



## NEWS RELEASE

# ZENTALIS PHARMACEUTICALS PROVIDES CORPORATE UPDATE AND HIGHLIGHTS KEY MILESTONES AND EXPECTED MOMENTUM IN THE AZENOSERTIB DEVELOPMENT PROGRAM FOR 2026

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- Completed enrollment in DENALI Part 2a; dose confirmation expected in 1H 2026
- DENALI Part 2 trial topline readout expected by year end 2026; potential to support accelerated approval
- Initiation of the ASPENOVIA Phase 3, randomized, confirmatory trial planned in 1H 2026

SAN DIEGO, Jan. 06, 2026 (GLOBE NEWSWIRE) -- Zentalis® Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical oncology innovator advancing late-stage development of investigational first-in-class WEE1 inhibitor azenosertib as a biomarker-driven treatment approach for ovarian cancer, today provided a corporate update and highlighted key milestones and expected momentum in the azenosertib development program for 2026.

"2026 represents a pivotal year for Zentalis as we advance azenosertib toward potential approval in Cyclin E1-positive platinum-resistant ovarian cancer (PROC) and continue to assess its role in additional indications," said Julie Eastland, Chief Executive Officer of Zentalis. "The completion of DENALI Part 2a enrollment marks significant progress, positioning us for dose confirmation in the first half of 2026, followed by an expected topline readout by year end that could support accelerated approval, subject to FDA feedback. Equally important, we expect to initiate ASPENOVIA, our randomized Phase 3 confirmatory trial in the first half of 2026, evaluating azenosertib vs. standard-of-care chemotherapy in this biomarker-selected population. Beyond the Cyclin E1-positive PROC setting, this year we plan to continue evaluating the potential of azenosertib in earlier lines of ovarian cancer and other indications where WEE1 inhibition may play a meaningful role.

"With our strong financial foundation providing an estimated runway into late 2027, we remain focused on executing our strategy to bring this potentially first-in-class, non-chemo, oral therapy to the approximately 50% of PROC patients who are Cyclin E1-positive—a population with significant unmet needs," Ms. Eastland added.

## 2025 Accomplishments

- **Completed enrollment in DENALI Part 2a, supporting registration-intended development of azenosertib.** The Company completed enrollment in Part 2a of the Phase 2 DENALI clinical trial (NCT05128825). Part 2a is designed to confirm the primary dose-of-interest with a target enrollment of up to approximately 30 patients at each of two dose levels: 400mg QD 5:2 and 300mg QD 5:2 (intermittent daily dosing with five days on, two days off dosing schedule).
- **Aligned with the FDA on confirmatory ASPENOV Phase 3 trial design.** The Company aligned with the FDA on the design for ASPENOV, a Phase 3 randomized, confirmatory trial of azenosertib vs. standard-of-care chemotherapy in patients with Cyclin E1-positive PROC.
- **Strong data across three trials in PROC established a solid foundation for the lead indication in Cyclin E1-positive platinum-resistant ovarian cancer.** For example, in Part 1b of DENALI at the 400mg 5:2 dosing schedule, azenosertib demonstrated clinically meaningful results with a manageable safety profile. In addition, Cyclin E1 overexpression, regardless of *CCNE1* gene amplification status, was observed as a predictive biomarker to identify patients who could potentially benefit from azenosertib. Zentaris estimates that approximately 50% of PROC patients overexpress Cyclin E1 protein based on its proprietary immunohistochemistry cutoff.
- **Maintained a strong cash position supporting an estimated runway into late 2027 following strategic restructuring to focus pipeline and resources.** As of September 30, 2025, the Company had cash, cash equivalents and marketable securities of \$280.7 million. The Company believes that its existing cash, cash equivalents and marketable securities is expected to provide runway into late 2027, beyond the anticipated DENALI Part 2 topline readout.

