

### INNATE PHARMA REPORTS PHASE II CLINICAL DATA WITH IPH 1101 IN ONCOLOGY

- Encouraging interim efficacy data in non-Hodgkin's lymphoma ("NHL") reported at the ESMO meeting in Berlin; complete response rate above current standard of care for the first set of patients
- Enrolment of patients in the initial Phase I/II and Phase II a program with IPH 1101 started in 2006 completed; final data to open window for partnering discussions

Marseilles, France, September 21, 2009

Innate Pharma (Euronext Paris: FR0010331421 – IPH) reports today interim data from the Phase I/II clinical trial evaluating IPH 1101 in combination with rituximab<sup>7</sup> in follicular non-Hodgkin's lymphoma ("fNHL") patients (study "IPH 1101-202") and final data for the Phase IIa trial evaluating IPH 1101 in chronic myeloid leukemia ("CML") patients (study "IPH 1101-204").

In the IPH 1101-202 study, IPH 1101 in association with low-dose IL-2 is administered in combination with the standard of care rituximab to fNHL patients relapsing after at least one prior line of rituximab-containing treatment.

The primary efficacy endpoint is the overall response rate (complete and partial responses) at six months. Forty-five patients were treated during this trial, recruitment for which is now completed.

From the first 16 evaluable patients assessed by independent central review at six months, 9 patients showed a response (i.e. 56% Overall Response Rate, or "ORR"), including 7 patients showing a complete response (i.e. 44% Complete Response Rate or "CRR"). The response rate observed with standard of care (rituximab alone) in similar settings is about 40% ORR and about 10% CRR<sup>2</sup>.

The Company expects to report efficacy data at three months for all evaluable patients by the end of 2009. Final data on all evaluable patients are expected by mid-2010.

In the IPH 1101-204 study, IPH 1101 in association with low-dose IL-2 was administered to CML patients showing an incomplete response to the standard of care imatinib. A per protocol analysis of the 14 patients enrolled in the stage 1 of the study did not demonstrate a sufficient effect to move forward the study in a second stage (absence of complete molecular response).

Overall, in both studies, the treatment was well tolerated. The most frequent adverse events were cytokine release related, manageable and reversible.

The administration of IPH 1101 plus IL-2 triggered a robust pharmacodynamic effect with the amplification of  $\gamma\delta$  T cells and the release of immuno-stimulatory and cytotoxic cytokines in both studies. In the fNHL study (IPH 1101-202), the up-regulation of the ADCC-mediating receptor CD16 on  $\gamma\delta$  T lymphocytes was observed, substantiating a potential synergy of the mechanisms of action of IPH 1101 and rituximab.

<sup>&</sup>lt;sup>1</sup> Rituximab is a monoclonal anti-CD20 antibody, marketed for oncology and inflammatory indications under the brand Rituxan/MabThera by Roche/Genentech and Biogen-Idec. 2008 global sales amounted CHF 5.9 billion.

<sup>&</sup>lt;sup>2</sup> Davis et al., Journal of Clinical Oncology, 2000



The interim data of the IPH 1101-202 study were reported today by Pr. Rossi (Head of the Hemato-Oncology Department and the Center of Clinical Investigation BT 509, University Hospital, Montpellier), co-lead investigator of the study, in an oral presentation at the 2009 ECCO-ESMO Congress in Berlin.

**Pr. Rossi commented:** "Although the number of patients assessed in the fNHL trial (IPH 1101-202) is limited thus far, I consider these results as very encouraging". He added: "Rituximab has revolutionized the treatment of NHL patients. Nevertheless, as of today, only a minority of patients achieve a complete response. Therefore, another treatment, which is well tolerated and would potentiate the activity of rituximab leading to more complete responses, would really meet a medical need."

"We are getting towards the completion of our initial Phase II program with IPH 1101, which was one of our key objectives when we went public in 2006", said Hervé Brailly, CEO of Innate Pharma. "As previously stated, as final data become available, we will look for a partner that would take responsibility for late-stage clinical development and marketing of this program."

*Conference call:* Innate Pharma management will be hosting a conference call to discuss these results, today at 2:30 pm (Paris time).

Investors, journalists and financial analysts are invited to participate in the conference call by dialing +33 (0)1 72 00 09 84.

A slideshow is available on Innate Pharma's website (www.innate-pharma.com).

## About the Phase I/II trial with IPH 1101 in follicular non-Hodgkin's lymphoma (the "IPH 1101-202" trial):

The Phase I/II fNHL study (IPH 1101-202) is a multicenter trial performed in France, Belgium, Tunisia, Morocco and Germany. The trial is aimed at evaluating the efficacy of IPH 1101 and low-dose IL-2 in combination with rituximab, as well as the biological activity and safety of this combination in fNHL patients having relapsed after at least one course of rituximab therapy, and who are due to undergo an additional course of rituximab therapy.

