



Zentalis Pharmaceuticals Announces FDA Has Lifted Partial Clinical Hold on Azenosertib Studies

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Company on track to present data from key clinical studies of azenosertib in the fourth quarter of 2024

SAN DIEGO, Sept. 16, 2024 (GLOBE NEWSWIRE) -- [Zentalis® Pharmaceuticals, Inc.](https://www.zentalis.com) (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company discovering and developing clinically differentiated small molecule therapeutics targeting fundamental biological pathways of cancers, today announced that the U.S. Food and Drug Administration (FDA) has lifted the partial clinical hold on studies of azenosertib, the Company's novel, selective, and orally bioavailable inhibitor of WEE1. The FDA has cleared the Company to resume enrollment in all ongoing azenosertib clinical studies with no changes in the clinical development plan. Zentalis will be working with clinical trial investigators to resume study activities across the azenosertib development program as quickly as possible.

"We are grateful to the FDA for their collaboration and review of our complete response package, which included a comprehensive safety assessment of the azenosertib program," said Kimberly Blackwell, M.D., Chief Executive Officer. "We are extremely pleased with the successful resolution of the partial clinical hold. Our confidence in the therapeutic index of azenosertib has been unwavering, and we continue to believe in the potential for this treatment to address unmet medical needs faced by people living with gynecologic malignancies."

At a corporate event later this year, Zentalis will present azenosertib monotherapy data and provide additional updates to azenosertib clinical development and other data presentation timelines. The Company remains on track to meet all previously disclosed data guidance for the remainder of 2024.

About Azenosertib

Azenosertib is a novel, selective, and orally bioavailable inhibitor of WEE1 currently being evaluated in monotherapy and combination clinical studies in ovarian cancer and additional tumor types. WEE1 acts as a master regulator of the G1-S and G2-M cell cycle checkpoints, through negative regulation of both CDK1 and CDK2, to prevent replication of cells with damaged DNA. By inhibiting WEE1, azenosertib enables cell cycle progression, despite high levels of DNA damage, thereby resulting in the accumulation of DNA damage and leading to mitotic catastrophe and cancer cell death.

About Zentalis Pharmaceuticals

Zentalis® Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company discovering and developing clinically differentiated small molecule therapeutics targeting fundamental biological pathways of cancers. The Company's lead product candidate, azenosertib (ZN-c3), is a potentially first-in-class and best-in-class WEE1 inhibitor for advanced solid tumors. Azenosertib is being evaluated as a monotherapy and in combination across multiple clinical trials and has broad franchise potential. In clinical trials, azenosertib has been well tolerated and has demonstrated anti-tumor activity as a single agent across multiple tumor types and in combination with several chemotherapy backbones. As part of its azenosertib clinical development program, the Company is exploring enrichment strategies targeting tumors of high genomic instability, such as Cyclin E1 positive tumors, homologous recombination deficient tumors and tumors with oncogenic driver mutations. The Company is also leveraging its extensive experience and capabilities across cancer biology and medicinal chemistry to advance its research on protein degraders. Zentalis has operations in San Diego.

For more information, please visit www.zentalis.com. Follow Zentalis on X/Twitter at [@ZentalisP](https://twitter.com/ZentalisP) and on LinkedIn at www.linkedin.com/company/zentalis-pharmaceuticals.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding our plans to resume study activities across the azenosertib development program as quickly as possible; the potential of azenosertib to benefit patients; our plans to disclose clinical data, and the timing thereof; our plans to provide additional updates to the azenosertib clinical development timelines and other data timelines and the timing thereof; the potential for azenosertib to be first-in-class and best-in-class; the broad franchise potential of azenosertib; and our plans with respect to the development of our product candidates. The terms "believe," "continue," "on track," "potential," and "will" and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability; we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our plans, including the costs thereof, of development of any diagnostic tools; our substantial dependence on the success of azenosertib; the outcome of preclinical testing and early trials may not be predictive of the success of later clinical trials; failure to identify additional product candidates and develop or commercialize marketable products; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process or ongoing regulatory obligations; failure to obtain U.S. or international marketing approval; our product candidates may cause serious adverse side effects; inability to maintain our collaborations, or the failure of these collaborations; our reliance on third parties; effects of significant competition; the possibility of system failures or security breaches; risks relating to intellectual property; our ability to attract, retain and motivate qualified personnel, and risks relating to management transitions; significant costs as a result of operating as a public company; and the other important factors discussed under the caption "Risk Factors" in our most recently filed periodic report on Form 10-K or 10-Q and subsequent filings with the U.S. Securities and Exchange Commission (SEC) and our other filings with the SEC. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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