

# INNATE PHARMA REPORTS IPH4102 RESULTS IN ADVANCED CUTANEOUS T CELL LYMPHOMA (CTCL)

- Oral presentation on data with longer follow-up of dose escalation patients and new data from cohort expansion in the Phase I study at the EORTC CLTF 2018 Meeting
- IPH4102 showed encouraging clinical activity, demonstrated by high response rate and long progression-free survival (PFS)
- Sézary syndrome (SS) subset patients treated in the dose-escalation part (n=20) now show median PFS of close to 1 year

## Marseille, France, September 29, 2018, 8:30 AM CEST

Innate Pharma SA (the "Company" - Euronext Paris: FR0010331421 – IPH), today announced new data from the Phase I clinical trial of IPH4102 in patients with relapsed/refractory cutaneous T-cell lymphomas (CTCL). The data, including longer follow up for patients treated in the dose-escalation and observations from an additional patient cohort, will be presented today at the EORTC Cutaneous Lymphoma Group meeting in St. Gallen, Switzerland, by Pr Martine Bagot, Principal Investigator and Head of the Dermatology Department at the Saint-Louis Hospital, Paris. IPH4102 is Innate Pharma's wholly-owned first-in-class anti-KIR3DL2 antibody, designed for treatment of T-cell lymphoma.

"These data support the positive trends observed in the dose-escalation part of the trial and demonstrated a high response rate and long progression-free survival for these heavily pretreated CTCL patients, a majority being Sézary syndrome," commented Pierre Dodion, Chief Medical Officer of Innate Pharma. "Additionally, these data will serve as a basis for the initiation of a broader Phase II clinical program in Sézary syndrome and other subtypes of T-cell lymphomas. We look forward to providing more insight into the data and subsequent clinical development plans in the near future."

As of June 28, 2018, a total of 44 patients with relapsed/refractory CTCL were evaluable for safety and clinical activity. The study consisted of two parts: a dose-escalation (n=25) and a cohort expansion (n=19). Patients received a median of 3 prior systemic therapies. IPH4102 demonstrated a favorable safety profile and was well-tolerated. The study showed clinical activity that was demonstrated by a high response rate and long progression free survival.

In the total study population, the objective response rate (ORR) was 36% and median duration of response (DOR) and progression free survival (PFS) were 13.8 and 8.2 months, respectively. Sézary syndrome (SS) subset patients treated in the dose-escalation part (n=20) now show median PFS of close to 1 year. At the cut-off date of June 28, 2018, median follow-up was 12.7 months and nine patients were still ongoing treatment.

Better outcomes were observed in patients without evidence of histologic large cell transformation (LCT) (n=29); these patients achieved an ORR of 51.7% and PFS of 12.8 months. LCT is present in approximatively 10% of all Mycosis fungoides/Sézary syndrome patients and is associated with poorer prognosis and shorter survival using currently available therapies.

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<sup>&</sup>lt;sup>1</sup> Talpur, CLML 2016



"This patient population remains a high unmet medical need as they continue to progress through several lines of treatments," **commented Pr Martine Bagot, Principal Investigator.** "The patients with complete response, partial response and even those with stable disease showed an improvement in quality of life parameters overtime including pruritus. IPH4102's encouraging clinical activity provides substantial support to explore its potential therapeutic benefits not only in SS patients but also in other T cell lymphoma patient populations. Together with a favorable safety profile, IPH4102 could emerge as a key therapeutic option in aggressive T-cell lymphomas."

The presentation is available in the IPH4102 section on Innate Pharma's website.

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

The Phase I trial (NCT02593045) is an open label, multicenter study of IPH4102 in patients with relapsed/refractory CTCL which is performed in Europe (France, Netherlands and United Kingdom) and in the US. 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 (Leiden, Netherlands), and the Guy's and St Thomas' Hospital (London, United Kingdom). Up to 55 patients with advanced CTCL having received at least two prior lines of systemic therapy were to be enrolled in two sequential study parts:

- The dose-escalation part has accrued 25 KIR3DL2-positive CTCL patients in 10 dose levels. The objective was to characterize IPH4102 safety profile, identify the MTD and/or the RP2D; the dose-escalation followed an accelerated 3+3 design. Safety data of all dose levels were presented at the ICML meeting on June 14, 2017. Final results of the dose-escalation part were presented at the EORTC CLTF Meeting on October 15, 2017.
- The cohort expansion enrolled 15 patients with Sézary Syndrome and 4 tMF receiving IPH4102 at the RP2D until progression.

The primary objective of this trial was to evaluate the safety and tolerability of repeated administrations of single agent IPH4102 in this patient population. The secondary objectives included assessment of the drug's antitumor activity. Clinical endpoints included global objective response rate, response duration and progression-free survival. Exploratory analyses are aimed at identifying biomarkers of clinical activity.

#### 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 85% of them with certain aggressive CTCL subtypes, in particular, Sézary syndrome and transformed mycosis fungoides. It has a restricted expression on normal tissues.

IPH4102 was granted orphan drug status in the European Union and in the United States 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 lymphomas 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 new CTCL cases in Europe and the United States per year.

#### **About Innate Pharma:**

Innate Pharma S.A. is a clinical-stage biotechnology company dedicated to improving cancer treatment and clinical outcomes for patients through first-in-class therapeutic antibodies that harness the body's own immune system.

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 broad pipeline includes several first-in-class clinical stage antibodies as well as preclinical candidates and technologies that have the potential to address a broad range of cancer indications with high unmet medical needs.

Innate Pharma has pioneered the discovery and development of checkpoint inhibitors, with a unique expertise and understanding of Natural Killer cell biology. This innovative approach has resulted in major alliances with leaders in the biopharmaceutical industry including AstraZeneca, Bristol-Myers Squibb, Novo Nordisk A/S and Sanofi. Innate Pharma is building the foundations to become a fully-integrated biopharmaceutical company.

Based in Marseille, France, Innate Pharma has more than 180 employees and is listed on Euronext Paris.

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

### **Information about Innate Pharma shares:**

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



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