

# INNATE PHARMA TO PRESENT IPH4102 "TELLOMAK" CLINICAL TRIAL DESIGN AND PRECLINICAL PTCL DATA AT THE 2019 ICML

- Multicohort, multi-center, international Phase II study to evaluate the efficacy and safety of IPH4102 in patients with advanced T-cell lymphoma is ongoing
- Sézary syndrome cohort of the TELLOMAK study is designed to support potential BLA filing
- New preclinical data show IPH4102 and chemotherapy combination enhances KIR3DL2 expression and has superior anti-tumor activity, providing rationale for peripheral T-cell lymphoma (PTCL) cohort
- Management to host KOL call on Thursday, June 20, 2pm CEST / 8am ET

## Marseille, France, June 12, 2019, 10:00 AM CEST

Innate Pharma SA (the "Company" - Euronext Paris: FR0010331421 – IPH) today announced that the design of the "TELLOMAK" Phase II trial and new preclinical data supporting the potential of IPH4102 in peripheral T-cell lymphoma ("PTCL") as well as Adult T-cell leukemia/lymphoma ("ATLL") will be presented at the International Conference on Malignant Lymphoma ("ICML"), held from 18 to 22 June 2019 in Lugano, Switzerland.

An oral presentation will take place on Wednesday, June 19, by Pr. Pierluigi Porcu, Director of the Division of Medical Oncology and Hematopoietic Stem Cell Transplantation at Thomas Jefferson University, Philadelphia.

"We are committed to an efficient execution of the TELLOMAK trial, which could potentially support a future BLA submission for IPH4102 in Sézary syndrome", said Pierre Dodion, Chief Medical Officer of Innate Pharma. "The 2-stage design for the mycosis fungoides ("MF") and PTCL cohorts stratified by KIR3DL2 expression will allow us to identify patients that are most likely to benefit from treatment. We believe this will optimize the delivery of proof of concept data to inform the design of future potential pivotal trials. We expect to provide an update on the outcome of the first stage of the MF and PTCL cohorts in the second half of 2020 and report initial efficacy data for the different cohorts starting in 2021."

New preclinical data further support the rationale to evaluate the potential of IPH4102 in larger subsets of T-cell lymphoma. The findings demonstrate that KIR3DL2 is expressed in multiple subtypes of PTCL and that incubation of T-cell lymphoma cell lines with a combination chemotherapy regimen consisting of Gemcitabine and Oxaliplatin (GemOx) enhances KIR3DL2 expression. Moreover, the combination of IPH4102 and GemOx improves anti-tumor activity against a KIR3DL2-positive T-cell line *in-vitro*.

Another set of preclinical data supports the expansion of the IPH4102 development program in ATLL, which is mostly prevalent in Asia. The data demonstrates that KIR3DL2 expression is mainly associated with the ATLL acute subtype, a subtype that is the most frequent and associated with the poorest prognosis.



#### Presentation and Posters:

- "TELLOMAK: T-cell lymphoma anti-KIR3DL2 therapy: An open label, multicohort, multicenter, international phase II study evaluating the efficacy and safety of IPH4102 alone or in combination with chemotherapy in patients with advanced T-cell lymphoma", P. Porcu, Philadelphia, PA (USA); article Nr OT06; "Ongoing trials", Wednesday, June 19, 17:55, Aula Magna (USI Università)
- "KIR3DL2 is expressed in peripheral T-cell lymphomas and may be a therapeutic target",
  M. Cheminant, Paris (France); poster Nr. 157, poster discussion June 20-21, 12:30-13:00, Marquee
- "KIR3DL2 contributes to delineate the Acute-type and is a therapeutic target in Adult T-cell leukemia/lymphoma", M. Cheminant, Paris (France); poster Nr. 218, poster discussion June 20-21, 12:30-13:00, Marquee

### **About TELLOMAK:**

TELLOMAK is a global, open-label, multicohort Phase II clinical trial conducted in the United States and Europe. In this trial, IPH4102 is evaluated alone and in combination with chemotherapy in patients with advanced TCL. TELLOMAK is expected to recruit up to 250 patients, with IPH4102 evaluated:

- As a single agent in approximately 60 patients with Sézary syndrome who have received at least two prior treatments, including mogamulizumab,
- As a single agent in approximately 90 patients with MF who have received at least two systemic therapies, and
- In combination with standard chemotherapy (GemOx) in approximately 100 patients with PTCL who have received at least one prior treatment.