The study rationale is based on two complementary data sets:

- the strong, well-established cytotoxicity of  $\gamma\delta$  T cells vis-à-vis lymphoma cells in cell culture models, and
- pre-clinical results showing synergy between rituximab and IPH 1101 activated  $\gamma\delta$  T cells in depleting lymphoma cells.

Efficacy is assessed based on standard response criteria:,best overall response within 6 months after treatment. Forty-five patients were entered. IPH 1101 therapy was started one week after the first administration of rituximab, and repeated at 3 week intervals for a total of 3 treatment courses.

In France, the trial is being performed with the assistance of the GELA and GOELAMS lymphoma collaborative study groups.



### About Non-Hodgkin's Lymphoma:

Non-Hodgkin lymphoma ("NHL") includes a heterogeneous group of more than 20 different malignant lymphoproliferative diseases that originate from lymphocytes.

NHL is the sixth most common cause of cancer related death in the United States and the incidence of the disease has increased up to 4% of all new cancer cases in 2006.

The second most frequent clinical entity that is recognised in the new lymphoma classification, after diffuse large B-cell lymphoma, is the follicular lymphoma (22% of all non-Hodgkin's Lymphoma). There were 63,190 new cases of follicular lymphoma in the United States in 2007 (Source: American Cancer Society, 2007).

### About the Phase II trial with IPH 1101 in Chronic Myeloid Leukemia (the "IPH 1101-204" study):

IPH 1101-204 was a Phase IIa study designed to evaluate the effect of IPH 1101 treatment combined with low dose IL-2 among patients with chronic myeloid leukemia and showing an incomplete molecular response under treatment with imatinib mesylate.

The rationale for the trial was based on pre-clinical studies showing a high level of cytotoxicity of  $\gamma\delta$  T cells against leukemic cells, even when they are resistant to imatinib. Approximately 40% of patients treated with imatinib mesylate and achieving a complete hematological response, still achieve an incomplete molecular response. These patients remain at risk of early disease relapse.

The effect of the treatment was evaluated on the BCR/ABL molecular marker. The protocol was designed according a two stage approach. A per protocol analysis of the 14 patients enrolled in the stage 1 of the study did not demonstrate a sufficient effect (absence of complete molecular response) to move forward the study in a second stage.

### About Chronic Myeloid Leukemia:

Chronic myeloid leukemia (CML) is a slowly progressing form of leukemia characterized by the proliferation of mature granulocytes and their bone marrow precursors. It was the first malignant disease to be associated with a genetic anomaly - the Philadelphia chromosome, which results from a reciprocal translocation between the ABL gene on chromosome 9 and the BCR gene on chromosome 22. The resulting BCR/ABL hybrid gene induces the production of a hybrid protein with strong tyrosine kinase activity; this deregulates the signal transduction pathways in the hematopoietic cells, which become leukemic. In the absence of treatment, CML evolves in three phases, usually beginning as a chronic, slowly worsening disease which then accelerates. The acceleration of the disease heralds progression into acute leukemia, with a very unfavorable prognosis.

In 2006, approximately 13,400 new cases of chronic myeloid leukemia occurred in the United States in 2006 (source: American Cancer Society, 2007). The disease can occur at any age but more commonly affects middle-aged and older people.



#### About IPH 1101:

IPH 1101 is a chemical agonist of the unconventional  $\gamma9\delta2$  T lymphocytes. It potentiates the direct cytotoxic activity of V $\gamma9V\delta2$  T cells against a large number of tumor cell lines and triggers the synthesis of pro-inflammatory cytokines - inducing the recruitment of other cell effectors and facilitating implementation of an adaptive response. It has been developed for intravenous delivery in association with subcutaneous, low-dose IL-2. While IPH 1101 activates  $\gamma9\delta2$  T lymphocytes, IL-2 enables the expansion of the V $\gamma9V\delta2$  T cell population.

IPH 1101 pharmacological activity involves the  $\gamma 9\delta 2$  TcR receptor. This is, as far as we know, the first example of a drug candidate activating a lymphocyte subpopulation by means of a receptor for the T cell antigen. IPH 1101 is tested in an exploratory Phase IIa program (more information on www.innate-pharma.com, in the Products/IPH 1101 section).

#### About Innate Pharma:

Innate Pharma S.A. ("the company") is a clinical-stage biopharmaceutical company developing first-in-class immunotherapy drugs for cancer and other severe diseases. The company was incorporated in 1999 and listed on NYSE-Euronext in Paris in 2006.

The company has significant expertise in identifying new targets and bringing novel drug candidates through to clinical proof-of-concept trials. It currently has seven proprietary drug candidates in development (two of which are in Phase II clinical trials) and two programs outlicensed to Novo Nordisk A/S.

Innate Pharma is based in Marseilles, France, and had 86 employees as at June 30, 2009.

Learn more about Innate-Pharma at www.innate-pharma.com.

Practical Information about Innate Pharma shares:

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### Disclaimer:

This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the *Document de Reference* prospectus filed with the AMF, which is available on the AMF website (http://www.amf-france.org) or on Innate Pharma's website.

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