

# PRESS RELEASE

**innate pharma**

## ENCOURAGING INITIAL RESULTS FOR IPH4102 PRESENTED AT THE THIRD WORLD CONGRESS OF CUTANEOUS LYMPHOMAS

- *Preliminary data from the dose-escalation part of an ongoing Phase I trial in elderly and heavily pretreated patients including a majority of patients with Sezary syndrome;*
- *IPH4102 shows good safety profile;*
- *Encouraging signs of clinical activity, with complete responses seen in skin and blood.*

Marseille, France, October 26, 2016

Innate Pharma SA (the "Company" - Euronext Paris: FR0010331421 – IPH), today announces encouraging preliminary safety and clinical activity results from the dose-escalation part of the Phase I study testing IPH4102 in patients with relapsed/refractory cutaneous T-cell lymphomas ("CTCL"), an orphan disease. IPH4102 is Innate Pharma's wholly-owned, first-in-class anti-KIR3DL2 humanized therapeutic antibody, designed to trigger immune cell-mediated killing of CTCL cancer cells.

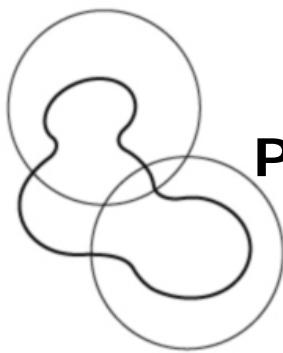
These data are presented in a poster at the Third World Congress of Cutaneous Lymphomas (October 26-28, 2016, New-York, USA) and will be discussed by the Principal Investigator, Professor Martine Bagot, Head of the Department of Dermatology at Saint-Louis Hospital (Paris) in the Scientific Session "Endpoints & Clinical Trials" on October 28, 2016, 1:30 – 2:45 p.m. EST.

The Phase I study is currently ongoing. Data are reported for the first seven dose levels (0.0001 to 1.5 mg/kg, 16 patients) of the dose-escalation part. In this population, IPH4102 was well-tolerated with no dose-limiting toxicity reported. The majority of adverse events is typical for CTCL or reflects low grade infusion-related reactions. As of September 10, 2016, the best global response rate was 38% across all dosage levels. Complete responses appeared with increasing doses and/or duration of exposure in skin and blood (respectively 2 and 3, seen in 4 patients)<sup>1</sup>. All responses are ongoing at the time of the analysis, which occurred after a median duration of treatment of 126+ days (range of 41+ to 298+).

Three additional dose levels (3, 6 and 10 mg/kg) remain to be evaluated and the dose escalation part of the trial is now expected to be completed by Q2 2017 (previously expected at the end of 2017).

*"These preliminary results are very encouraging and fully support the continuation of the development of the antibody candidate. By targeting KIR3DL2 on CTCL cells and triggering their killing by immune effector cells, IPH4102 has the potential to deliver a new treatment option for patients in high medical need at advanced stages of the disease," said Pierre Dodion, Chief Medical Officer of Innate Pharma. "The development of IPH4102 benefits from long lasting collaborations with Saint Louis Hospital in Paris and reference centers, such*

<sup>1</sup> In CTCL, global clinical response assessment is a composite of response evaluation in all organs involved with tumor cells, such as skin, blood, lymph nodes and viscera (E. Olsen et al, JCO 2011)



# PRESS RELEASE

**innate pharma**

as Stanford (US). Together we look forward to the complete safety data of the dose-escalation part of the trial and commencing cohort expansion of this new drug candidate, which is wholly-owned by Innate Pharma."

**Martine Bagot, Principal Investigator and Head of the Dermatology Department at the Saint-Louis Hospital, Paris, added:** "This study offers preliminary safety and efficacy results that are promising for IPH4102, in patients with CTCL subtypes that historically have been shown to be particularly difficult to treat. We are delighted with the progress that has been made with this candidate through translational research and an exceptional academic-industrial partnership."

The study started enrolling patients in November 2015. So far, 16 patients with KIR3DL2-positive CTCL have been enrolled in seven dose-cohorts, including 13 patients with Sézary syndrome, 2 patients with mycosis fungoides and 1 patient with CD4<sup>+</sup> CTCL. Median age was 71 years and patients had received 2 to 8 lines of prior systemic therapy for their disease.

