



IPH 1101

HCV Phase IIa results

June 29, 2009



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IPH 1101-203 Phase IIa in HCV patient

Key highlights

- Positive trial providing evidence of HCV viral load decrease upon IPH1101 treatment in monotherapy setting
- First proof of concept in man for $\gamma\delta$ T cell agonist IPH 1101
- 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



Rationale for HCV trial





Hepatitis C

Overview

- RNA flavivirus with 6 genotypes (genotype 1 = ~60%)
- Prevalence worldwide ~200 millions (~3 millions new cases per year)
- Risk of developing liver cirrhosis and hepatocarcinoma (1-5% of cases)
- Current standard of care with a combination of interferon (PEG-IFN) and ribavirin
 - Genotype 1 least sensitive to SOC (40% to 50% SVR)
- New anti-viral therapies in development (protease inhibitors),
 - Combination with SOC
 - Genotype 1 expected to reach 65-70% SVR
- The HCV market was worth \$2.3Bn in 2007 and is expected to grow to \$4.5Bn in 2017 (source: Datamonitor)



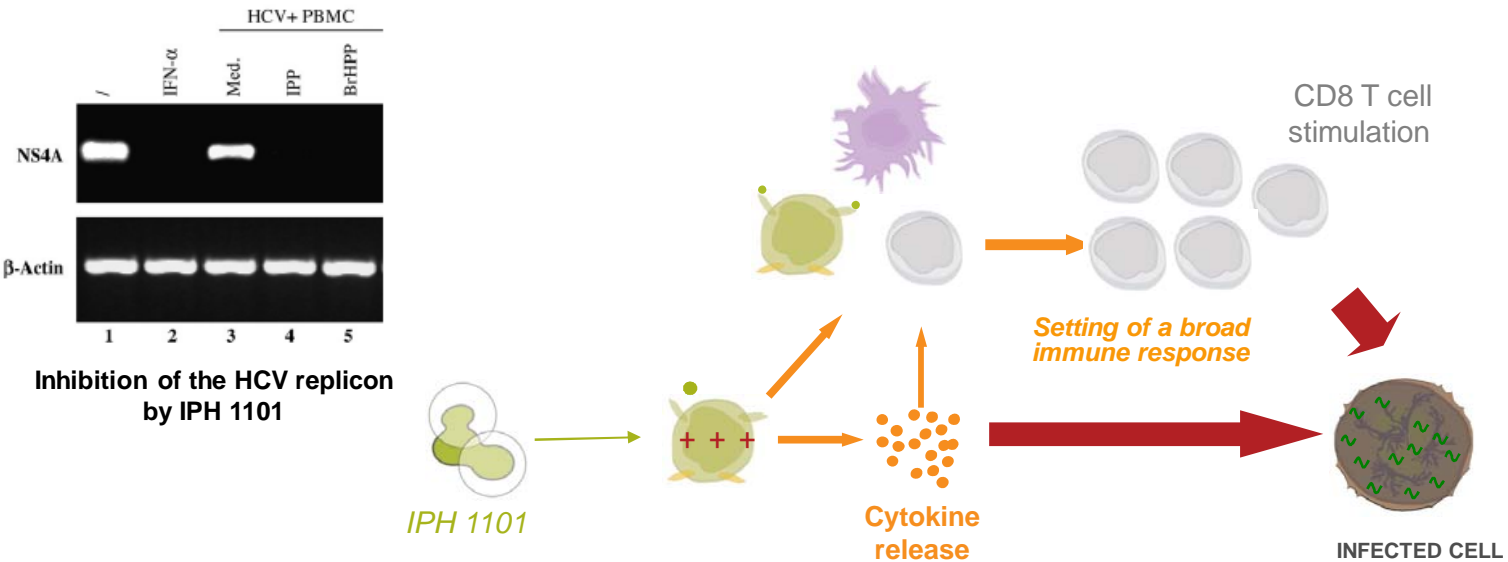
Hepatitis C

Persistent medical need

- Despite their efficacy, new targeted anti-viral treatments will leave an unmet medical need
 - A significant portion of the patients will not show a sustained viral response
 - They are given in combination with standard of care without reducing neither the dose nor duration of SOC
 - Compliance is an issue due to poor tolerance
- Need for new drugs to accelerate viral load decrease at treatment initiation
 - Initial kinetics of VL decrease correlates with long term and complete response
- Immunotherapy will remain a core component of treatment backbone
 - Virus clearance depends on effective immune response to overcome mutations

Mechanism of action of IPH 1101 in HCV

- $\gamma\delta$ T cells activated by IPH 1101:
 - Release soluble mediators that inhibit HCV replication (synergy with IFN α in pre-clinical models)
 - Might modulate the adaptive immune response to the virus by interacting with other immunocompetent cells





IPH 1101-203
Phase IIa trial in Type C Viral Hepatitis

- Open-label multicenter Phase IIa performed in France and Tunisia
- Patients chronically infected with HCV naïve or relapsing after a first line of therapy
- 2 administrations of IPH 1101 (750 mg/m², 30-min i.v. infusion, 3 weeks apart)
- 28 patients randomly assigned to 2 treatment arms:
 - Arm A (14 patients): IPH 1101 alone
 - Arm B (14 patients): IPH 1101 combined with low dose IL-2 (2 MIU daily for 5 days)
- Primary endpoint: decrease in viral load of at least 0.50 log₁₀*
- Objective for primary endpoint: >5 patients out of 13 evaluable in each arm
- Secondary endpoints: biomarkers for immune activation (cytokine release) and tolerance

