

# U.S. FOOD AND DRUG ADMINISTRATION LIFTS PARTIAL CLINICAL HOLD ON LACUTAMAB TELLOMAK TRIAL IN ADVANCED T-CELL LYMPHOMAS

Innate Pharma to re-activate TELLOMAK trial in the US

New GMP-certified batch has been successfully manufactured

Conference call to be held today on the lacutamab clinical trial program

Marseille, France, June 24, 2020, 7:00 AM CEST

Innate Pharma SA (Euronext Paris: IPH – ISIN: FR0010331421; Nasdaq: IPHA) ("**Innate**" or the "**Company**") today announced that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold placed on the lacutamab TELLOMAK Phase II clinical trial, evaluating the efficacy and safety of lacutamab (formerly IPH4102) in patients with advanced T-cell lymphomas.

The FDA decision is based on a quality assessment of a new Good Manufacturing Practice (GMP)-certified batch that has been successfully manufactured for the lacutamab clinical development program, including the TELLOMAK trial. The Company can now resume recruitment of new patients in the US with relapsed/refractory Sézary syndrome and mycosis fungoides (MF) who have received at least two prior systemic therapies.

In light of the FDA feedback, the Company is taking the operational measures to re-activate the US clinical trial sites.

"We are pleased that the FDA has approved the new clinical batch for the TELLOMAK trial, and we can resume enrollment of patients with Sézary syndrome and mycosis fungoides given the importance of novel and effective treatment options needed for these patient populations," commented Pierre Dodion, MD, Executive Vice President and Chief Medical Officer of Innate Pharma. "We're confident in our ability to supply lacutamab in this important trial moving forward, and look forward to reactivating the trial globally as quickly as possible."

As a reminder, the FDA placed the TELLOMAK trial on partial hold due to GMP deficiencies at the Company's manufacturing subcontractor site that managed the fill and finish operations of the lacutamab clinical vials for TELLOMAK. In Europe, the national regulatory authorities in Spain, Italy and Germany temporarily halted the trial whereas the French and UK regulatory authorities agreed to resume trial recruitment in those respective countries earlier this year. The Company is consulting the regulatory authorities in Germany, Italy and Spain in order to resume the trial in these countries soon.

The Company expects to start sharing data from the TELLOMAK trial for mycosis fungoides in 2021 and Sézary syndrome in 2022.



Analyst webcast and conference call will be held today at 4:00pm CEST (10:00am EST)

Innate Pharma will host a live webcast and conference call today to discuss its lacutamab clinical trial program, including the Company's PTCL strategy.

The presentation and live webcast details are available on Innate Pharma's web site at www.innate-pharma.com, and below:

**Webcast:** <a href="https://edge.media-server.com/mmc/p/e65nrsvu">https://edge.media-server.com/mmc/p/e65nrsvu</a>

#### **Conference call dial in details:**

France: +33 (0)170 700 781 | US: + 1 877 870 9135 | International: +44 (0) 2071 928 338

Conference ID: 20679317

A replay will be available on Innate Pharma's website after the conference call.

#### **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 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 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 in patients with advanced t-cell lymphomas (TCL). TELLOMAK is expected to recruit up to 150 patients, with lacutamab evaluated:

- As a single agent in approximately 60 patients with Sézary syndrome who have received at least two prior systemic therapies, including mogamulizumab
- As a single agent in approximately 90 patients with mycosis fungoides (MF) who have received at least two systemic therapies

In patients with MF, the study is designed to evaluate the benefit of lacutamab according to KIR3DL2 expression. The study comprises two cohorts in MF, 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 cohort 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 <a href="www.innate-pharma.com">www.innate-pharma.com</a>

# **Information about Innate Pharma shares:**

**ISIN code** FR0010331421

**Ticker code** Euronext: IPH Nasdaq: IPHA **LEI** 9695002Y8420ZB8HJE29

### Disclaimer:

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "believe,"



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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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