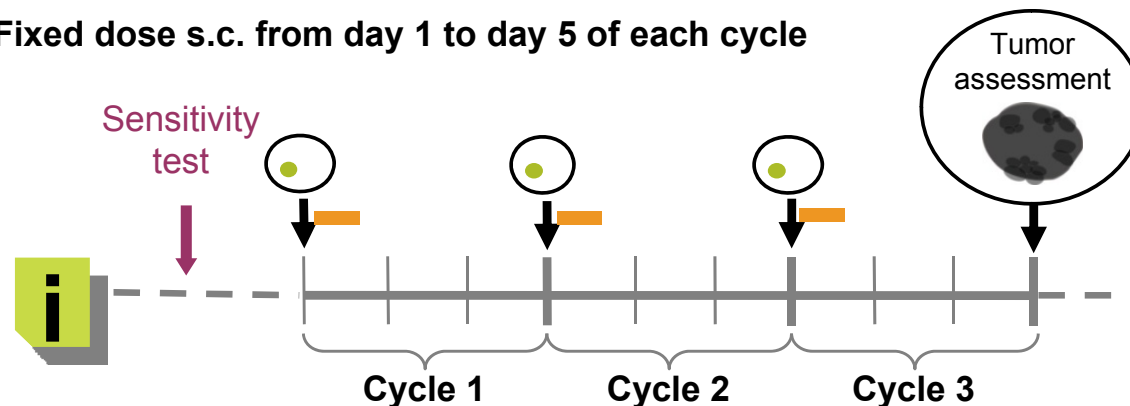


Trial	Period & location	Population	Randomization	Endpoints
Phase IIa Open protocole	2006/2007 France, Russia, Ukraine 15 centers	Metastatic renal cell carcinoma patients Progressive disease after a first line of immunotherapy 69 patients	2 arms: Arm A: 1MIU/m ² IL-2 Arm B: 4MIU/m ² IL-2	Primary endpoint: progression-free survival (“PFS”) rate at 12 weeks Secondary endpoints: safety profile pharmacodynamics

- Treatment regimen:

 IPH 1101: 750 mg /m² on day 1 of successive 3 week cycles, i.v. infusion

 IL-2: Fixed dose s.c. from day 1 to day 5 of each cycle





IPH 1101-201 study results

Study demographics

	Arm A	Arm B	Total
Number of patients	35	34	69
Sex M/F	27/8	23/11	50/19
Age median (y)	53.0 [39-74]	56.0 [33-77]	54.0 [33-77]
ECOG			
0	17	17	34
1	18	17	35
MSKCC Prognostic Risk Group			
Intermediate	13	12	25
Favorable	22	22	44

- ⇒ Population with risk factors similar to standard 2nd line population
- ⇒ Well balanced characteristics of the population in the two arms with respect to disease status and prognosis factors



IPH 1101-201 study results

Primary endpoint: **Efficacy data**

	Patients with stable disease	Number of evaluated patients	Total number of patients	% patients with stable disease (per protocol)
Arm A	11	31	35	35%
Arm B	16	32	34	50%

