Pfizer Logo

Pfizer Announces Topline Phase 3 Results for Sigvotatug Vedotin in Previously Treated Metastatic Non-Squamous Non-Small Cell Lung Cancer

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced topline results from the Phase 3 SigVie-002 study (previously known as Be6A Lung-01) evaluating sigvotatug vedotin, an investigational, potential first-in-class integrin beta-6 (IB6) directed antibody-drug conjugate (ADC). The study enrolled adults with locally advanced, unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) who had received one or more lines of prior therapy.

- In the overall population, sigvotatug vedotin did not show a statistically significant improvement in the primary endpoint of overall survival (OS) compared to docetaxel.
- The safety profile of sigvotatug vedotin was manageable and consistent with prior studies.
- Encouragingly, in patients who received only one prior line of systemic therapy, which represents two-thirds of the study population, a stronger trend was observed for OS and progression-free survival (PFS) for sigvotatug vedotin over docetaxel.
- In the exploratory analysis, no clear IB6 expression-response relationship was observed.

Detailed results from SigVie-002 will be submitted for presentation at a future medical congress.

“Patients with previously treated advanced NSCLC are a historically difficult-to-treat population, and there is clearly more work to be done to improve the outcomes for this population,” said Jeff Legos, Chief Oncology Officer, Pfizer. “Although the overall study results did not demonstrate superiority over docetaxel, it is encouraging that second-line patients treated with sigvotatug vedotin achieved strong efficacy outcomes compared to an established standard of care, alongside a manageable safety profile. This observed clinical benefit, along with our Phase 1 combination data in the first-line setting, reinforces our confidence in the potential of the sigvotatug vedotin program, including an ongoing Phase 3 trial in combination with pembrolizumab in first-line advanced NSCLC.”

“It is important not to underestimate the activity of docetaxel as a comparator in this setting. Patients enrolled in this trial were heavily pre-treated, with most having previously received both platinum-based chemotherapy and immunotherapy, yet docetaxel continues to provide meaningful clinical benefit. Although the study did not meet its overall survival endpoint, in second-line patients the data suggest a clinically meaningful survival benefit for sigvotatug vedotin over docetaxel, supporting continued scientific evaluation of sigvotatug vedotin in earlier lines in combination with immunotherapy,” said Solange Peters, M.D., PhD, Chair of Medical Oncology & Thoracic Cancers Clinic, Lausanne University Hospital, Switzerland. “The ability of sigvotatug vedotin to induce immunogenic cell death provides a strong rationale for combination approaches with immunotherapy, particularly in earlier treatment settings where immune competence is better preserved. In this context, the promising phase 1 efficacy signals observed in treatment-naïve patients with high PD-L1 expression warrant

further evaluation and may represent a more effective clinical application of this strategy."

In NSCLC, IB6 is expressed on approximately 90% of tumors. IB6 is associated with poor prognosis. Sigvotatug vedotin is a novel ADC designed for high target selectivity of IB6 and rapid internalization, which may help limit binding to other integrins more likely to be expressed in normal tissues and potentially reduce off-target toxicity.

Pfizer is evaluating sigvotatug vedotin in several ongoing studies across multiple stages and patient populations in NSCLC and other solid tumors, including:

- An ongoing Phase 3 study evaluating sigvotatug vedotin + pembrolizumab in 1L NSCLC with PD-L1 tumor proportion score (TPS) ?50%; and
- Exploration of sigvotatug vedotin in novel combinations, including with PF'4404, the novel bispecific antibody targeting PD-1 and VEGF, in early-stage lung cancers and other IB6-expressing tumors.

Since the acquisition of Seagen, Pfizer has continued to advance a broad ADC portfolio spanning marketed medicines and pipeline programs. Pfizer is progressing multiple differentiated ADC candidates, including fetrastobart vedotin, a PD-L1–directed ADC currently in Phase 3 in NSCLC, additional IB6-targeted ADCs with alternate payloads, and early-stage candidates exploring novel targets and payloads, including topoisomerase I (Topo1) inhibitors and novel auristatin-based payloads. This breadth reinforces the strength of Pfizer's Oncology pipeline, including the potential for novel combinations with its investigational PD-1xVEGF bispecific antibody (PF-08634404), supporting the company's goal of delivering 8 potential Oncology breakthroughs by 2030.

About the SigVie-002 Trial

SigVie-002 (NCT06012435) is an ongoing, open-label randomized, Phase 3, global study evaluating sigvotatug vedotin compared with docetaxel in adult participants with previously treated locally advanced, unresectable or metastatic non-small cell lung cancer (NSCLC). Patients were randomized to receive sigvotatug vedotin administered intravenously on Days 1 and 15 of each 28-day cycle or docetaxel administered intravenously on Day 1 of each 21-day cycle.

The primary endpoint of this trial is overall survival (OS). The study enrolled 703 participants. Descriptive, secondary endpoints include progression-free survival (PFS), confirmed objective response rate (ORR) and duration of response (DOR) per RECIST v1.1 as assessed by blinded independent central review (BICR).

For more information, visit ClinicalTrials.gov and reference NCT06012435.

About Pfizer Oncology

At Pfizer Oncology, we are at the forefront of a new era in cancer care. Our industry-leading portfolio and extensive pipeline includes three core mechanisms of action to attack cancer from multiple angles, including small molecules, antibody-drug conjugates (ADCs), and multispecific antibodies, including other immune-oncology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, gastrointestinal cancer, genitourinary cancer, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to help people with cancer live better and longer lives.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and

manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For over 175 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on X at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of June 22, 2026. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer Oncology, sigvotatug vedotin, an investigational, potential first-in-class integrin beta-6 directed antibody-drug conjugate, other oncology pipeline candidates and Pfizer's ADC portfolio, including their potential benefits, the development program for sigvotatug vedotin and Pfizer's oncology pipeline portfolio, the SigVie-002 results for sigvotatug vedotin and Pfizer's goal of delivering 8 or more potential Oncology blockbuster medicines by 2030, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of Pfizer's oncology products; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data, as well as uncertainties regarding the future of the sigvotatug vedotin program; risks associated with initial, preliminary or interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for sigvotatug vedotin or any other product candidates or combinations may be filed in particular jurisdictions for any potential indications; whether and when any such applications for sigvotatug vedotin or any other product candidates or combinations may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether sigvotatug vedotin or any such other product candidates or combinations will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of sigvotatug vedotin or any other product candidates or combinations; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its reports subsequent on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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