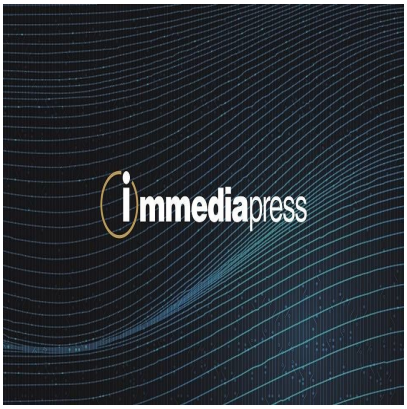

EUROPEAN COMMISSION APPROVES AMGENâ??S IMDYLLTRAÂ® FOR THE TREATMENT OF EXTENSIVE-STAGE SMALL CELL LUNG CANCER

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

Approval Based Upon Phase 3 DeLLphi-304 Trial Demonstrating 40% Reduction in Risk of Death with IMDYLLTRA Compared to Chemotherapy

Novel Treatment Option for Patients with Extensive-Stage Small Cell Lung Cancer That Has Progressed

THOUSAND OAKS, Calif., June 1, 2026 /PRNewswire/ â?? Amgen (NASDAQ:AMGN) today announced that the European Commission (EC) has granted marketing authorization for IMDYLLTRAÂ® (tarlatamab) as a monotherapy to treat adults with extensive-stage small cell lung cancer (ES-SCLC) who require systemic therapy following disease progression on or after first-line treatment with platinum-based chemotherapy.

The approval was based on results from DeLLphi-304, the first global Phase 3 trial to demonstrate a significant survival benefit over chemotherapy in this setting.1

â??Small cell lung cancer is one of the most aggressive solid tumors, with high rates of relapse following first-line treatment and limited treatment options,â?• said Jean-Charles Soria, senior vice president of Oncology at Amgen. â??The European Commissionâ??s approval of IMDYLLTRA, the first and only T-cell engager therapy approved to treat small cell lung cancer, marks an important step forward for patients in Europe and reflects our commitment to advancing innovative medicines that can meaningfully improve outcomes for people living with this devastating disease.â?•

DeLLphi-304, the global Phase 3 clinical trial, demonstrated that IMDYLLTRA reduced the risk of death by 40% and significantly extended median overall survival (OS) by more than five months compared to standard of care (SOC) chemotherapy as a treatment for patients with ES-SCLC who progressed on or after one line of platinum-based chemotherapy (median OS: 13.6 vs. 8.3 months; hazard ratio (HR),

0.60; 95% confidence interval (CI): 0.47, 0.77; P < 0.001).1

â??Patients with small cell lung cancer have historically faced a hard road when they progress after initial treatment, surviving only a few months,â?• said Debra Montague, president, Lung Cancer Europe (LuCE). â??Approval of a novel treatment option for people in Europe living with this challenging cancer represents meaningful progress and underscores the urgent need for innovation in lung cancer care.â?•

The safety profile for IMDYLLTRA was consistent with its known profile. The most common adverse reactions were cytokine release syndrome (CRS) (56.7%), decreased appetite (36.4%), pyrexia (31.9%), dysgeusia (31.3%), constipation (30.4%), anaemia (30.0%), fatigue (29.8%), nausea (24.9%), asthenia (19.0%), neutropenia (16.9%), hyponatraemia (16.7%), headache (16.3%) and lymphopenia (15.6%). The most common serious adverse reactions were CRS (19.7%) and pyrexia (4.7%).

CRS primarily occurred after the first two doses. As reflected in the Summary of Product Characteristics (SmPC), patients should be monitored from the start of the IMDYLLTRA infusion for 6 to 8 hours on Cycle 1 Day 1 and Cycle 1 Day 8 in an appropriate healthcare setting.2

Amgenâ??s robust IMDYLLTRA clinical development program includes the DeLLphi clinical trials, which evaluate IMDYLLTRA as a monotherapy and as part of combination regimens, including in both earlier stages of SCLC and earlier lines of treatment.

About the Phase 3 DeLLphi-304 StudyDeLLphi-304 is a global Phase 3, randomized, controlled, open-label clinical trial evaluating the efficacy and safety of IMDYLLTRA as a treatment for patients living with SCLC who progressed on or after one platinum-based chemotherapy regimen. Five hundred and nine patients were randomized to receive either IMDYLLTRA or local standard of care chemotherapy (topotecan in all countries except Japan; lurbinectedin in the U.S., Canada, Australia, Singapore, South Korea; and amrubicin in Japan). The primary outcome measure of the trial is OS. Key secondary outcome measures include progression-free survival (PFS) and patient-reported outcomes (PROs) including disease-related symptoms, physical function, and quality of life.3 Results from DeLLphi-304 were reviewed as a late-breaking presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and simultaneously published in The New England Journal of Medicine.1,4

