INNATE PHARMA ANNOUNCES UPDATED RESULTS THAT SUPPORT ADVANCEMENT OF IPH4102 IN REFRACTORY SÉZARY SYNDROME AT THE AMERICAN SOCIETY OF HEMATOLOGY (ASH) 2018 ANNUAL MEETING

- Differentiating profile of IPH4102 confirmed: high and durable response, favorable safety profile with long-term follow-up and substantial improvement in quality of life
- Innate Pharma expects to initiate a global Phase II study ("TELLOMAK") in different subtypes of T-cell lymphomas in the first half of 2019
- Management to host KOL call Tuesday, December 4, 5pm CET (8am PST)

Marseille, France, December 3, 2018, 20:45 PM CET

Innate Pharma SA (the “Company” - Euronext Paris: FR0010331421 – IPH), today announced updated data from the Phase I trial (including an expansion cohort) evaluating IPH4102 in refractory patients with Sézary syndrome (SS) and its plan to advance IPH4102 in a multi-cohort Phase II study in different subtypes of T-cell lymphoma. An oral presentation will take place on Monday, December 3, at the ASH 2018 Annual Meeting in San Diego, USA, by Pr Martine Bagot, Head of the Dermatology Department at the Saint Louis Hospital, Paris and Principal Investigator of the study. IPH4102 is Innate Pharma’s wholly-owned first-in-class anti-KIR3DL2 antibody, designed for treatment of T-cell lymphoma.

As of October 15, 2018, data from the subgroup of 35 SS patients revealed strong clinical activity, demonstrated by an overall response rate (ORR) of 42.9%, median duration of response (DoR) of 13.8 months and median progression-free survival (PFS) of 11.7 months.

Mogamulizumab pretreated patients (n=7) showed an ORR (42.9%), median DoR (13.8 months) and median PFS (16.8 months) similar to the entire group. The ORR appeared to be higher (n = 28, 53.6%) in patients with no histologic evidence of large cell transformation (LCT)\(^1\).

“The solid updated data on IPH4102 presented today strongly encourage us to advance IPH4102 in refractory Sézary syndrome patients. We believe that the planned Phase II study, together with the Phase I data, has the potential to support a BLA submission in this indication,” commented Pierre Dodion, Chief Medical Officer of Innate Pharma. "In addition, the expression profile of KIR3DL2 provides a strong rational to explore the potential of IPH4102 in other subtypes of T-cell lymphomas in the TELLOMAK phase II study”.

Importantly, clinical activity was associated with a substantial improvement in quality of life as assessed by the SkinDex29 and Pruritus Visual Analog Scale (VAS) scores. IPH4102 displayed a favorable safety profile, consistent with previous observations.

\(^1\) LCT is present in approximatively 10% of Sézary syndrome patients (Talpur, CLML 2016) and is associated with poorer prognosis and shorter survival.
“Refractory Sézary syndrome patients have limited effective treatment options in later lines of therapy, with toxicity remaining an area of great concern with currently approved drugs,” commented Professor Martine Bagot, Principal Investigator of the study. “IPH4102, in addition to demonstrating an impressive clinical activity, has shown a favorable safety profile and substantially improves the quality of life even in patients with stable disease. Translational results show relevant pharmacodynamics effects of IPH4102 in skin and in blood, which are in line with the clinical efficacy of the drug.”

Exploratory biomarker analysis show early elimination of aberrant tumor cells and peripheral blood KIR3DL2+ CD4 T cells upon IPH4102 administration in responding patients.

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

KOL webcast and conference call on Tuesday, December 4, at 5pm CET (8am PST)

Pierre Dodion, Chief Medical Officer, Innate Pharma, will be joined by Prof. Martine Bagot, Head of Dermatology Department at the Saint Louis Hospital, Paris and lead investigator of the study, for a live webcast and conference call with a Q&A session on Tuesday, December 4 at 5pm CET to discuss the announcement.

The presentation and access to the live webcast will be available at this link: https://edge.media-server.com/m6/p/229ej2mw

Participants can also join the conference call using the following dial-in numbers:

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The participation code is: 4535688

An audio replay file will be made available after the session via Innate Pharma’s website: www.innate-pharma.com

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 at 10 dose levels. The objective was to characterize IPH4102 safety profile and to 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 19 patients with Sézary Syndrome (n=15) and tMF (n=4) 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 Peripheral T-Cell Lymphoma (“PTCL”):
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 recently approved by the US FDA in combination with first line chemotherapy for patient with CD30 positive PTCL (FDA press release, Nov 16, 2018). Stem cell transplantation (SCT) is a potentially curative option but is rather restricted to a minority of patients who are young, fit and achieve 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 EMA. Brentuximab vedotin is also approved in the 2nd line setting (Pro, Advani et al. 2017), but if used in the first line, it may no longer be an option in 2nd line patients.

About Innate Pharma:

Innate Pharma S.A. is a fully integrated 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 first-in-class clinical and preclinical candidates in cancers with high unmet medical need.

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 Bristol-Myers Squibb, Novo Nordisk A/S, Sanofi, and a landmark and multi-products partnership with AstraZeneca/MedImmune.

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

Learn more about Innate Pharma at www.innate-pharma.com
ISIN code
FR0010331421
Ticker code
IPH
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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 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.

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