

# INNATE PHARMA PROVIDES UPDATE ON LACUTAMAB TELLOMAK TRIAL

# Marseille, France, December 13, 2019, 7:00 am CET

Innate Pharma SA (Euronext Paris: IPH – ISIN: FR0010331421; Nasdaq: IPHA) ("**Innate**" or the "**Company**") announced an update regarding its TELLOMAK Phase II trial evaluating the efficacy and safety of lacutamab (IPH4102, a potentially first-in-class anti-KIR3DL2 antibody). The Company will take the following actions based on ongoing discussions with regulatory authorities regarding a quality issue related to the chemistry, manufacturing and controls (CMC) process:

- Lacutumab will not be administered to new patients in the TELLOMAK trial until additional feedback is received from the respective regulatory agencies overseeing our clinical trial.
- Until further notice, the Company will continue to treat patients who are currently enrolled in the multi-center trial, except in Italy where the clinical trial has been suspended due to the feedback from Italian regulatory authorities.

This decision is related to issues with the Company's manufacturing subcontractor, Rentschler Fill Solutions GmbH or "RFS" (now known as Impletio Wirkstoffabfüllung GmbH). RFS has recently withdrawn the Certificate of Conformity of batches they have produced, including the lacutamab batch currently used in the TELLOMAK trial. RFS was granted a Good Manufacturing Practice (GMP) certificate by the Austrian regulatory agency in August 2018 and further confirmed in October 2019. In parallel, RFS filed for bankruptcy.

The Company's utmost priority is to ensure patient safety, and no new safety issues have been reported to date in the TELLOMAK trial. An extensive internal and third-party analysis concluded that there was no element that would affect the CMC quality of the product.

Innate will provide an update once it has received additional feedback from the relevant regulatory agencies. In parallel, the Company is working on resolution of the quality issues related to the CMC matter.

#### **About Lacutamab:**

Lacutamab (formerly IPH4102) is a potentially 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 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 TCL. TELLOMAK is 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 MF who have received at least two prior treatments, and
- In combination with standard chemotherapy (gemcitabine and oxaliplatin) 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 lacutamab according to KIR3DL2 expression. The study comprises two cohorts for each of the two indications, testing lacumatab 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 Nasdaq in the US.

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

**Information about Innate Pharma shares:** 

ISIN code Ticker code LEI FR0010331421 Euronext: IPH Nasdaq: IPHA 9695002Y8420ZB8HJE29





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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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