	Median Progression Free Survival (weeks)
Arm A	7
Arm B	15
p	Not significant

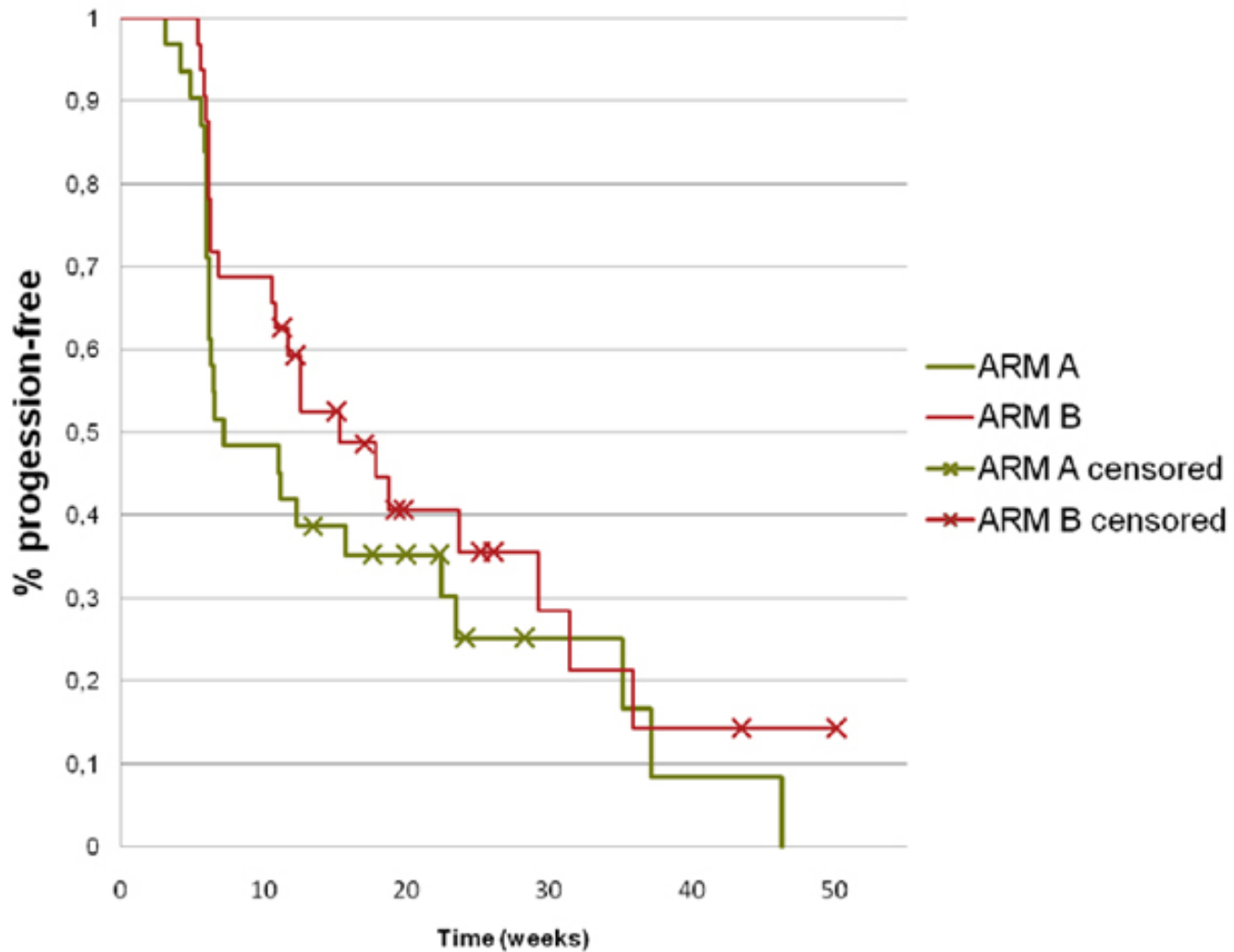
- Independent central review of scan performed on 67 patients to date
 - current per protocol population: 63 patients
 - 2 pts non evaluable / non eligible in each arm



