Eisai and Nuvation Bio Announce Marketing Authorisation Application for Taletrectinib for the Treatment of Advanced ROS1-Positive Non-Small Cell Lung Cancer Validated by the European Medicines Agency

The Marketing Authorisation Application (MAA) has been validated and accepted for full approval consideration with a standard review timeline

Additional filings are planned for the U.K., Canada and other regions included in Eisai's licensed territories

Taletrectinib is already approved in the U.S., China and Japan for advanced ROS1-positive non-small cell lung cancer

TOKYO & NEW YORK, NY., March 27, 2026 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai"), a human-centered global leading research-based pharmaceutical company working in the neurology and oncology therapeutic areas, and Nuvation Bio Inc. (NYSE: NUVB, Corporate Headquarters: New York, NY, CEO: David Hung, M.D., "Nuvation Bio"), a global oncology company focused on tackling some of the toughest challenges in cancer treatment, today announced that the European Medicines Agency (EMA) has validated the Marketing Authorisation Application (MAA) for taletrectinib for the treatment of advanced ROS1-positive (ROS1+) non-small cell lung cancer (NSCLC). The filing will follow a standard review timeline.

Taletrectinib (marketed as IBTROZI® in the U.S. and Japan) is a highly selective, next-generation oral treatment for patients living with advanced ROS1+ NSCLC.[1] In January 2026, Eisai and Nuvation Bio announced they had entered into an exclusive licensing and collaboration agreement in Europe and additional countries* outside the U.S., China and Japan to extend the global reach of taletrectinib. Following this filing to the EMA, additional filings are planned for the U.K., Canada and other regions included in Eisai's licensed territories.

Across Europe, nearly 400,000 people are diagnosed with lung cancer each year with NSCLC accounting for 80% of cases.[2,3] It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease.[4,5]

"The validation of the MAA is a significant moment for patients in Europe with ROS1+ NSCLC," said Terushige Iike, Chief Business Officer of Eisai Co., Ltd. "With its efficacy and safety profile, we believe taletrectinib has the potential to become a standard of care therapy for the thousands of patients living with this aggressive disease in Europe. We look forward to working closely with the EMA during the review process with the goal of making this treatment available to appropriate patients who urgently need targeted options."

The application is based on data from the two pivotal Phase 2 clinical studies, TRUST-I and TRUST-II, evaluating taletrectinib in patients globally.[6,7] Results from a pooled analysis of the TRUST clinical program were published in the *Journal of Clinical Oncology* in April 2025[8], and Nuvation Bio anticipates near-term disclosure of updated data reflecting even longer patient follow-up, further building on the depth and durability of responses observed to date. Additionally, given the comprehensive nature of the taletrectinib clinical dataset and based on favorable feedback received at a pre-submission meeting with the CHMP Rapporteur and Co-Rapporteur, the accepted MAA will be considered to support full approval.

"Having seen the meaningful impact taletrectinib has already made for patients with ROS1+ NSCLC in the U.S., China and Japan, we are thrilled to partner with Eisai and have an accepted MAA for review in Europe," said David Hung, M.D., Founder, President and Chief Executive Officer of Nuvation Bio. "This accepted filing represents an important milestone in our global development strategy and brings us one step closer to delivering this highly selective, next-generation oral therapy to more patients who need it in Europe and around the world."

In June 2025, the U.S. Food and Drug Administration (FDA) granted full approval to taletrectinib for the treatment of locally advanced or metastatic ROS1+ NSCLC across lines of therapy, following a Priority Review and double Breakthrough Therapy designations. Taletrectinib is also approved for patients with advanced ROS1+ NSCLC in Japan, where it is marketed by Nippon Kayaku, and in China, where it is marketed by Innovent Biologics under the brand name DOVBLERON®.

* Eisai's licensed territories：Europe, the Middle East, North Africa, Russia, Turkey, Canada, Australia, New Zealand, Singapore, the Philippines, Indonesia, Thailand, Malaysia, Vietnam and India

MEDIA CONTACTS

Eisai Co., Ltd.	**Nuvation Bio Inc.**
Public Relations Department	Kaitlyn Nealy
TEL: +81 (0)3-3817-5120	media@nuvationbio.com

INVESTOR CONTACTS

Eisai Co., Ltd.	**Nuvation Bio Inc.**
Investor Relations Department	JR DeVita
TEL: +81 (0) 3-3817-5122	ir@nuvationbio.com

Notes to Editors

1. **About ROS1+ NSCLC**
   Each year, more than one million people globally are diagnosed with non-small cell lung cancer (NSCLC), the most common form of lung cancer.[9] It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease.[4,5] About 35% of patients newly diagnosed with metastatic ROS1+ NSCLC have tumors that have spread to their brain.[10] The brain is also the most common site of disease progression, with about 50% of previously treated patients developing central nervous system (CNS) metastases.[10,11]

