FOR EUROPEAN TRADE AND MEDICAL MEDIA

Eisai and Nuvation Bio announce European Medicines Agency validation of the Marketing Authorisation Application for taletrectinib for the treatment of advanced ROS1-positive non-small cell lung cancer

The Marketing Authorisation Application (MAA) has been validated for assessment consideration with a standard review timeline

HATFIELD, HERTFORDSHIRE, UNITED KINGDOM (UK) & NEW YORK (US) March 27, 2026 – Eisai Europe Ltd, a human-centred global leading research-based pharmaceutical company working in the neurology and oncology therapeutic areas, and Nuvation Bio Inc. (NYSE: NUVB), a global oncology company focused on tackling some of the toughest challenges in cancer treatment, today announced the European Medicines Agency (EMA) has validated a Marketing Authorisation Application (MAA) for taletrectinib for the treatment of advanced ROS1-positive (ROS1+) non-small cell lung cancer (NSCLC), which will follow a standard review timeline.

Across Europe, nearly 400,000 people are diagnosed with lung cancer each year with NSCLC accounting for 80% of cases.[1,2] It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease.[3,4]

The validated application is based on data from two pivotal Phase 2 clinical studies, TRUST-I and TRUST-II, evaluating taletrectinib in patients globally.[5,6] Results from a pooled analysis of the TRUST clinical program were published in April 2025.[7] Additional filings are planned for the U.K., Canada and other regions included in Eisai's licensed territories.

On January 12, 2026, Eisai and Nuvation Bio announced they had entered into an exclusive licensing and collaboration agreement in Europe and additional countries excluding the U.S., China and Japan to extend the global reach of taletrectinib. Eisai serves as the lead of taletrectinib regulatory submissions in the territories within the licensing and collaboration agreement.

Media and Investor Contacts

Eisai Europe Ltd. Media Contact
Helena Symeou
(0)7507 309 895
EMEA-comms@eisai.net

Nuvation Bio Media Contact
Kaitlyn Nealy
media@nuvationbio.com

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Eisai Co., Ltd.
Investor Relations Department
+81 (0) 3-3817-5122

Nuvation Bio Investor Contact
JR DeVita
ir@nuvationbio.com

Notes to editors

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.[8] It is estimated that approximately 2% of patients with NSCLC have ROS1+ disease.[3,4] About 35% of patients newly diagnosed with metastatic ROS1+ NSCLC have tumours that have spread to their brain.[3] The brain is also a common site of disease progression with patients developing central nervous system (CNS) metastases.[3]

About Taletrectinib
Taletrectinib is an oral, next-generation ROS1 inhibitor therapy. On June 11, 2025, the U.S. Food and Drug Administration (FDA) approved taletrectinib for the treatment of adult patients with locally advanced or metastatic ROS1+ NSCLC.[9] Taletrectinib is also approved for patients with advanced ROS1+ NSCLC in Japan and China, where it is marketed by other companies.

About the TRUST Clinical Program
The TRUST clinical program evaluates 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.[7,10]

About Eisai Europe Ltd.
At Eisai everything we do is dedicated to giving our first thought to patients and their families through our *human health care (hhc)* philosophy. We are the European hub of Tokyo-based Eisai Co. Ltd., forming part of a multinational team working across a global network of R&D facilities, manufacturing sites and marketing subsidiaries.

Our collective passion and dedication to patient care is the driving force behind our efforts to discover, and develop, innovative medicines in areas where a high unmet medical need remains including oncology. We continue to drive the discovery, development and production of oncology therapies that can impact the lives of patients and their families.

Our mission is clear; we strive to make a significant long-lasting contribution to society in an ethical, compliant and sustainable way by embodying our *hhc* concept in everything we do.

For more information about Eisai in the EMEA region please visit www.eisai.eu or find us on LinkedIn.

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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 may create a profound, positive impact on patients' lives.

Nuvation Bio was founded in 2018 by biopharma industry veteran David Hung, M.D., who previously founded Medivation, Inc. Nuvation Bio has offices in New York, San Francisco, Boston, and Shanghai.

Nuvation Bio Forward-Looking Statements
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 and commercial potential, our expectations for a MAA filing 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.

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