Press release

AbilityPharma's IBRILATAZAR (ABTL0812) doubles overall survival in patients with squamous non-small cell lung cancer

- **Ibrilatazar's Phase I/IIa ENDOLUNG clinical trial was recently published in the prestigious scientific journal *Lung Cancer*.**
- **The trial evaluated the safety and efficacy of ibrilatazar (ABTL0812) combined with paclitaxel/carboplatin in 40 patients with stage III/IV squamous non-small cell lung cancer (sq-NSCLC), at 6 leading oncology hospitals in Spain and France.**
- **Ibrilatazar in combination with chemotherapy (paclitaxel/carboplatin) demonstrated improvements across all efficacy endpoints compared to historical controls including doubling Overall Survival from 12.3 to 22.5 months.**
- **These results support ibrilatazar as a potential backbone therapy for patients with one of the most common subtypes of lung cancer worldwide, addressing a high-unmet need.**

Cerdanyola del Vallès (Barcelona), June 5 2025. AbilityPharma, a clinical stage biopharmaceutical company specializing in the development of innovative oncology therapies, announced that the data of its Phase I/IIa ENDOLUNG trial evaluating ibrilatazar (ABTL0812) in combination with chemotherapy (paclitaxel/carboplatin) for patients with stage III/IV squamous non-small cell lung cancer (sq-NSCLC) has been published in the *Lung Cancer* journal.

The trial was conducted at the Catalan Institute of Oncology (ICO) in Badalona, Girona and l'Hospitalet (Barcelona), Paoli-Calmettes Institute in Marseille, Virgen del Rocío University Hospital in Seville and Clinic University Hospital in Valencia.

The publication builds upon AbilityPharma's previous research featured in the *International Journal of Cancer* (Leary et al., 2024). These advancements further consolidate the company's **leadership in the development of autophagy-mediated oncology drugs that selectively kill cancer cells while sparing normal cells**.

Dr. Carles Domènech, AbilityPharma's CEO & Co-Founder, stated, "This publication represents a crucial development in the study of new drugs and combinations for advanced squamous lung cancer. For AbilityPharma it is a significant milestone in our mission to deliver transformative treatments to cancer patients".

Dr. Joaquim Bosch, medical oncologist from the ICO Girona and researcher from the Dr. Josep Trueta Biomedical Research Institute of Girona (IDIBGI), and first author of the article, explained:

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"Squamous cell lung cancer is one of the lung cancer subtypes with the fewest therapeutic options and the poorest prognosis. That's why it is especially relevant that a new molecule like ibrilatazar, with a different mechanism of action, has shown promising antitumor activity. This molecule targets the PI3K pathway and autophagy, making it a very attractive and innovative therapeutic target. Ibrilatazar also demonstrated a favorable tolerability profile in combination with chemotherapy in this study."

Fellow senior author on the publication **Dr. Teresa Morán**, medical oncologist at ICO Badalona and researcher of B·ARGO group at the Germans Trias i Pujol Research Institute (IGTP), added: "ibrilatazar, when administered in combination with chemotherapy and subsequently as maintenance therapy, has shown a median overall survival of over 22 months in sq-NSCLC. These results are highly promising. If confirmed in a randomized study, ibrilatazar could become a treatment option for this complex disease."

Summary of the main results reported in the publication

- The combination of ibrilatazar plus paclitaxel/carboplatin demonstrated an increase in all efficacy endpoints when compared with historical controls: i) overall response rate (ORR) of 52% versus 31.7% in historical controls which represents a 40% increase, ii) median progression-free survival (PFS) of 6.2 months (95% CI: 4.4–8.8) versus 4.2 months in historical controls which represents a 44% increase, and iii) median overall survival (OS) of 22.5 months (95% CI 10.4-ND) versus 11.3 months in historical controls which represents doubling the survival.
- The combination of ibrilatazar plus paclitaxel/carboplatin exhibited a good safety profile. The safety profile of the addition of ibrilatazar to paclitaxel/carboplatin aligned with that of paclitaxel/carboplatin historical controls and did not introduce additional significant adverse events beyond those associated with paclitaxel/carboplatin.
- Ibrilatazar's pharmacokinetic parameters aligned with target engagement observed in preclinical studies, and blood pharmacodynamic biomarkers indicated sustained target regulation for at least 28 days following the initiation of treatment.

Reference articles:

ENDOLUNG trial, part II. A phase II study of the Akt/mTOR inhibitor and autophagy inducer ibrilatazar (ABTL0812) in combination with paclitaxel/ carboplatin in patients with squamous non-small cell lung cancer

ENDOLUNG trial. A phase 1/2 study of the Akt/mTOR inhibitor and autophagy inducer Ibrilatazar (ABTL0812) in combination with paclitaxel/carboplatin in patients with advanced/recurrent endometrial cancer

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About Squamous Non-Small Cell Lung Cancer

Squamous Non-Small Cell Lung Cancer (sq-NSCLC) is one of the most common subtypes of lung cancer worldwide, accounting for approximately 20-30% of all Non-Small Cell Lung Cancer (NSCLC) cases. Globally, lung cancer ranks as the second most frequently diagnosed cancer, with over 2.2 million new cases reported annually. The incidence has risen by 50% over the past 30 years and is expected to continue to increase due to an aging population and rising global rates of obesity and diabetes. More than 90% of cases occur in patients over 50 years of age.

About ibrilatazar (ABTL0812)

Ibrilatazar is a first-in-class, fully differentiated oral targeted anticancer compound that induces cell death selectively in cancer cells (and not in normal cells) through autophagy (self-digestion). The mechanism of action of ibrilatazar is both unique and novel. The robust autophagy comes from the combined induction of PPAR-dependent endoplasmic reticulum stress (ER stress) and the inhibition of Akt activation, the central kinase in the PI3K/Akt/mTOR pathway. The mechanism of action was published in *Clinical Cancer Research* (2016) and in *Autophagy* (2020).

In clinical trials, ibrilatazar has demonstrated clinical benefit for patients with endometrial and lung cancer. Also, it showed robust preclinical proof-of-concept in animal models of cancer types, including lung, endometrial and pancreatic cancer, neuroblastoma, and glioblastoma.

Ibrilatazar is nearing completion in a 140 patient Phase 2b, proof-of-concept trial in metastatic pancreatic adenocarcinoma (mPDAC), as first-line therapy in combination with FOLFIRINOX. The trial is being conducted in Spain, USA, France, and Israel, with all patients already recruited. Recruitment was completed in January 2024 and an efficacy interim analysis was successfully passed on April 2024.

Ibrilatazar received Orphan Drug Designations (ODD) for pancreatic cancer, biliary cancer, and neuroblastoma by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About AbilityPharma

AbilityPharma is a clinical-stage biopharmaceutical company developing innovative cancer treatments, with a focus on autophagy as a new therapeutic strategy to induce selective death of cancer cells.

Current shareholders include CTI Life Sciences Fund, Inveready, EIC Fund, FiTalent, CDTI Innvierte, SODENA, SciClone Pharmaceuticals, its founders, and private investors. The company also receives financial support from the European Commission, the Ministry of Science and Innovation (Government of Spain), the Center for the Development of Industrial Technology (CDTI), the Official Credit Institute (ICO), ENISA and ACCIÓ (Government of Catalonia). The company is headquartered in the Parc Tecnològic del Vallès (Cerdanyola del Vallès, Barcelona).

More information: www.abilitypharma.com

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