Press Release

U.S. FDA grants Ipsen's IPN60340 (ICT01) Breakthrough Therapy Designation in first line unfit Acute Myeloid Leukemia

- Breakthrough Therapy Designation granted for investigational therapy IPN60340 in combination with venetoclax and azacitidine in first line unfit acute myeloid leukemia

PARIS, FRANCE, 13 JANUARY 2026 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for IPN60340 in combination with venetoclax and azacitidine (Ven-Aza) in first line unfit acute myeloid leukemia, an aggressive blood cancer affecting older adults. IPN60340 is an investigational first-in-class monoclonal antibody targeting BTN3A, a key immune-regulatory molecule broadly expressed across cancer. Breakthrough Therapy Designation is intended to expedite the development and review of medicines for serious or life-threatening conditions with evidence of a substantial clinical improvement. IPN60340 previously received Orphan Drug Designations from the U.S. Food and Drug Administration and European Medicines Agency in July 2025.

"This Breakthrough Therapy Designation recognizes both the urgent need for new treatment options for people living with acute myeloid leukemia and the promising data seen so far in the development program for IPN60340," said Christelle Huguet, PhD, EVP and Head of R&D, Ipsen. "We look forward to working closely with the FDA as we advance to the next stage of clinical development and continue to deliver medicines with the potential to be transformative to people living with cancer."

This Breakthrough Therapy Designation is based on data from the Phase I/II EVICTION trial. Updated clinical data orally presented at the American Society of Hematology (n=57)[1] from the EVICTION trial showed treatment with IPN60340 in combination with Ven-Aza achieved very encouraging high responses. In this single-arm trial, treatment with IPN60340 and Ven-Aza (n=38), resulted in a near doubling of the complete response relative to those seen in historical standard of care data across all molecular subtypes in newly diagnosed patients including sub-types typically less responsive to standard of care (Ven-Aza).[1,2] IPN60340 in combination with Ven-Aza was also shown to be well tolerated, underscoring IPN60340's potential as a novel immunotherapy to improve outcomes for patients with AML. Based on these preliminary data, we look forward to discussing the design of the Phase II/III development plans with the FDA for IPN60340 in H1 2026.

About the EVICTION trial

EVICTION is a first-in-human, dose-escalation (Part 1) and cohort-expansion (Part 2) clinical trial of IPN60340 (ICT01) in patients with various advanced relapsed or refractory solid or hematologic cancers that have exhausted standard-of-care treatment options, as well as newly-diagnosed AML. More information on the EVICTION trial can be found at clinicaltrials.gov (NCT04243499).

About IPN60340 (ICT01)

IPN60340 is a humanized, anti-BTN3A (also known as CD277) monoclonal antibody that promotes the recognition and elimination of tumor cells by γ9δ2 T cells, which are responsible for immunosurveillance of malignancy and infections. The three isoforms of BTN3A targeted by IPN60340 are overexpressed on many solid tumors (e.g., melanoma, urothelial cell, colorectal, ovarian, pancreatic, and lung cancer) and hematologic malignancies (e.g., leukemia and lymphomas) and are also expressed on the surface of innate (e.g., γδ T cells and NK cells) and adaptive immune cells (T cells and B cells). Binding to BTN3A is essential for the activation of the anti-tumor immune response of γ9δ2 T cells. By altering the conformation of BTN3A, IPN60340 promotes this binding, thereby selectively activating circulating γ9δ2 T cells. This leads to migration of γ9δ2 T cells out of the circulation and into the tumor tissue, and triggers a downstream immunological cascade through secretion of pro-inflammatory cytokines, including but not limited to IFNγ and TNFα, further augmenting the anti-tumor immune response. Anti-tumor activity and efficacy of IPN60340 have been shown in patients across several cancer indications. IPN60340 is an investigational therapy under evaluation for people 75 years or older living with acute myeloid leukemia who due to comorbidities are prevented from receiving treatment with intensive chemotherapy.

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Our pipeline is fueled by internal and external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit www.Ipsen.com

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References

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