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Pfizer Announces Positive Topline Phase 2 Results for Next-Generation CDK4 Inhibitor, Atirmociclib, in Second-Line Metastatic Breast Cancer

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- *Primary endpoint met in first randomized Phase 2 study, FOURLIGHT-1, showing a 40% reduction in the risk of disease progression or death with manageable safety profile*
- *More than 90% of patients initiated atirmociclib within 3 months of prior CDK4/6 inhibitor therapy*
- *Results strengthen confidence in atirmociclib as a potential first-in-class, next-generation cell cycle inhibitor backbone for HR+, HER2- breast cancer and provide further support for development strategy in earlier lines of treatment*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive topline results from the randomized Phase 2 FOURLIGHT-1 study evaluating atirmociclib in combination with fulvestrant, versus fulvestrant or everolimus plus exemestane, in people with hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer (MBC) who had received prior cyclin-dependent kinase (CDK) 4/6 inhibitor-based treatment. The study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) as assessed by the investigator [HR: 0.60 (95% CI: (0.440, 0.825)), p=0.0007].

The PFS results were consistent across all prespecified subgroups, including performance status, menopausal status, presence of visceral disease, duration of treatment with prior CDK4/6 inhibitor ($< \text{or} \geq 12$ months), and regardless of prior CDK4/6 inhibitor received. More than 90% of patients initiated treatment with atirmociclib within three months of their last CDK4/6 inhibitor treatment. Overall survival (OS), a secondary endpoint, was not mature at the time of the analysis, with approximately 20% of participants having an event. These are the first randomized Phase 2 data in HR+ MBC for atirmociclib, an investigational, potential first-in-class CDK4 inhibitor.

“These results are especially encouraging given that the FOURLIGHT?1 study enrolled patients whose disease had progressed soon after prior CDK4/6 inhibitor therapy, a difficult-to-treat population,” said Jeff Legos, Chief Oncology Officer, Pfizer. “The strength of these data reinforces our confidence that atirmociclib may meaningfully differentiate from the CDK4/6 inhibitor class, the standard-of-care backbone in HR-positive breast cancer, with the potential for improved efficacy and tolerability. We are continuing to accelerate development of this next-generation cell cycle inhibitor in earlier lines of therapy where it may offer even greater benefit for patients.”

In FOURLIGHT-1, atirmociclib demonstrated manageable safety and was well tolerated, with 6.4 percent of patients discontinuing atirmociclib due to treatment-emergent adverse events. Its safety profile was consistent with prior studies, and no new safety signals were identified. Detailed results will be submitted for presentation

at a future medical meeting.

These findings support Pfizer's strategy to advance atirmociclib in first-line and early-stage disease, where durable endocrine-based control has the potential to have the greatest impact. A Phase 3 registrational study for atirmociclib in the first-line metastatic setting is ongoing and results from a Phase 2 neoadjuvant study in early breast cancer will be shared at a future medical meeting.

About the FOURLIGHT-1 Trial

FOURLIGHT-1 (NCT06105632) is an interventional, open-label, randomized, multicenter Phase 2 study evaluating atirmociclib plus fulvestrant compared with fulvestrant or everolimus plus exemestane, in adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer (MBC). The trial enrolled 264 patients in 14 countries whose disease progressed after cyclin-dependent kinase (CDK) 4/6 inhibitor-based treatment. The primary endpoint was progression-free survival (PFS) as determined by investigator assessment. Secondary endpoints include overall survival, objective response, duration of response and clinical benefit response.

About Atirmociclib

Atirmociclib is an investigational oral inhibitor of cyclin-dependent kinase 4 (CDK4), a key regulator of the cell cycle that triggers cellular progression. It was conceptualized and discovered at Pfizer and is being developed for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (HER2-) breast cancer.

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 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 March 17, 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 and atirmociclib, an investigational CDK4 inhibitor, including its potential benefits, results from the Phase 2 FOURLIGHT-1 study and Pfizer's strategy to advance atirmociclib in first-line and early-stage disease, 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, 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; whether the FOURLIGHT-1 trial will meet the secondary endpoint for overall survival; 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 the clinical studies; whether and when drug applications may be filed in any jurisdictions for atirmociclib for any potential indications; whether and when any such applications 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 atirmociclib 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 atirmociclib or any such other product candidates; 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 subsequent reports 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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