IPH 1101-201 study results

Primary endpoint: **Efficacy data**

- Kaplan-Meier curve





IPH 1101-201 study results

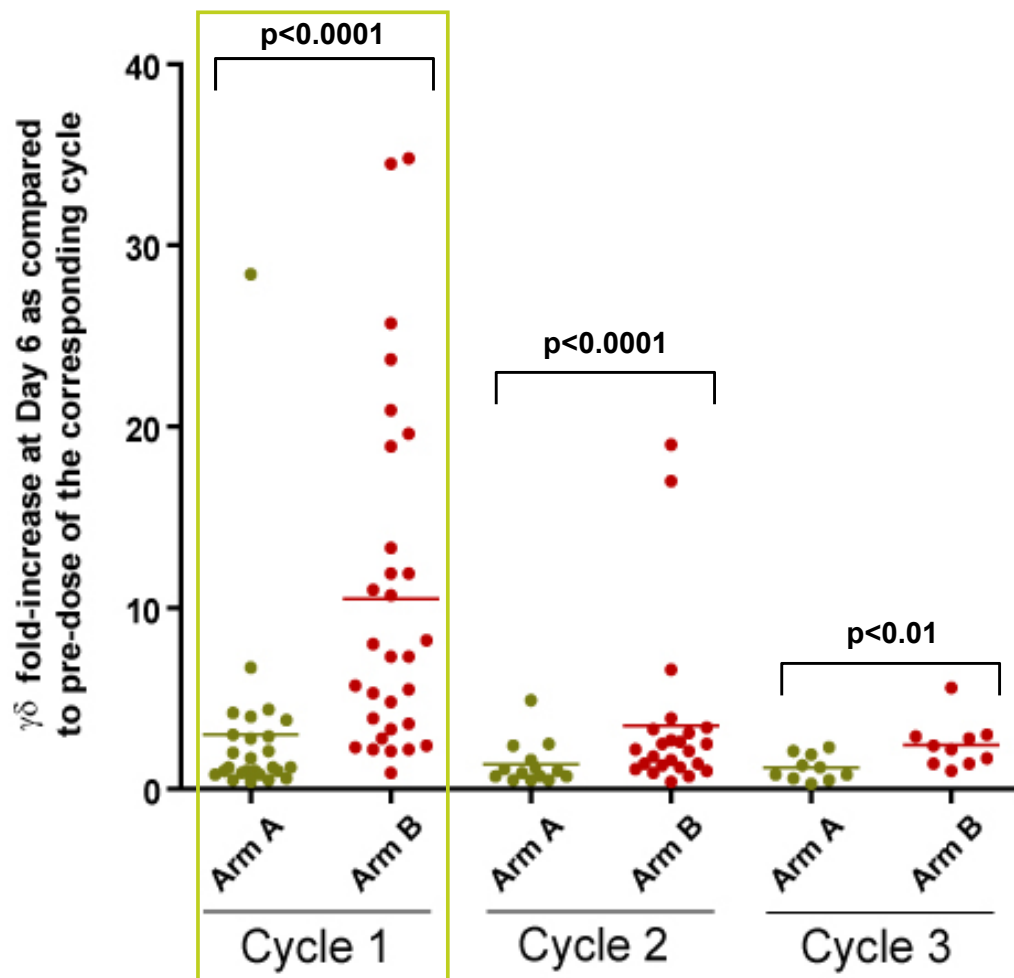
Secondary endpoint: Safety data

- 4 SAEs possibly or probably related to treatment (3 patients):
 - Pt 010701 /B grade 3 pneumonia
 - Pt 020202 /B grade 3 pneumonia
 - Pt 010201 /B grade 3 hypotension
grade 3 sinusal dysfunction + grade 3 hypothyroidism
 - Other related grade 3 adverse events: chills, hypotension (4 patients)
 - Grade 1 or 2 related adverse events: transient, mild or moderate (flu-like symptoms)
- ⇒ **Very good safety profile of the combination of IPH1101 with 4 MIU/m² IL-2**