In patients with MF and PTCL, the study is designed to evaluate the benefit of IPH4102 according to KIR3DL2 expression: the study will comprise two cohorts for each of the 2 indications, testing IPH4102 in KIR3DL2 expressing and non-expressing patients. These cohorts will follow a Simon 2-stage design that will terminate if treatment is considered futile. The Sézary syndrome arm of the study could enable the registration of IPH4102 in this indication.

The primary endpoint of the trial is objective response rate. Key secondary measures include incidence of treatment emergent adverse events, quality of life, overall response rate, progression-free survival and overall survival.

#### About IPH4102:

IPH4102 is a first-in-class anti-KIR3DL2 humanized cytotoxicity-inducing antibody, designed for treatment of Cutaneous T-Cell Lymphoma ("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. In January 2019, the US Food and Drug Administration ("FDA") granted Innate Pharma Fast Track designation for IPH4102 for the treatment of adult patients with relapsed or refractory Sézary syndrome who have received at least two prior systemic therapies.

### **About Cutaneous T-Cell Lymphoma:**

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.

MF, 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. 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 Peripheral T-Cell Lymphoma:

PTCL represents a group of non-Hodgkin lymphomas of mature T-cell origin with generally aggressive clinical behavior (Armitage, 2015). The three predominant aggressive PTCL subtypes in the Western countries are: PTCL not otherwise specified ("NOS"); angioimmunoblastic T-cell lymphoma ("AITL"); and anaplastic T-cell lymphoma ("ALCL"). In aggregate, PTCL accounts for approximately 10% of all non-Hodgkin's lymphomas and has a median age at diagnosis around 65 years.

Multi-agent chemotherapy is the recommended first line treatment for the majority of patients with PTCL (NCCN guidelines). Brentuximab vedotin has been approved by the US FDA in combination with first line chemotherapy for patients with CD30 positive PTCL in November 2019 (Horwitz et al., The Lancet 2019, ECHELON-2 Study Group). Stem cell transplantation ("SCT") is a potentially curative option but is restricted to a minority of patients who are young, fit and achieve a complete response to systemic therapy (Wilhelm, Smetak et al. 2016). Hence a high proportion of patients need second line therapy. Belinostat, pralatrexate and romidepsin have been approved by the FDA in this setting, but efficacy is generally limited (O'Connor, Zcan et al. 2015). None of these treatments have been approved by the EMA. Brentuximab vedotin is also approved in the second line setting (Pro, Advani et al. 2017), but if used in the first line, it may no longer be second line treatment option for patients.

### **About Innate Pharma:**

Innate Pharma S.A. is a commercial stage oncology-focused biotech company dedicated to improving treatment and clinical outcomes for patients through therapeutic antibodies that harness the immune system to fight cancer.

Innate Pharma's commercial-stage product, Lumoxiti, in-licensed from AstraZeneca, was approved by the FDA in September 2018. Lumoxiti is a first-in class specialty oncology product for hairy cell leukemia ("HCL"). Innate Pharma's broad pipeline of antibodies includes several potentially first-in-class clinical and preclinical candidates in cancers with high unmet medical need.



Innate has been a pioneer in the biology of NK cells, and has expanded its expertise in the tumor microenvironment and tumor-antigens, as well as antibody engineering fields. This innovative approach has resulted in a diversified proprietary portfolio and major alliances with leaders in the biopharmaceutical industry including Bristol-Myers Squibb Novo Nordisk A/S, Sanofi, and a multi-products collaboration with AstraZeneca.

Based in Marseille, France, Innate Pharma is listed on Euronext Paris.

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

### 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 French Financial Markets Authority ("AMF") on April 30, 2019 under number no. D.19-0444, which is available on the AMF website www.amffrance.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.

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