

## INNATE PHARMA REPORTS PRELIMINARY PHASE I CLINICAL DATA FOR IPH 2101 (A NOVEL, ANTI-KIR MONOCLONAL ANTIBODY ACTIVATING NK CELLS) AT THE ASCO MEETING

- IPH 2101 was very well tolerated at all tested doses; the pharmacodynamic endpoint was met
- First Phase II trial with IPH 2101 used as a single agent in multiple myeloma to begin in 2009

### Marseilles, France, May 30, 2009

Innate Pharma (Euronext Paris: FR0010331421 – IPH) reports today preliminary results for two Phase I trials with IPH 2101 ("anti-KIR"<sup>\*</sup>) for patients with acute myeloid leukemia ("AML") and multiple myeloma ("MMy") at the 2009 American Society of Clinical Oncology ("ASCO") Meeting in Orlando (Florida, USA).

These results cover 44 patients (23 enrolled in the AML study and 21 enrolled in the MMy study), treated for a maximum of six cycles. They showed that IPH 2101 was very well tolerated: adverse events were rare, transient and of moderate intensity. Only two severe adverse events possibly drug-related were observed: transient and moderate bradycardia and hypotension for a patient in the AML study who received the maximum dose (3 mg/kg) and acute renal failure for a patient in the MMy study at dose level 4 (0.075 mg/kg).

In pharmacological terms, the objective of receptor saturation by IPH 2101 was met, with occupancy above 90% for four weeks at the highest doses in the AML study.

On the basis of these results, the dose and treatment schedules for the Phase II program have been chosen. The first Phase II trial of IPH 2101 as a single agent for MMy patients with stable residual disease after a first line of treatment should begin in 2009. Other trials with IPH 2101, including in combination with reference treatments, should follow.

"Even though a number of new treatments have been recently approved, multiple myeloma remains a devastating disease. There are several settings that can be considered in the disease course to demonstrate the efficacy of IPH 2101 either in combination or as a single agent." commented Dr. Don Benson (The Ohio State University Comprehensive Cancer Center in Columbus, Ohio), principal investigator in the MMy trial.

"Acute myeloid leukemia is a severe disease for which too many patients relapse after chemotherapy and only a few can benefit from bone marrow transplantation. A drug candidate such as IPH 2101, with a very novel mechanism of action, can improve the prognosis for this disease. First data from this study showed that IPH 2101 is very well tolerated and prompt us to investigate it further", said Dr. Norbert Vey (Institut Paoli Calmettes, Marseille), principal investigator in the AML trial.

"These results confirm our expectations in terms of safety; we have chosen a dose that has a clear pharmacodymamic effect. We will initiate our Phase II trials in multiple myeloma, that represents a strong medical need and benefits from a known surrogate endpoint: these two features should enable us to rapidly obtain efficacy data with IPH 2101", stated Dr. Marcel Rozencweig, Innate Pharma's Senior Vice President, Clinical and Regulatory Strategy.

<sup>&</sup>lt;sup>\*</sup> IPH 2101 targets and inhibits inhibitory receptors on NK cells (KIR), thereby potentiating their anti-tumor activity.



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## About the Phase I trial in acute myeloid leukemia (IPH 2101-101)

This Phase I trial evaluates the safety, tolerability and pharmacological profile of IPH 2101 in elderly AML patients in complete remission after induction and consolidation treatment. The trial features a dose-escalation protocol with seven dose levels (from 0.0003 to 3 mg/kg and 3 patients per dose level) and a single dose administration. The objective is to determine a safe and pharmacologically active dose. Patients who have not relapsed at the end of their treatment cycle can enter an extension study with repeated administrations.

23 patients were enrolled in this study. Preliminary data for these patients revealed good tolerance at all tested doses of IPH 2101, with rare, transient and moderate adverse events. Drug-related adverse events were mostly fever, rash and pruritis. The maximum tolerated dose has not been reached.

A clear relationship between dose/ blood concentration/ receptor occupancy was observed, in accordance with preclinical models and with low inter-patient variability. The full receptor occupancy objective was met.

These results are to be presented at the ASCO meeting (abstract 09-AB-34267) at the Poster Discussion Session of Sunday May 31, 2009, 2 PM - 6 PM. The poster will be available on the company's website (www.innate-pharma.com, in the IPH 2101 / AML section).

