

INNATE PHARMA HIGHLIGHTS FDA-APPROVED LUMOXITI® AT ASH 2019

Final analysis expands on efficacy results from pivotal Phase III trial of Lumoxiti in hairy cell leukemia; durable, complete responses maintained in long-term follow-up data

Marseille, France, December 8, 2019, 9:00 am ET

Innate Pharma SA (Euronext Paris: IPH – ISIN: FR0010331421; Nasdaq: IPHA) ("**Innate**" or the "**Company**") shared new, long-term data from the pivotal Phase III trial of Lumoxiti (moxetumomab pasudotox-tdfk) today at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, USA, which expands on the efficacy results and affirms the manageable safety profile of the medicine.

The final analysis showed that 36 percent (29/80) of the relapsed or refractory hairy cell leukemia patients achieved durable complete response (CR) with Lumoxiti at Day 181 of patients' respective evaluation, compared to the primary analysis in which 30 percent durable CR rate was reported. In addition, there was a 61 percent probability that patients who achieved a CR would maintain it after five years.

"Lumoxiti is a first-in-class medicine and the only treatment approved in the US for relapsed or refractory hairy cell leukemia in more than twenty years; therefore, it is important for the hematology-oncology community to receive additional analysis of its long-term efficacy," commented Pierre Dodion, MD, Executive Vice President and Chief Medical Officer of Innate Pharma. "We are grateful to the patients and health care professionals who participated in the clinical development of Lumoxiti and we are passionate about continuing to address the unmet need in this rare form of cancer."

The single-arm, multi-center, open-label Phase III '1053' clinical trial assessed the efficacy, safety, immunogenicity and pharmacokinetics of Lumoxiti monotherapy in 80 patients with relapsed or refractory hairy cell leukemia who had received at least two prior therapies, including one purine nucleoside analog. The primary endpoint of durable CR was defined as CR with hematologic remission (HR) for >180 days.

Findings from the final analysis of the Lumoxiti Phase III trial include:

Efficacy measure	Result* (n=80, 95% Confidence Interval)
Durable CR (CR with HR > 180 days)	36.3% (25.8 to 47.8)
CR with HR ≥ 360 days	32.5% (22.4 to 43.9)
CR rate	41.3% (30.4 to 52.8)
CR with MRD-negative status	33.8% (23.6 to 45.2)
Partial Response Rate	33.8%
Hematologic Remission Rate	80.0%
Median duration of CR	62.8 months (0.0+ to 62.8)
Median Progression-Free Survival	41.5 months (range 0.0+ to 71.7)

^{*} BICR = blinded independent central review

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"A key treatment goal for patients with relapsed or refractory hairy cell leukemia is to achieve sustained remission, which can be particularly challenging in patients in whom prior therapies have failed. This long-term analysis demonstrates that Lumoxiti achieved a high rate of durable efficacy, while maintaining the benefit risk profile we saw in the primary analysis," said Robert J. Kreitman, MD, Senior Investigator, Head of Clinical Immunotherapy Section, Laboratory of Molecular Biology, Center for Cancer Research, National Cancer Institute, and Principal Investigator of the Phase III clinical trial.

The final analysis shows that the risk-benefit profile of Lumoxiti is maintained. There were no new serious adverse events and no change in hemolytic uremic syndrome or capillary leak syndrome. Per the primary analysis on the 1053 study, the most frequent treatment-related adverse events (AEs) were peripheral edema (39%), nausea (35%), fatigue (34%), headache (33%), and pyrexia (31%). Treatment-related grade 3/4 AEs were reported in 24 patients (30%) and treatment-related serious AEs in 14 patients (18%). Grade 3/4 CLS events occurred in two patients (2.5%) and any grade of HUS occurred in six patients (7.5%). CLS and HUS events were manageable and reversible with appropriate supportive care and monitoring.

Treatment-emergent AEs led to study drug discontinuation in eight patients (10.0%): hemolytic uremic syndrome (HUS), n=4 (5.0%); capillary leak syndrome (CLS), n=2 (2.5%); increased blood creatinine, n=2 (2.5%); renal failure, n=1 (1.3%); vomiting, n=1 (1.3%); and chills, n=1 (1.3%). There were four deaths reported (including the three reported during the primary analysis): two due to disease progression and two due to an AE (1 each of pneumonia and septic shock). No death was considered treatment related.

About Lumoxiti (moxetumomab pasudotox-tdfk):

Lumoxiti is a CD22-directed immunotoxin and a first-in-class treatment in the US for adult patients with relapsed or refractory (r/r) hairy cell leukemia (HCL) who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog. Lumoxiti is not recommended in patients with severe renal impairment (CrCl \leq 29 mL/min). It comprises the CD22 binding portion of an antibody fused to a truncated pseudomonas exotoxin. The toxin inhibits protein synthesis and ultimately triggers apoptotic cell death. Lumoxiti received U.S. FDA approval in September 2018 and has been granted Orphan Drug Designation by the FDA and the European Medicines Agency for the treatment of r/r HCL. AstraZeneca is the current Biologics License Application (BLA) holder for Lumoxiti.

About the '1053' Phase III trial:

The approval of Lumoxiti was based on data from the AstraZeneca-sponsored, open-label '1053' trial, which was a single-arm, multi-center Phase III clinical trial assessing the efficacy, safety, immunogenicity and pharmacokinetics of Lumoxiti monotherapy in patients with r/r HCL who have received at least two prior therapies, including one purine nucleoside analog. The trial enrolled 80 patients and was conducted across 34 sites in 14 countries. The primary endpoint was durable complete response (CR), defined as CR with hematologic remission (blood count normalization) for more than 180 days. Secondary endpoints included overall response rate, relapse-free survival, progression-free survival, time to response, safety, pharmacokinetics and immunogenic potential.

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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 Nasdag in the US.

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

Information about Innate Pharma shares:

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