2. **About Taletrectinib**
   Taletrectinib is an oral, potent, CNS-active, selective, next-generation ROS1 inhibitor therapy. On June 11, 2025, following Priority Review and Breakthrough Therapy designations for both TKI-naive and TKI-pretreated disease, the U.S. Food and Drug Administration (FDA) approved taletrectinib for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC. Learn more about taletrectinib in the U.S. at IBTROZI.com.[1]

3. **About the TRUST Clinical Program**
   The TRUST clinical program comprises three registrational studies evaluating the safety and efficacy of taletrectinib. TRUST-I (NCT04395677) and TRUST-II (NCT04919811) are Phase 2 single-arm studies evaluating taletrectinib for the treatment of adults with advanced ROS1+ NSCLC in China (N=173) and globally (N=189), respectively. The primary endpoint of both studies is confirmed objective response rate (cORR) as assessed by an independent review committee. TRUST-IV (NCT07154706) is a Phase 3 placebo-controlled study evaluating taletrectinib for the

adjuvant treatment of adults with resected early-stage ROS1+ NSCLC. The study will enroll approximately 180 patients in the U.S., Canada, Europe, Japan and China. The primary endpoint is disease-free survival as determined by investigator, and the primary completion date is estimated to be in 2030. Nuvation Bio is also sponsoring TRUST-III (NCT06564324), a confirmatory randomized Phase 3 study evaluating taletrectinib versus crizotinib in 138 patients in China with advanced ROS1+ NSCLC who have not previously received ROS1 TKIs.[6,7]

4. About Eisai Co., Ltd.

Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept (also known as *human health care* (*hhc*) Concept), we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, we demonstrate our commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), by working on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), and connect with us on X, LinkedIn and Facebook. The website and social media channels are intended for audiences outside of the UK and Europe.

5. About Nuvation Bio

Nuvation Bio is a global oncology company focused on tackling some of the toughest challenges in cancer treatment with the goal of developing therapies that create a profound, positive impact on patients' lives. Our diverse pipeline includes taletrectinib (IBTROZI®), a next-generation ROS1 inhibitor; safusidenib, a brain-penetrant IDH1 inhibitor; and an innovative drug-drug conjugate (DDC) program.

Nuvation Bio was founded in 2018 by biopharma industry veteran David Hung, M.D., who previously founded Medivation, Inc., which brought to patients one of the world's leading prostate cancer medicines. Nuvation Bio has offices in New York, San Francisco, Boston, and Shanghai. For more information, visit www.nuvationbio.com or follow the company on LinkedIn and X (@nuvationbioinc).

U.S. Indication

IBTROZI is indicated for the treatment of adult patients with locally advanced or metastatic ROS1+ non-small cell lung cancer (NSCLC).

IMPORTANT SAFETY INFORMATION FOR IBTROZI® (taletrectinib)[1]

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Hepatotoxicity, including drug-induced liver injury and fatal adverse reactions, can occur. 88% of patients experienced increased AST, including 10% Grade 3/4. 85% of patients experienced increased ALT, including 13% Grade 3/4. Fatal liver events occurred in 0.6% of patients. Median time to first onset of AST or ALT elevation was 15 days (range: 3 days to 20.8 months).

Increased AST or ALT each led to dose interruption in 7% of patients and dose reduction in 5% and 9% of patients, respectively. Permanent discontinuation was caused by increased AST, ALT, or bilirubin each in 0.3% and by hepatotoxicity in 0.6% of patients.

Concurrent elevations in AST or ALT ≥3 times the ULN and total bilirubin ≥2 times the ULN, with normal alkaline phosphatase, occurred in 0.6% of patients.

Interstitial Lung Disease (ILD)/Pneumonitis: Severe, life-threatening, or fatal ILD or pneumonitis can occur. ILD/pneumonitis occurred in 2.3% of patients, including 1.1% Grade 3/4. One fatal ILD case occurred at the 400 mg daily dose. Median time to first onset of ILD/pneumonitis was 3.8 months (range: 12 days to 11.8 months).

ILD/pneumonitis led to dose interruption in 1.1% of patients, dose reduction in 0.6% of patients, and permanent discontinuation in 0.6% of patients.

QTc Interval Prolongation: QTc interval prolongation can occur, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death. IBTROZI prolongs the QTc interval in a concentration-dependent manner.

In patients who received IBTROZI and underwent at least one post baseline ECG, QTcF increase of >60 msec compared to baseline and QTcF >500 msec occurred in 13% and 2.6% of patients, respectively. 3.4% of patients experienced Grade ≥3. Median time from first dose of IBTROZI to onset of ECG QT prolongation was 22 days (range: 1 day to 38.7 months). Dose interruption and dose reduction each occurred in 2.8% of patients.

