

# Innate Pharma Provides Update on Lacutamab Clinical Program

10/5/2023

- Phase 2 TELLOMAK trial fully recruited, final data expected Q4 2023
- Phase 1b PTCL trial awaiting futility interim analysis, preliminary data expected Q4 2023
- US FDA places lacutamab IND on partial clinical hold for new patient enrollment following one unexpected severe adverse reaction

MARSEILLE, France--(BUSINESS WIRE)-- Innate Pharma SA (Euronext Paris: IPH; Nasdaq: IPHA) ("**Innate**" or the "**Company**") today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on the lacutamab IND leading to a pause in new patient enrollment to the Company's ongoing lacutamab trials IPH4102-201 (Phase 2 TELLOMAK) and 102 (Phase 1b PTCL). The partial clinical hold follows one fatal case of hemophagocytic lymphohistiocytosis (HLH), a rare hematologic disorder. Patients already on study treatment who are deriving clinical benefit may continue treatment after being reconsented.

TELLOMAK, Innate Pharma's ongoing Phase 2 trial of lacutamab in cutaneous T-cell lymphoma (CTCL), completed enrollment in Q2 2023 (n=170 patients). Enrollment is also completed to the initial cohort (n=20 patients) of the Phase 1b PTCL trial and is awaiting a futility interim analysis to progress to the next stage. Innate Pharma is on track for final data from the Phase 2 TELLOMAK trial and preliminary data on PTCL in Q4 2023.

"Patient safety is of paramount importance to us, and we are currently undertaking efforts to address the FDA requests, which include incorporation of risk mitigation and management strategies for hemophagocytic lymphohistiocytosis in ongoing lacutamab studies," said **Mondher Mahjoubi, Chief Executive Officer of Innate Pharma**. "Additionally, with all patients recruited into the Phase 2 TELLOMAK study, we do not currently anticipate any delay for the TELLOMAK Phase 2 final data due shortly."

## About Lacutamab

Lacutamab is a first-in-class anti-KIR3DL2 humanized cytotoxicity-inducing antibody that is currently in clinical trials for treatment of cutaneous T-cell lymphoma (CTCL), an orphan disease, and peripheral T cell lymphoma (PTCL). Rare cutaneous lymphomas of T lymphocytes have a poor prognosis with few efficacious and safe 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 90% of patients with certain aggressive CTCL subtypes, in particular, Sézary syndrome. It is expressed by up to 50% of patients with mycosis fungoides and peripheral T-cell lymphoma (PTCL). It has a restricted expression on normal tissues.

Lacutamab is granted European Medicines Agency (EMA) PRIME designation and US Food and Drug Administration (FDA) granted Fast Track designation for the treatment of patients with relapsed or refractory Sézary syndrome who have received at least two prior systemic therapies. Lacutamab is granted orphan drug status in the European Union and in the United States for the treatment of CTCL.

### About TELLOMAK:

TELLOMAK (**NCT03902184**) is a global, open-label, multi-cohort Phase 2 clinical trial recruiting patients with Sézary syndrome and mycosis fungoides (MF) in the United States and Europe. Specifically:

- Cohort 1: lacutamab being evaluated as a single agent in approximately 60 patients with Sézary syndrome who have received at least two prior systemic therapies, including mogamulizumab. The Sézary syndrome cohort of the study could enable the registration of lacutamab in this indication.
- Cohort 2: lacutamab being evaluated as a single agent in patients with MF that express KIR3DL2, as determined at baseline with a Simon 2-stage design.
- Cohort 3: lacutamab being evaluated as a single agent in patients with MF that do not express KIR3DL2, as determined at baseline, with a Simon-2 stage design.
- All comers: lacutamab being evaluated as a single agent in patients with both KIR3DL2 expressing and non-expressing MF to explore the correlation between the level of KIR3DL2 expression and treatment outcomes utilizing a formalin-fixed paraffin embedded (FFPE) assay under development as a companion diagnostic.

The trial is now fully enrolled. The primary endpoint of the trial is objective global response rate. Key secondary endpoints are progression-free survival, duration of response, overall survival, quality of life, pharmacokinetics and immunogenicity and adverse events.

### About the Phase 1b in PTCL:

The Phase 1b clinical trial (**NCT05321147**) is investigating lacutamab monotherapy in KIR3DL2-expressing patients with relapsed/refractory PTCL who have received at least one prior systemic therapy (N=20, with futility interim ungating N=20 expansion). The trial is designed to evaluate safety, as well as characterize clinical outcomes, pharmacokinetics and immunogenicity of lacutamab alone in PTCL. Further expansion will be determined based on preliminary efficacy signals.

## About Innate Pharma

Innate Pharma S.A. is a global, clinical-stage biotechnology company developing immunotherapies for cancer patients. Its innovative approach aims to harness the innate immune system through therapeutic antibodies and its ANKET® (Antibody-based NK cell Engager Therapeutics) proprietary platform.

Innate's portfolio includes lead proprietary program lacutamab, developed in advanced form of cutaneous T cell lymphomas and peripheral T cell lymphomas, monalizumab developed with AstraZeneca in non-small cell lung cancer, as well as ANKET® multi-specific NK cell engagers to address multiple tumor types.

Innate Pharma is a trusted partner to biopharmaceutical companies such as Sanofi and AstraZeneca, as well as leading research institutions, to accelerate innovation, research and development for the benefit of patients.

Headquartered in Marseille, France with a US office in Rockville, MD, Innate Pharma is listed on Euronext Paris and Nasdaq in the US.

Learn more about Innate Pharma at [www.innate-pharma.com](http://www.innate-pharma.com) and follow us on **Twitter** and **LinkedIn**.

## Information about Innate Pharma shares

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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,” “potential,” “expect” and “will” and similar expressions, is intended to identify forward-looking statements. Forward-looking statements in this press release include, but are not limited to, the Company’s expectations regarding the timing of data for TELLOMAK Phase 2 clinical trial and Phase 1b PTCL clinical trial and statements concerning the Company’s efforts to address the FDA requests relating to the partial clinical hold. 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. These risks and uncertainties include, among other things, Innate Pharma’s ability to address the FDA requests including the incorporation of risk mitigation and management strategies for hemophagocytic lymphohistiocytosis in ongoing lacutamab studies and the effectiveness of such strategies, the timing of release of the TELLOMAK Phase 2 trial final data, the timing of release of the Phase 1b PTCL trial preliminary data, the uncertainties inherent in research and development, including related to safety, progression of and results from its ongoing and planned clinical trials and preclinical studies, review and approvals by regulatory authorities of its product candidates, the Company’s commercialization efforts and the Company’s continued ability to raise capital to fund its development. For an additional 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 Universal Registration Document filed with the French Financial Markets Authority (“AMF”), which is available on the AMF website <http://www.amf-france.org> or on Innate Pharma’s website, and public filings and reports filed with the U.S. Securities and Exchange Commission (“SEC”), including the Company’s Annual Report on Form 20-F for the year ended December 31, 2022, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company.

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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