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## INNATE PHARMA ANNOUNCES U.S. FDA LIFTS PARTIAL CLINICAL HOLD ON LACUTAMAB CLINICAL PROGRAM

- ***FDA lifts partial clinical hold on lacutamab clinical program***
- ***Fatal case related to disease progression and unrelated to the treatment***

**Marseille, France, January 4, 2024, 7:00 AM CET**

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Innate Pharma SA (Euronext Paris: IPH; 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 IND. On October 5, Innate announced that the lacutamab IND has been placed on partial clinical hold by FDA following a recent patient death in the TELLOMAK study. The death of a patient affected by Sézary syndrome was initially considered due to hemophagocytic lymphohistiocytosis (HLH), a rare hematologic disorder.

The FDA decision to lift the partial clinical hold is based on the FDA review of the fatal case which Innate, together with a steering committee of independent experts, determined to be related to aggressive disease progression and lacutamab unrelated.

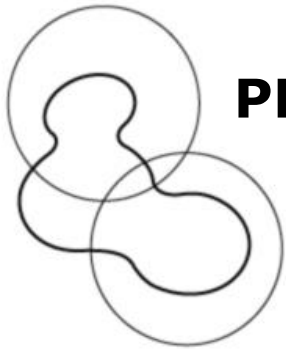
*"We have worked closely with the FDA to diligently resolve the partial clinical hold on the lacutamab IND, which included an in-depth analysis of the fatal case which was due to progression of an aggressive form of the disease," said **Dr Quaratino, Chief Medical Officer of Innate Pharma**. "The lacutamab program continues to plan following the publication of the positive Sézary syndrome results at the recent ASH Annual Meeting 2023. We now look forward to sharing final data in Mycosis Fungoides."*

### **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 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



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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.

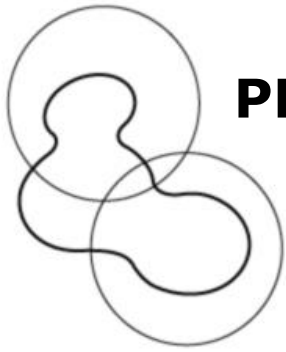
The trial is now fully enrolled. The primary endpoint of the trial is objective global response rate. Key secondary endpoints are progression-free survival, duration of response, overall survival, quality of life, pharmacokinetics and immunogenicity and adverse events.

## 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. The trial is designed to evaluate safety, as well as characterize clinical outcomes, pharmacokinetics and immunogenicity of lacutamab alone in PTCL.

## 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.



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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.

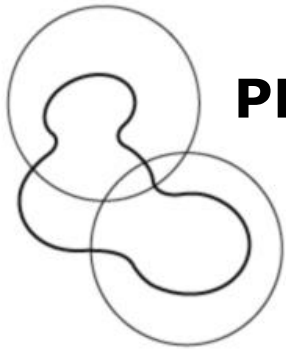
Learn more about Innate Pharma at [www.innate-pharma.com](http://www.innate-pharma.com) and follow us on [Twitter](#) and [LinkedIn](#).

## Information about Innate Pharma shares

<b>ISIN code</b>	FR0010331421
<b>Ticker code</b>	Euronext: IPH Nasdaq: IPHA
<b>LEI</b>	9695002Y8420ZB8HJE29

## Disclaimer on forward-looking information and risk factors

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. 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, 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,



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and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company.

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