

# PRESS RELEASE

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## INNATE PHARMA ANNOUNCES U.S. FDA GRANTED BREAKTHROUGH THERAPY DESIGNATION TO LACUTAMAB FOR RELAPSED OR REFRACTORY SÉZARY SYNDROME

- ***Designation is based on TELLOMAK Phase 2 results demonstrating efficacy and a favorable safety profile in heavily pretreated patients with advanced Sézary syndrome***
- ***Breakthrough Therapy Designation is intended to accelerate the development and regulatory review in the U.S. of drugs that are intended to treat a serious condition; adding to a Fast Track designation by the U.S. FDA received in 2019 as well as a PRIME designation by European Medicines Agency in 2020***
- ***Innate continues to align with regulatory agencies around the confirmatory Phase 3 trial in Cutaneous T Cell Lymphoma and is actively seeking for a partner***

**Marseille, France, February 17, 2025, 7:00 AM CET**

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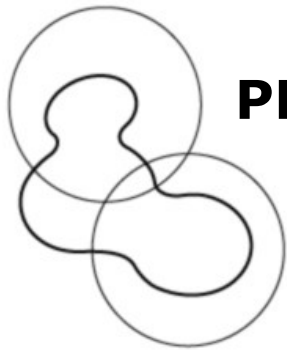
Innate Pharma SA (Euronext Paris: IPH; Nasdaq: IPHA) ("**Innate**" or the "**Company**") today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to lacutamab, an anti-KIR3DL2 cytotoxicity-inducing antibody, for the treatment of adult patients with relapsed or refractory (r/r) Sézary Syndrome (SS) after at least 2 prior systemic therapies including mogamulizumab.

The BTD is granted based on Phase 1 study results as well as results from the Phase 2 TELLOMAK study, where lacutamab demonstrated encouraging efficacy and a favorable safety profile in heavily pretreated, post-mogamulizumab patients with advanced Sézary syndrome.

*"There is a high unmet medical need for patients with Sézary syndrome. In this aggressive and rare form of cutaneous T-cell lymphoma, patients in advanced disease often experience very poor quality of life and are in strong need of new, targeted treatment options,"* commented **Sonia Quaratino, MD, Chief Medical Officer of Innate Pharma**. *"The Breakthrough Therapy Designation underscores lacutamab's potential to transform the patient's care by achieving clinically meaningful efficacy and favorable safety profile compared to available therapies. This is an important step in Innate's strategy for lacutamab. We are excited to work with the U.S. FDA to accelerate the development of this therapy."*

A Breakthrough Therapy Designation by the FDA is intended to accelerate the development and regulatory review in the U.S. of drugs that are intended to treat a serious condition and that have shown encouraging early clinical results, which may demonstrate substantial improvement on a clinically significant endpoint over available medicines.

Lacutamab previously received a Fast Track designation by the FDA in 2019 for the treatment of adult patients with relapsed or refractory Sézary syndrome who have received at least two prior systemic therapies as well as a PRIME designation by European Medicines Agency in 2020.



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Innate continues to align with the regulatory agencies around the confirmatory Phase 3 trial in CTCL and is actively seeking for a partner

## About Cutaneous T-Cell Lymphoma:

Cutaneous T-Cell Lymphoma (CTCL) is a heterogeneous group of non-Hodgkin's lymphomas which arise primarily in the skin and are characterized by the presence of malignant clonal mature T-cells. CTCL accounts for approximately 4% of all non-Hodgkin's lymphomas and has a median age at diagnosis of 55-65 years. Mycosis fungoides, and Sézary syndrome, its leukemic variant, are the most common CTCL subtypes. The overall 5-year survival rate, which depends in part on disease subtype, is approximately 10% for Sézary syndrome. There are approximately 6,000 new CTCL cases in Europe and the United States per year.

## About Sézary syndrome:

Sézary syndrome is the leukemic variant of CTCL. Patients often experience very poor quality of life with severe and debilitating pruritus (chronic itchy skin). Despite recent advancements, Sézary syndrome is associated with a high relapse rate with currently available therapies.

## 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.

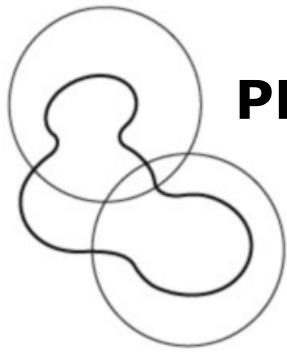
KIR3DL2 is an inhibitory receptor of the KIR family, expressed by approximately 65% of patients across all CTCL subtypes and expressed by up to 90% of patients with certain aggressive CTCL subtypes, in particular Sézary syndrome. It is expressed by up to 50% of patients with mycosis fungoides and peripheral 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 and Breakthrough Therapy 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 in 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.



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- 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 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 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 three therapeutic approaches: multi-specific NK Cell Engagers via its ANKET® (Antibody-based **NK** cell **E**ngager **T**herapeutics) proprietary platform and Antibody Drug Conjugates (ADC) and monoclonal antibodies (mAbs).

Innate's portfolio includes several ANKET® drug candidates to address multiple tumor types as well as IPH4502, a differentiated ADC in development in solid tumors. In addition, anti-KIR3DL2 mAb lacutamab is developed in advanced form of cutaneous T cell lymphomas and peripheral T cell lymphomas, and anti-NKG2A mAb monalizumab is developed with AstraZeneca in non-small cell lung cancer.

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.

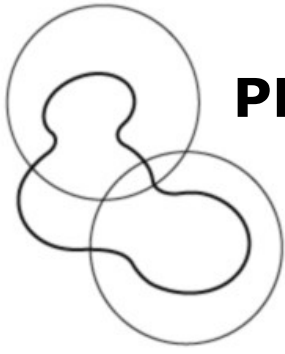
Learn more about Innate Pharma at [www.innate-pharma.com](http://www.innate-pharma.com) and follow us on [LinkedIn](#) and [X](#).

## Information about Innate Pharma shares

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|--------------------|----------------------------|
| <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 applicable securities laws, including the Private Securities Litigation Reform Act of 1995. The use of certain words, including "anticipate," "believe," "can," "could," "estimate," "expect," "may," "might," "potential," "expect" "should," "will," or the negative of these and



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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 reliance on third parties to manufacture 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, 2023, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public by the Company. References to the Company's website and the AMF website are included for information only and the content contained therein, or that can be accessed through them, are not incorporated by reference into, and do not constitute a part of, this press release.

In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by the Company or any other person that the Company will achieve its objectives and plans in any specified time frame or at all. The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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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