IPH 1101-201 study results

Secondary endpoint: Pharmacodynamic data



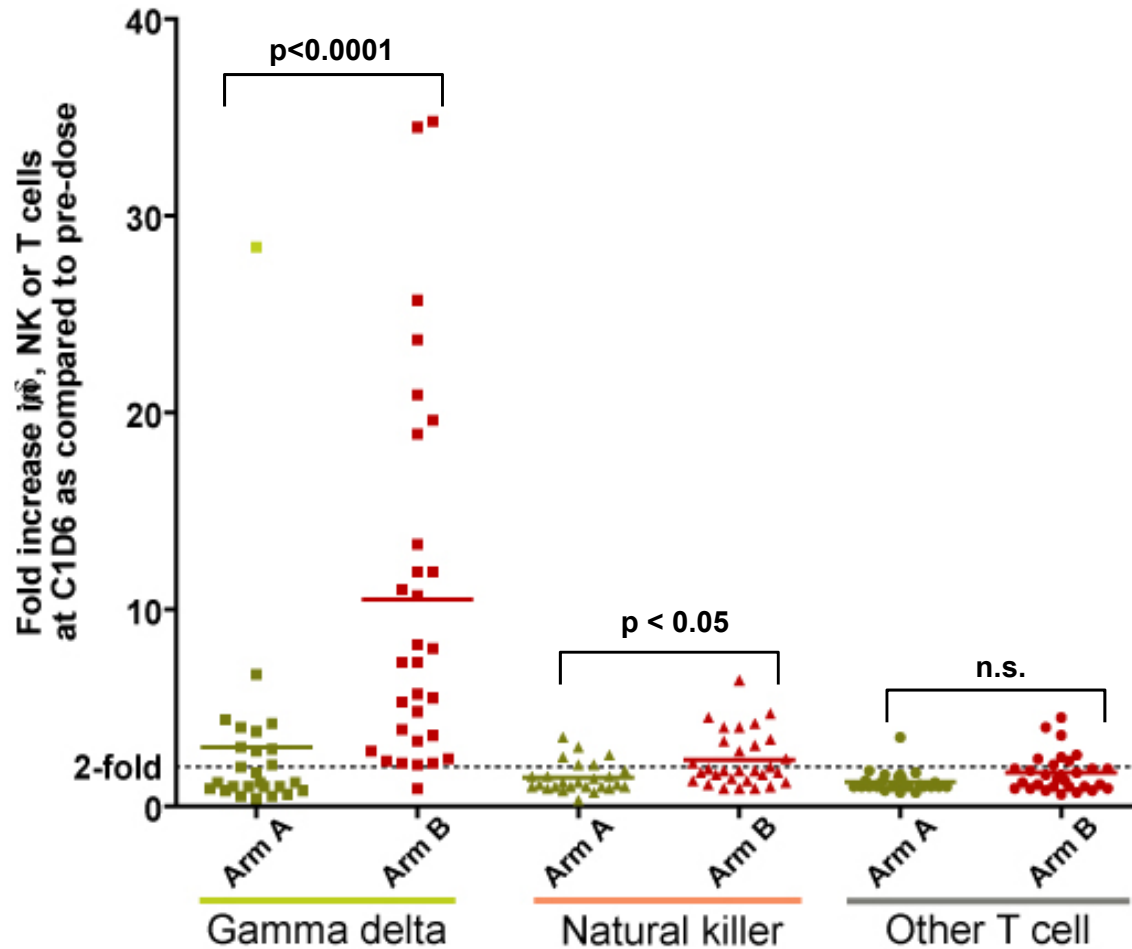
Amplification can be depicted until third treatment cycle at least

⇒ Robust dose-dependent pharmacodynamic effect



IPH 1101-201 study results

Secondary endpoint: Pharmacodynamic data



⇒ Amplification is specific to $\gamma\delta$ cell subset



IPH 1101-201 study results

Summary

- 69 patients randomized and treated
- Very good tolerance of the 4 MIU/m² IL-2 dose
- Significant higher in vivo amplification of the $\gamma\delta$ T cells with IL-2 at 4 MIU/m² vs 1 MIU/m²
- Tumor evaluation assessed by central review (67 patients reviewed, 63 patients evaluable)
- Primary end point not reached
- Difference between arm A and B on median PFS, yet non significant



IPH 1101-201 study results

Conclusions

- Efficacy endpoint not reached
- Challenging indication, previous failure to immunotherapy, high tumor burden, monotherapy
 - ⇒ **No further development of IPH 1101 in mRCC in monotherapy**
- Very good safety profile
- Robust and specific pharmacodynamics
- Choice of the IL-2 dosage enabling initiation of other Phase IIa trials
 - ⇒ **Other Phase IIa trials are ongoing in other settings and in combination**



IPH 1101: clinical **development plan**

Multiple **exploratory trials** to position the product

- **Oncology**

<i>Monotherapy</i>	<i>2nd line, metastatic</i>	<i>mRCC</i>
Combinations	2 nd & 3 rd line	fNHL Combination with rituximab
	Residual disease	CML Combination with imatinib
	1 st line, metastatic	Melanoma Combination with dacarbazine

- **Infectious diseases**

Monotherapy	1 st line	HCV
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