Significant QTc interval prolongation may occur when IBTROZI is taken with food, strong and moderate CYP3A inhibitors, and/or drugs with a known potential to prolong QTc. Administer IBTROZI on an empty stomach. Avoid concomitant use with strong and moderate CYP3A inhibitors and/or drugs with a known potential to prolong QTc.

Hyperuricemia: Hyperuricemia can occur and was reported in 14% of patients, with 16% of these requiring urate-lowering medication without pre-existing gout or hyperuricemia. 0.3% of patients experienced Grade ≥3. Median time to first onset was 2.1 months (range: 7 days to 35.8 months). Dose interruption occurred in 0.3% of patients.

Myalgia with Creatine Phosphokinase (CPK) Elevation: Myalgia with or without CPK elevation can occur. Myalgia occurred in 10% of patients. Median time to first onset was 11 days (range: 2 days to 10 months).

Concurrent myalgia with increased CPK within a 7-day time period occurred in 0.9% of patients. Dose interruption occurred in 0.3% of patients with myalgia and concurrent CPK elevation.

Skeletal Fractures: IBTROZI can increase the risk of fractures. ROS1 inhibitors as a class have been associated with skeletal fractures. 3.4% of patients experienced fractures, including 1.4% Grade 3. Some fractures occurred in the setting of a fall or other predisposing factors. Median time to first onset of fracture was 10.7 months (range: 26 days to 29.1 months). Dose interruption occurred in 0.3% of patients.

Embryo-Fetal Toxicity: Based on literature, animal studies, and its mechanism of action, IBTROZI can cause fetal harm when administered to a pregnant woman.

ADVERSE REACTIONS

Among patients who received IBTROZI, the most frequently reported adverse reactions (≥20%) were diarrhea (64%), nausea (47%), vomiting (43%), dizziness (22%), rash (22%), constipation (21%), and fatigue (20%).

The most frequently reported Grade 3/4 laboratory abnormalities (≥5%) were increased ALT (13%), increased AST (10%), decreased neutrophils (5%), and increased creatine phosphokinase (5%).

DRUG INTERACTIONS

- **Strong and Moderate CYP3A Inhibitors/CYP3A Inducers and Drugs that Prolong the QTc Interval:** Avoid concomitant use.
- **Gastric Acid Reducing Agents:** Avoid concomitant use with PPIs and H2 receptor antagonists. If an acid-reducing agent cannot be avoided, administer locally acting antacids at least 2 hours before or 2 hours after taking IBTROZI.

OTHER CONSIDERATIONS

- **Pregnancy:** Please see important information in Warnings and Precautions under Embryo-Fetal Toxicity.
- **Lactation:** Advise women not to breastfeed during treatment and for 3 weeks after the last dose.
- **Effect on Fertility:** Based on findings in animals, IBTROZI may impair fertility in males and females. The effects on animal fertility were reversible.
- **Pediatric Use:** The safety and effectiveness of IBTROZI in pediatric patients has not been established.
- **Photosensitivity:** IBTROZI can cause photosensitivity. Advise patients to minimize sun exposure and to use sun protection, including broad-spectrum sunscreen, during treatment and for at least 5 days after discontinuation.

Please see accompanying full U.S. Prescribing Information.

Forward-Looking Statements of Nuvation Bio Inc.

Certain statements included in this press release that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are sometimes accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding taletrectinib's therapeutic potential and the urgent need for new therapeutic options for patients with advanced ROS1+ NSCLC in Europe, our expectations that the MAA filing for taletrectinib will follow a standard review with a decision in 1H 2027 and be considered for full approval, plans for additional filings for the U.K., Canada and other regions included in Eisai's licensed territories, and expectations for near-term disclosure of updated data. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the management team of Nuvation Bio and are not predictions of actual performance. These forward-looking statements are subject to a number of risks and uncertainties that may cause actual results to differ from those anticipated by the forward-looking statements, including but not limited to the challenges associated with conducting drug discovery and commercialization, and initiating or conducting clinical studies due to, among other things, difficulties or delays in the regulatory process, enrolling subjects or manufacturing or acquiring necessary products; the emergence or worsening of adverse events or other undesirable side effects; risks associated with preliminary and interim data, which may not be representative of more mature data; physician and patient behavior; and competitive developments. Risks and uncertainties facing Nuvation Bio are described more fully in its Form 10-K filed with the SEC on March 2, 2026 under the heading "Risk Factors," and other documents that Nuvation Bio has filed or will file with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Nuvation Bio disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

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