All of the 16 patients treated with IPH4102 were evaluable for safety and clinical activity assessments.

As of September 10, 2016, patients had received up to 18 administrations of IPH4102. Treatment is ongoing in 12 patients. Preliminary results of exploratory endpoints such as pharmacodynamics in skin and blood are in line with clinical activity results (see poster #O-11), and show depletion of KIR3DL2-expressing tumor cells in skin and blood of patients after IPH4102 administrations.

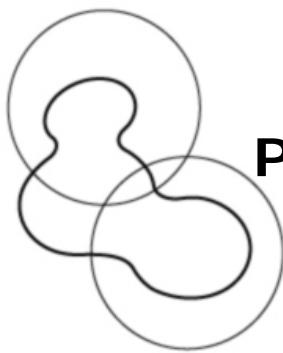
## **Presentation/ Poster Details**

The oral presentation, entitled "*First-in-Human, open label, multicenter phase I study of IPH4102, first-in-class humanized anti-KIR3DL2 mAb, in relapsed/refractory CTCL: preliminary safety and clinical activity results*" will take place on October 28, 2016, 1:30 – 2:45 p.m. EST. It will be available on the Company's website, in the Product Pipeline - IPH4102 section following the session. The associated poster is displayed during the entire congress and is available on Innate Pharma's website.

Simultaneously, poster #O-11 entitled "*First-in-Human, open label, multicenter phase I study of IPH4102, first-in-class humanized anti-KIR3DL2 mAb, in relapsed/refractory CTCL: preliminary results of exploratory biomarkers*" has been presented by Hélène Sicard, Anne Marie-Cardine and Maxime Battistella and is available on Innate Pharma's website under Product Pipeline - IPH4102.

## **About IPH4102 Phase I trial:**

The Phase I trial is an open label, multicenter study of IPH4102 in patients with relapsed/refractory CTCL which is performed in Europe (France, Netherlands, United Kingdom) and in the US (NCT02593045). Participating institutions include several hospitals with internationally recognized expertise: the Saint-Louis Hospital (Paris, France), the Stanford University Medical Center (Stanford, CA), the Ohio State University (Columbus, OH), the MD Anderson Cancer Center (Houston, Texas), the Leiden University Medical Center (Netherlands), and the Guy's and St Thomas' Hospital (United Kingdom). 45 to 60 patients with KIR3DL2-positive CTCL having received at least two prior lines of systemic therapy are expected to be enrolled in two sequential study parts:



## PRESS RELEASE

**innate pharma**

- A dose-escalation part including 25 to 40 CTCL patients in 10 dose levels. The objective is to identify the Maximum Tolerated Dose and/or the Recommended Phase 2 Dose (RP2D); the dose-escalation follows an accelerated 3+3 design;
- A cohort expansion part with 2 cohorts of 10 patients each in 2 CTCL subtypes (transformed mycosis fungoides and Sézary syndrome) receiving IPH4102 at the RP2D until progression. The cohort design (CTCL subtype, number of patients) could be revisited based on the findings in the dose escalation part of the study.

The primary objective of this trial is to evaluate the safety and tolerability of repeated administrations of single agent IPH4102 in this patient population. The secondary objectives include assessment of the drug's antitumor activity. A large set of exploratory analyses aims at identifying biomarkers of clinical activity. Clinical endpoints include overall objective response rate, response duration and progression-free survival.

### **About IPH4102:**

IPH4102 is a first-in-class anti-KIR3DL2 humanized cytotoxicity-inducing antibody, designed for treatment of CTCL, an orphan disease. This group of rare cutaneous lymphomas of T lymphocytes has a poor prognosis with few therapeutic options at advanced stages.

KIR3DL2 is an inhibitory receptor of the KIR family, expressed by approximately 65% of patients across all CTCL subtypes and expressed by up to 95% of certain aggressive CTCL subtypes, in particular, Sézary Syndrome and transformed mycosis fungoides. It has a restricted expression on normal tissues.