* About 3-fold decrease



Trial demography

Arm		A	B
Evaluable for primary endpoint		13/14	12/14
Males/Females		9/5	10/4
Naïve / Relapsers		11 / 3	12 / 2
Genotypes	1	9	10
	2	3	1
	4	2	1
	Not assessed	0	2

3 patients not evaluable for technical reasons: 1 in Arm A and 2 in Arm B

Arm	A	B	A+B
Responders / Total population	5 / 13	7 / 12	12 / 25
Responders / Genotype 1 patients	4 / 9	6 / 10	10 / 19
Median decrease in responders	-0.69 log ₁₀ (+/- 0.15)	-0.65 log ₁₀ (+/- 0.13)	-0.67 log ₁₀ (+/- 0.13)

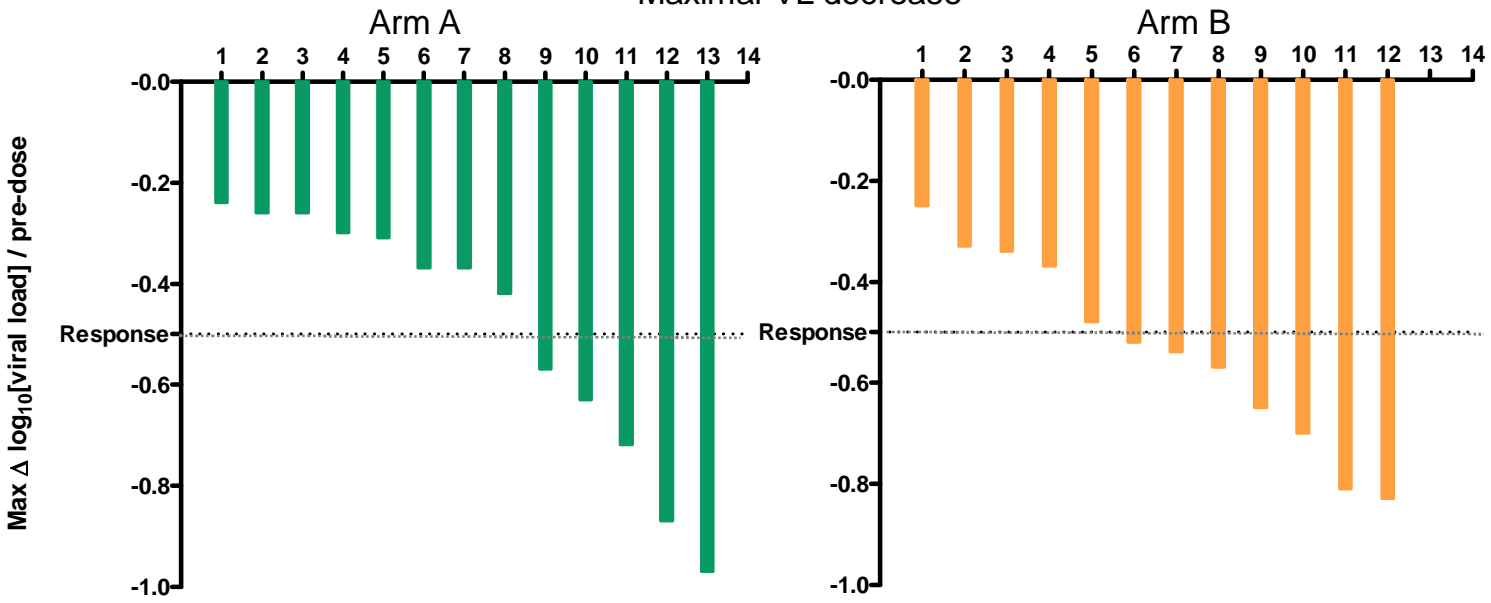
- Primary objective is met in arm B
- Evidence of antiviral activity in both arms
- Good response rate in genotype 1 patients
- Decrease is rapid (D2 for 11/12) and lasts up to 3 days after injection
- Very good tolerance in both arms, no SAE reported



Trial results (2/3)

Viral load decrease

Maximal VL decrease





Trial results (3/3)

Biological response

- Cytokine are released after IPH 1101 injection
 - Minor and transient cytokine release syndrome
 - Cytokines released are IFN γ , MCP1 and MIP 1 β
- Cytokine release is not dependent on IL-2 administration
- Cytokine release is strongly correlated with antiviral activity

	p-Value (Pearson correlation analysis)	
	Arm A	Arm B
$\Delta\log_{10}$ VL <i>versus</i> IFN γ	0.001	0.026
$\Delta\log_{10}$ VL <i>versus</i> MCP1	0.0004	0.0009
$\Delta\log_{10}$ VL <i>versus</i> TNF α	0.02	0.08
$\Delta\log_{10}$ VL <i>versus</i> MIP1 β	0.005	0.032



Trial results

Conclusions

- Demonstration that IPH 1101 has an anti-viral effect
- Proof of concept for the mechanism of action
- Very good tolerance of IPH 1101
- Significant response rate in genotype 1 patients
- Detailed results have been submitted to forthcoming international congresses



- Novel mechanism of action with demonstrated antiviral effect
- Strong pre-clinical rationale for combining with current SOC
- Persistent medical need in the indication
- Future step in Phase II program to position IPH 1101 in the context of emerging SOC



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