## Anticipated 2026 Milestones

- **DENALI Part 2a dose confirmation expected in first half of 2026.**
- **Confirmatory ASPENOV Phase 3 trial initiation expected in first half of 2026.** The planned Phase 3 trial is expected to be conducted concurrently with DENALI Part 2.
- **DENALI Part 2 topline readout on track and expected by year end 2026.** DENALI Part 2, if successful, has the potential to support an accelerated approval, subject to FDA feedback.

## About Azenosertib

Azenosertib is an investigational, potentially first-in-class, selective, and orally bioavailable inhibitor of WEE1 currently being evaluated in 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.

Azenosertib is in late-stage development as a potential treatment for Cyclin E1-positive platinum-resistant ovarian cancer (PROC). There is currently no approved treatment option specifically for this biomarker-selected population which comprises approximately 50% of PROC patients. Cyclin E1 protein overexpression has been established as a sensitive and specific predictive biomarker for identifying patients who could potentially derive benefit from azenosertib treatment.

## About DENALI Clinical Trial

DENALI is a multi-part Phase 2 registration-intent clinical trial (NCT05128825) studying azenosertib in platinum-resistant ovarian cancer (PROC) patients. Part 1b enrolled patients with PROC regardless of Cyclin E1 protein expression, all treated at 400mg QD 5:2 (intermittent daily dosing with five days on, two days off dosing schedule). Interim results from Part 1b were presented at the Society of Gynecologic Oncology (SGO) 2025 Annual Meeting. Part 2 is enrolling PROC patients with Cyclin E1 protein overexpression based on Zentaris' proprietary immunohistochemistry cutoff. Part 2 includes Part 2a, a dose confirmation portion evaluating two doses, 300mg QD 5:2 and 400mg QD 5:2, and Part 2b, a portion designed to complete enrollment at the selected dose informed by Part 2a results. The

trial design was aligned with the U.S. Food and Drug Administration (FDA). Part 2, in total, is designed for accelerated approval, pending study outcome and discussions with the FDA.

### **About Zentalis Pharmaceuticals**

Zentalis is a clinical oncology innovator developing a treatment approach for ovarian cancer and multiple tumor types. Leveraging therapeutics development and biomarker expertise, Zentalis is advancing monotherapy and combination studies of its first-in-class WEE1 inhibitor, azenosertib. Focused on translating WEE1 science into clinical practice, we aim to equip physicians with a targeted, non-chemo, orally available medicine that enhances treatment experience, choice, and outcomes. Our mission: to unburden cancer patients with more convenience and care.

For more information, please visit [www.zentalis.com](http://www.zentalis.com). Follow Zentalis on LinkedIn at [www.linkedin.com/company/zentalis-pharmaceuticals](https://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, as amended. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the potential for azenosertib to be first-in-class; the significance of the referenced data on the late-stage development of azenosertib; the potential benefits of azenosertib, including the potential for azenosertib to be an important treatment option for patients with ovarian cancer or other indications; the broad franchise potential of azenosertib; the Company's biomarker-driven strategy for azenosertib; the potential to advance research on additional areas of opportunity for azenosertib outside PROC; our anticipated milestones and the timing thereof, including the anticipated timing of DENALI Part 2a dose confirmation and the topline readout from DENALI Part 2, and the initiation, design, conduct and timing of our confirmatory APSENOVA Phase 3 trial; our anticipated cash runway; and our planned regulatory strategy for azenosertib and the timing thereof, including the potential for DENALI Part 2 to support an accelerated approval. The terms "anticipate," "advance," "believe," "design," "develop," "expect," "intent," "look forward," "on track," "plan," "position," "potential," "runway," "strategy," "target," 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 substantial dependence on the success of azenosertib; our plans, including the costs thereof, of development of companion diagnostics; the outcome of preclinical testing and early trials may not be predictive of the success of later clinical trials; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process or ongoing regulatory obligations; 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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**Contact:**

Aron Feingold  
VP, Investor Relations & Corporate Communications  
[ir@zentalis.com](mailto:ir@zentalis.com)