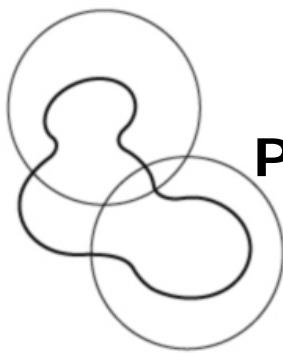
Potent antitumor properties of IPH4102 were shown against human CTCL cells *in vitro* and *in vivo* in a mouse model of KIR3DL2+ tumors, in which IPH4102 reduced tumor growth and improved survival. The efficacy of IPH4102 was further evaluated in laboratory assays using the patients' own natural killer (NK) cells against their primary tumor samples in the presence of IPH4102. These studies were performed in patients with Sézary Syndrome, the leukemic form of CTCL, which is known to have a very poor prognosis. In these experiments, IPH4102 selectively and efficiently induced killing of the patients' CTCL cells. These results were published in Cancer Research in 2014 (<http://www.ncbi.nlm.nih.gov/pubmed/25361998>).

IPH4102 was granted orphan drug status in the European Union for the treatment of CTCL.

### **About Cutaneous T-Cell Lymphoma ("CTCL"):**

CTCL is a heterogeneous group of non-Hodgkin's lymphomas which arise primarily in the skin and are characterized by the presence of malignant clonal mature T-cells. CTCL accounts for approximately 4% of all non-Hodgkin's lymphoma cases and has a median age at diagnosis of 55-65 years.

Mycosis fungoides, and Sézary Syndrome, its leukemic variant, are the most common CTCL subtypes. The overall 5-year survival rate, which depends in part on disease subtype, is approximately 10% for Sézary Syndrome and less than 15% for transformed mycosis fungoides. CTCL is an orphan disease and patients with advanced CTCL have a poor prognosis with few therapeutic options and no standard of care. There are approximately 6,000 CTCL patients in Europe and the United States.



# PRESS RELEASE

**innate pharma**

## About Innate Pharma:

Innate Pharma S.A. is a clinical-stage biotechnology company with a focus on discovering and developing first-in-class therapeutic antibodies that harness the innate immune system to improve cancer treatment and clinical outcomes for patients.

Innate Pharma specializes in immuno-oncology, a new therapeutic field that is changing cancer treatment by mobilizing the power of the body's immune system to recognize and kill cancer cells.

The Company's aim is to become a commercial stage biopharmaceutical company in the area of immunotherapy and focused on serious unmet medical needs in cancer. Innate Pharma has pioneered the discovery and development of checkpoint inhibitors to activate the innate immune system. Innate Pharma's innovative approach has resulted in three first-in-class, clinical-stage antibodies targeting natural killer cell receptors that may address a broad range of solid and hematological cancer indications as well as additional preclinical product candidates and technologies. Targeting receptors involved in innate immunity also creates opportunities for the Company to develop therapies for inflammatory diseases.

The Company's expertise and understanding of natural killer cell biology have enabled it to enter into major alliances with leaders in the biopharmaceutical industry including AstraZeneca, Bristol-Myers Squibb and Sanofi.

Based in Marseille, France, Innate Pharma has more than 130 employees and is listed on Euronext Paris.

Learn more about Innate Pharma at [www.innate-pharma.com](http://www.innate-pharma.com).

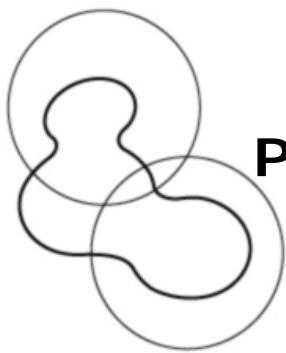
## About Innate Pharma shares:

<b>ISIN code</b>	FR0010331421
<b>Ticker code</b>	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.

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in Innate Pharma in any country.



## PRESS RELEASE

**innate pharma**

---

For additional information, please contact:

**Innate Pharma**

Laure-Hélène Mercier  
Director, Investor Relations  
Tel.: +33 (0)4 30 30 30 87  
[investors@innate-pharma.com](mailto:investors@innate-pharma.com)

**Press Contacts**

**ATCG Press (France)**  
Marie Puvieux  
Mob: +33 (0)6 10 54 36 72  
[presse@atcg-partners.com](mailto:presse@atcg-partners.com)

**Consilium Strategic Communications  
(ROW)**

Mary-Jane Elliott / Sue Stuart /  
Jessica Hodgson / Hendrik Thys

Tel.: +44 (0)20 3709 5700  
[InnatePharma@consilium-commms.com](mailto:InnatePharma@consilium-commms.com)