

FRENCH REGULATORY AGENCY AGREES LACUTAMAB TELLOMAK TRIAL CAN RESUME RECRUITMENT IN SEZARY SYNDROME AND MYCOSIS FUNGOIDES

Marseille, France, January 13, 2020, 11:00 pm CET

Innate Pharma SA (Euronext Paris: IPH – ISIN: FR0010331421; Nasdaq: IPHA) ("**Innate**" or the "**Company**") today announced that the French National Agency for Medicines and Health Product Safety (ANSM) has agreed that the lacutamab (IPH4102) TELLOMAK Phase II trial can resume recruitment of new patients with relapsed/refractory Sézary syndrome and mycosis fungoides (MF) who have received at least two lines of prior systemic therapy.

Following discussions with the Company, the ANSM decision to allow new patient recruitment to resume in Sézary syndrome and MF in France is based on an assessment of the unmet medical need and the lack of currently available standard of care options. Conversely, because standard of care options are available to patients with peripheral T-cell lymphoma (PTCL), no new patients can enroll in the trial until a new Good Manufacturing Practice (GMP)-certified batch is available. However, currently enrolled PTCL patients can continue treatment in the trial.

In light of this feedback, the Company will take the operational measures to reactivate the lacutamab TELLOMAK trial in Sézary syndrome and MF in France and UK, where regulatory agencies have authorized it.

"We are pleased that the ANSM agrees to resume enrollment of patients with Sézary syndrome and mycosis fungoides in the lacutamab TELLOMAK trial in France given the high medical need and lack of adequate treatment options currently available," **commented Pierre Dodion, MD, Executive Vice President and Chief Medical Officer of Innate Pharma.** "Our utmost priority has been to ensure patient safety, and ANSM did not cite any safety concerns related to the trial medication."

As a reminder, the Company has been in ongoing discussions with US and European national regulatory authorities regarding GMP deficiencies at the Company's manufacturing subcontractor site that manages the fill and finish operations of the lacutamab clinical vials for the TELLOMAK trial. TELLOMAK has been on partial clinical hold globally since Dec. 13, 2019, except in Italy where the clinical trial has been suspended. On Jan. 9, 2020, the US Food and Drug Administration placed the TELLOMAK trial on partial clinical hold. The Company has not yet received feedback from regulatory authorities in Germany and Spain.

About the GMP Deficiency:

This situation is related to GMP deficiencies put forward by the Company's manufacturing subcontractor, Rentschler Fill Solutions GmbH or "RFS" (now known as Impletio Wirkstoffabfüllung GmbH). RFS was granted a Good Manufacturing Practice (GMP) certificate by the Austrian regulatory agency in August 2018, which was further confirmed in October 2019 after two on-site inspections. In November, RFS unilaterally withdrew the Certificate of Conformity of batches they have produced, including the lacutamab batch currently used in the TELLOMAK trial. RFS also filed for bankruptcy.



The Company's utmost priority is to ensure patient safety. An extensive internal and third-party analysis concluded that there was no evidence that the integrity of the product was questioned.

About Lacutamab:

Lacutamab (formerly 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. It has a restricted expression on normal tissues.

Lacutamab 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 lacutamab for the treatment of adult patients with relapsed or refractory Sézary syndrome who have received at least two prior systemic therapies.

About the TELLOMAK Trial:

TELLOMAK is a global, open-label, multi-cohort Phase II clinical trial conducted in the United States and Europe. In this clinical trial, lacutamab is being evaluated alone and in combination with chemotherapy in patients with advanced t-cell lymphomas (TCL). TELLOMAK was expected to recruit up to 250 patients, with lacutamab 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 mycosis fungoides (MF) who have received at least two prior treatments, and
- In combination with standard chemotherapy (gemcitabine and oxaliplatin) in approximately 100 patients with peripheral t-cell lymphoma (PTCL) who have received at least one prior treatment.

In patients with MF and PTCL, the study is designed to evaluate the benefit of lacutamab according to KIR3DL2 expression. The study comprises two cohorts for each of the two indications, testing lacutamab in KIR3DL2 expressing and non-expressing patients. These cohorts 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 lacutamab 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 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 in the US, EU and Switzerland, was approved by the FDA in September 2018. Lumoxiti is a first-in class specialty oncology product for hairy cell leukemia. 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 understanding of natural killer cell biology and has expanded its expertise in the tumor microenvironment and tumor-antigens, as well as antibody engineering. 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 and Nasdag in the US.

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

Information about Innate Pharma shares:

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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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