## About the Phase I trial in multiple myeloma (IPH 2101-103)

This Phase I trial evaluates the safety, tolerability and pharmacological profile of IPH 2101 in subjects with relapsed or refractory multiple myeloma who have relapsed or progressed on at least one prior systemic treatment. The trial features a dose-escalation protocol with seven dose levels (from 0.0003 to 3mg/kg and 3 patients per dose level) and multiple administration (four administrations, one every four weeks). The objective is to determine a safe and pharmacologically active dose. At the highest dose level, seven additional patients, less heavily pre-treated, will be enrolled.

Preliminary data on 21 patients (dose levels 0.0003 to 1 mg/kg; patients for the 1mg/kg level are being currently enrolled) show good tolerance at all tested doses of IPH 2101 with rare, transient and moderate adverse events. The maximum tolerated dose has not been reached so far.

In line with the results from the AML study and preclinical models, a clear relationship between dose/ blood concentration/ receptor occupancy was observed, with low inter-patient variability.

These results are to be presented at the ASCO meeting (abstract 09-AB-3032) on Saturday, May 30, 2009, 8 AM-12 AM. The poster will be available on the Company's website (www.innate-pharma.com, in the IPH 2101 / MMy section).



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### About acute myeloid leukemia ("AML")

Acute myeloid leukemia is one of the most common types of leukemia in adults in the United States and Europe. 13,290 new cases of AML were diagnosed in the United States in 2008, accounting for less than 1% of all cancers but more than 30% of all leukemias (source: American Cancer Society). The incidence of AML is low below the age of 40 but increases progressively with age, from approximately 1 per 100,000 at 40 to more than 15 per 100,000 at 75 and over. Most patients are diagnosed with AML after the age of 65 (Source: SEER Cancer Statistics Review, 2003).

In elderly patients, the prognosis for AML is very unfavorable, with a 5-year survival rate of about 5%. Although the complete treatment response rate is 50 to 60%, most patients relapse rapidly.

At present, the usual induction therapy (aimed at reducing the leukemic cell burden) is chemotherapy. One of the post-remission therapies is stem cell transplantation.

Successful treatment is far less frequent in elderly AML patients than in younger patients. Therefore, there is a need for an efficient drug with a better safety profile than existing AML treatment regimens - especially for elderly patients.

### About multiple myeloma ("MMy")

Multiple myeloma is the second most common hematological malignancy, with 19,900 new cases diagnosed every year in the United States and a similar incidence in Europe (Jemal et al., 2008). It is a plasmocyte malignancy, with overproduction of a monoclonal immunoglobulin (known as M Protein).

Standard treatment corresponds to induction chemotherapy and corticotherapy, followed (when possible) by intensification treatment with high dose chemotherapy and hematological rescue by autologous bone marrow transplantation. New classes of drugs combined with steroids and conventional chemotherapy have delivered major progress in terms of response rates and remission durations. Nevertheless, the disease remains mostly incurable.

#### About IPH 2101:

IPH 2101 is a fully human anti-KIR monoclonal antibody which potentiates NK cells' anti-cancer activity by blocking inhibitory NK cell receptors.

This cancer therapeutic approach has been indirectly validated by the work of Professor Andrea Velardi's research group at the University of Perugia in Italy (first published in 2002 and regularly updated since then). The work shows that in bone marrow transplantation for patients suffering from myeloid leukemia or multiple myeloma, grafted NK cells lacking functional KIR (inhibitory) receptors demonstrate high anti-tumoral activity - resulting in significantly higher patient survival rates (for more details, see www.innate-pharma.com, in the IPH 2101 section).

IPH 2101 was recently listed as one of the 100 most promising investigational drugs by R&D Directions magazine (the March 2008 edition).



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### About natural killer (NK) cells:

Natural killer cells are a type of white blood cell from the lymphocyte family, which also includes T cells and B cells.

These NK cells are present in large numbers in the bloodstream (accounting for up to 10% of circulating lymphocytes) and form part of the so-called innate immune system - the body's first line of defense against pathogens.

Natural killer cells are controlled by stimulatory and inhibitory signals received by surface receptors and can kill both malignant and virally-infected cells. They also play a key role in the control of inflammatory reactions and in the triggering and regulation of long-term adaptive immune responses.

#### 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. Founded in 1999, the company 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 clinical trials with lead compound in Phase II clinical trial) and two programs out-licensed to Novo Nordisk A/S.

Based in Marseilles, France, Innate Pharma had 88 employees as at March 31, 2009.

Learn more about Innate-Pharma at <u>www.innate-pharma.com</u>

Practical Information about Innate Pharma shares:

## ISIN code FR0010331421

## Ticker code IPH

#### 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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