About IMDELLTRAÂ®/IMDYLLTRAÂ® (tarlatamab)IMDYLLTRA is a first-in-class targeted immunotherapy engineered by Amgen researchers to bind to both DLL3 on tumor cells and CD3 on T cells, thereby activating T cells to kill DLL3-expressing SCLC cells. This results in the formation of a cytolytic synapse with lysis of the cancer cell. 5,6 DLL3 is a protein that is expressed on the surface of SCLC cells in up to 96% of patients with SCLC, but is minimally expressed on healthy cells, making it an exciting target.7,8

About Small Cellâ?¯Lung Cancerâ?¯(SCLC)â?¯â?¯ SCLC is one of the most aggressive and devastating forms of solid tumor cancer. Each year, SCLC accounts for approximately 13-15% of more than 2.4 million cases of lung cancer diagnosed worldwide.9-11 Despite initial high response rates to first-line platinum-based chemotherapy, most patients quickly relapse within months and require subsequent treatment options.10

About Tarlatamab Clinical TrialsTarlatamab is being investigated in multiple studies including DeLLphi-303, a Phase 1b study investigating tarlatamab in combination with SOC therapies in first-line ES-SCLC; DeLLphi-305, a randomized Phase 3 study comparing tarlatamab in combination with durvalumab vs. durvalumab alone in first-line ES-SCLC in the maintenance setting; DeLLphi-306, a randomized placebo-controlled Phase 3 study of tarlatamab following concurrent chemoradiotherapy in limited-stage SCLC; DeLLphi-308, a Phase 1b study evaluating subcutaneous tarlatamab in second-line or later ES-SCLC; DeLLphi-309, a Phase 2 study evaluating alternative intravenous dosing regimens with tarlatamab in second-line ES-SCLC; DeLLphi-310, a Phase 1b study of tarlatamab in combination with YL201, a B7-H3 targeting antibody drug conjugate, with or without anti-programmed death ligand 1 (PD-L1) in patients with ES-SCLC; DeLLphi-311, a Phase 1b study of tarlatamab in combination with etakafusp alfa (AB248), a novel CD8+ T-cell selective interleukin-2 (IL-2), in patients with ES-SCLC; DeLLphi-312, a randomized Phase 3 study evaluating tarlatamab in combination with carboplatin, etoposide and durvalumab as an induction and maintenance therapy in first-line treatment of ES-SCLC; and DeLLphi-313, a Phase 1b study of tarlatamab in combination with zocilurtatug pelitecan, a DLL3 targeting antibody drug conjugate, with and without a PD-L1 inhibitor in patients with ES-SCLC.12

For more information, please visit www.tarlatamabclinicaltrials.com.

About AmgenAmgen discovers, develops, manufactures and delivers innovative medicines to fight some of the worldâ??s toughest diseases. Harnessing the best of biology and technology, Amgen reaches millions of patients with its medicines.

More than 45 years ago, Amgen helped establish the biotechnology industry at its U.S. headquarters in Thousand Oaks, California, and it remains at the cutting edge of innovation, using technology and human genetic data to push beyond what is known today. Amgen is advancing a broad and deep pipeline and portfolio of medicines to treat cancer, inflammatory conditions, rare diseases, heart disease and obesity and obesity-related conditions.

Amgen has been consistently recognized for innovation and workplace culture, including honors from Fast Company and Forbes. Amgen is one of the 30 companies that comprise the Dow Jones Industrial AverageÂ®, and it is also part of the Nasdaq-100 IndexÂ®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, YouTube, Facebook, TikTok and Threads.

EU INDICATION

IMDYLLTRAÂ® (tarlatamab) is indicated as monotherapy for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC), who require systemic therapy following disease progression on or after first-line treatment with platinum-based chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

ADVERSE REACTIONS

DOSAGE AND ADMINISTRATION: Important Dosing Information

U.S. INDICATION

IMDELLTRAÂ® (tarlatamab-dlle) is indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy in the United States.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

WARNINGS AND PRECAUTIONS

ADVERSE REACTIONS

DOSAGE AND ADMINISTRATION: Important Dosing Information

Please see U.S. IMDELLTRAÂ® full Prescribing Information, including BOXED WARNINGS.

Amgen Forward-Looking StatementsThis news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeOne Medicines Ltd.), the performance of OtezlaÂ® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. or Horizon Therapeutics plc (including the prospective performance and outlook of Horizonâ??s business, performance and opportunities, and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on our business, outcomes, progress, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans.

The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions, including those resulting from geopolitical relations and government actions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions. A breakdown, cyberattack or information security breach of our information technology systems could compromise the

confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our sustainability objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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REFERENCES

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Categoria

1. Comunicati

Tag

1. ImmediaPress

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