

### THE US NATIONAL CANCER INSTITUTE STARTS A PHASE II CLINICAL TRIAL WITH INNATE PHARMA'S IPH 2101

### *IPH 2101 anti-KIR monoclonal antibody is tested in patients with smoldering myeloma*

Marseilles, France, January 12, 2011

Innate Pharma (the "Company" - Euronext Paris: FR0010331421 – IPH) announces that the National Cancer Institute ("NCI", National Institutes of Health, "NIH", Bethesda, Maryland, USA) has enrolled a first patient in a new Phase II clinical trial testing Innate Pharma's anti-KIR monoclonal antibody IPH 2101, in patients with smoldering myeloma, an early stage of the blood malignancy multiple myeloma.

This trial is developed, sponsored and funded by the NCI and performed in the United States under a clinical trial agreement with Innate Pharma. Innate Pharma will provide drug supply and has collaborated to the protocol design. The principal investigator of this trial is Ola Landgren, MD, PhD (Head, Multiple Myeloma Section, Center of Cancer Research, NCI, NIH, Bethesda, Maryland, USA).

"The launch of this novel clinical trial for patients with myeloma precursor disease at the NCI is an additional validation of the interest of the KIR blockade as a potential therapeutic approach", said Marcel Rozencweig, MD, EVP, Chief Medical Officer. He added: "Dr. Landgren is an international expert of multiple myeloma and its precursor conditions. His work will complement our own study and help us understand the role of activated NK cells in preventing and delaying transformation from smoldering myeloma into full-blown multiple myeloma".

### About the NCI-sponsored Phase II trial testing IPH 2101:

This study is a single-center, open label Phase II clinical trial designed to evaluate IPH 2101 as a single agent in patients with previously untreated smoldering myeloma.

The rationale of this trial is based on the capacity of activated NK cells to directly kill tumor cells and trigger a broad immune activation. This rationale is further strengthened by clinical studies showing that activated NK cells can very significantly lower the recurrence of various hematological malignancies, including multiple myeloma, following bone marrow transplantation\*.

The primary efficacy endpoint is the response rate, based mainly on the decrease in M protein blood and urine levels, a surrogate marker of the disease. Other endpoints include safety and pharmacodynamics. NIH's research laboratories will also conduct extensive correlative studies to define molecular underpinnings of clinical responses.

The protocol calls for inclusion of 19 patients in a two-stage design and will test a new administration regimen of IPH 2101.

Innate Pharma sponsors another Phase II trial testing IPH 2101 in smoldering myeloma patients (KIRMONO trial, see the Product section on the Company's website www.innate-pharma.com).

<sup>\*</sup> See the "About IPH 2101" section



#### About smoldering myeloma:

Multiple myeloma ("MM") is the second most common hematological malignancy, with over 20,000 new cases diagnosed every year in the United States and a similar incidence in Europe (Jemal et al., 2009). It is characterized by a malignant proliferation of abnormal plasma cells which populate the marrow-containing bones of the body. This translates into the overproduction of a monoclonal immunoglobulin (known as M-protein) which can be detected in the blood and used as a marker for the diagnosis and the follow-up of the disease.

Smoldering myeloma is an asymptomatic precursor state of MM. On average, patients with smoldering myeloma have an annual 10% risk of progressing to MM (Waxman AJ et al. Clin Lymphoma Myeloma Leuk. 2010; 10(4):248-57). At present, it has been estimated that smoldering myeloma accounts for approximately 15% of all newly diagnosed MM patients (Dimopoulos MA et al Blood 2000; 96:2037-44). Because it is asymptomatic and not treated today, smoldering myeloma is likely to be significantly under-diagnosed. It is reasonable to conjecture that the actual incidence for smoldering myeloma should be equal to or greater than the one of MM, as nearly all MM appear to derive from asymptomatic plasma cell proliferation (Landgren O. et al Blood 2009; 113: 5412-7 and Weiss BM et al Blood 2009; 113: 5418-22).

#### 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 therapeutic approach to cancer 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 following bone marrow transplantation from healthy donors in patients suffering from myeloid leukemia, grafted NK cells lacking functional KIR (inhibitory) receptors demonstrate high anti-tumoral activity - resulting in significantly higher patient survival rates. Another group published in 2005 similar results in patients transplanted with healthy donor hematopoietic cells for treatment of multiple myeloma. By blocking KIR receptors on NK cells, IPH 2101 aims at mimicking this situation (for more details, see the "IPH 2101" section at www.innate-pharma.com).

IPH 2101 has been tested in more than 50 patients so far. In these patient populations, IPH 2101 has been very well tolerated and met the pharmacodynamic objective of receptor saturation.

#### About natural killer (NK) cells:

Natural killer (NK) 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 the NIH and the NCI:

The NIH, a part of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting medical research. Helping to lead the way toward important medical discoveries that improve people's health and save lives, composed of 27 Institutes and Centers, the NIH provides leadership and financial support to researchers in every state and throughout the world.

With the headquarters in Bethesda, Maryland, the NIH has more than 18,000 employees on the main campus and at satellite sites across the U.S. With the support of the American people, the NIH annually invests over \$28 billion in medical research. More than 83% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world. About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.

The NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

The Center for Cancer Research (CCR) is home to more than 250 scientists and clinicians working in intramural research at NCI. CCR is part of the Clinical Center at the NIH in Bethesda, Maryland, the largest hospital devoted entirely to clinical research in the U.S. The Clinical Center is a national resource that makes it possible to rapidly translate scientific observations and laboratory discoveries into new approaches for diagnosing, treating, and preventing disease. CCR's investigators are basic, clinical, and translational scientists who work together to advance scientific knowledge and to develop new therapies.



About Innate Pharma:

Innate Pharma S.A. is a biopharmaceutical company developing first-in-class immunotherapy drugs for cancer and inflammatory diseases.

The Company specializes in the development of new monoclonal antibodies targeting receptors and pathways controlling the activation of innate immunity cells. It has two proprietary clinicalstage drug candidates: IPH 1101, a small molecule agonist of gamma delta T cells, has achieved proof-of-concept in two Phase IIa trials, in type C viral hepatitis and follicular lymphoma. IPH 2101, an anti-KIR monoclonal antibody potentiating NK cells activation, is currently in Phase II clinical trials in hematologic cancers. Innate Pharma is also developing a preclinical portfolio of immunomodulatory or cytotoxic monoclonal antibodies. Two of its preclinical programs in chronic inflammation have been out-licensed to Novo Nordisk A/S.

Innate Pharma's key expertise is in immunopharmacology and antibody technology. The Company has implemented in-house a large panel of molecular and cellular assays and in vivo models for assessing the pharmacodynamics and pharmacotoxicology of drug candidates. In addition, Innate Pharma has access to a very large set of unique research tools in cellular immunology through its worldwide network of scientific collaborations.

Incorporated in 1999 and listed on NYSE-Euronext in Paris in 2006, Innate Pharma is based in Marseilles, France, and had 84 employees as at September 30, 2010.

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 (<u>http://www.amf-france.org</u>) or on Innate Pharma's website.

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