Eisai and Nuvation Bio Enter into Exclusive Licensing Agreement for Taletrectinib in Europe and Additional Countries Outside the U.S., China and Japan

Eisai will receive exclusive development, registration and commercialization rights for taletrectinib for the treatment of ROS1-positive non-small cell lung cancer in Europe, the Middle East, Canada, Australia, New Zealand, Singapore, the Philippines, Indonesia, Thailand, Malaysia, Vietnam and India

Nuvation Bio will receive double-digit tiered royalties up to the high-teens as a percentage of taletrectinib sales in the licensed territories, in addition to up to €195 million (approx. USD $230 million) in upfront and milestone payments

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

TOKYO and NEW YORK, NY., Jan. 13, 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 an exclusive license and collaboration agreement that significantly expands the long-term global footprint of taletrectinib (generic name, marketed as IBTROZI® in the U.S. and Japan). Taletrectinib is a highly selective, next-generation oral treatment currently approved for patients living with advanced ROS1-positive (ROS1+) non-small cell lung cancer (NSCLC) in the U.S., China, and Japan.

Eisai will now have exclusive development, registration and commercialization rights for taletrectinib for the treatment of ROS1+ NSCLC in Europe, the Middle East, North Africa, Russia, Turkey, Canada, Australia, New Zealand, Singapore, the Philippines, Indonesia, Thailand, Malaysia, Vietnam and India. Nuvation Bio will continue to lead global development and retain full U.S. commercial rights, maintaining its strong focus on U.S. launch activities and ongoing pivotal studies of taletrectinib across early- and late-stage ROS1+ NSCLC.

"Our partnership with Eisai represents a major global expansion milestone for taletrectinib, strengthening the long-term potential of this clinically meaningful treatment option for even more patients living with ROS1+ NSCLC," said David Hung, M.D., Founder, President, and Chief Executive Officer of Nuvation Bio. "With Eisai's world-class infrastructure and track record of bringing innovative medicines to market in major regions, we believe the expanse of this collaboration illustrates the commercial potential of taletrectinib while accelerating the opportunity for providers and patients around the world to access this important treatment option."

Under the terms of the exclusive license and collaboration agreement, Eisai will pay EUR 50 million (approx. USD 60 million) upfront and up to EUR 145 million (approx. USD 170 million) in regulatory and commercial milestone payments, as well as double-digit tiered royalties up to the high-teens as a percentage of future net sales in the licensed territories. Following the upfront payment, Eisai will pay the first milestone payment of EUR 25 million (approx. USD 30 million) from this transaction upon

achievement of EU regulatory approval (conditional or full) of taletrectinib. The USD amounts are approximated based on an exchange rate of EUR1= USD1.2. Eisai anticipates no changes to its consolidated financial forecast for the period ending March 31, 2026.

“With its efficacy and safety profile, we believe taletrectinib has the potential to become a standard of care for patients with ROS1+ NSCLC in the EU and beyond, as it is already becoming the standard of care in the U.S. just six months from approval,” said Terushige Iike, Chief Business Officer of Eisai Co., Ltd. “We are thrilled to partner with Nuvation Bio and prioritize taletrectinib as our flagship oncology product in NSCLC, bringing this innovative medicine to patients as quickly as possible.”

A Marketing Authorization Application (MAA) for the treatment of advanced ROS1+ NSCLC is expected to be filed in Europe in the first half of 2026. Additional filings are then planned for Canada and other regions.

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®.

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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. It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease. About 35% of patients newly diagnosed with metastatic ROS1+ NSCLC have tumors that have spread to their brain. The brain is also the most common site of disease progression, with about 50% of previously treated patients developing central nervous system (CNS) metastases.

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-naïve 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.

3. 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.

4. 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; NUV-868, a BD2-selective BET 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).

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.

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)

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 IBTROZI’S therapeutic and commercial potential, our expectations for a MAA filing for IBTROZI in Europe and the timing thereof, and the receipt and timing of a regulatory and commercial milestone payment under our license and collaboration agreement with Eisai. 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-Q filed with the SEC on November 3, 2025 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.