Zentalis Pharmaceuticals Provides Update on Azenosertib Clinical Development Program

June 18, 2024

FDA has placed a partial clinical hold on ZN-c3-001, DENALI and TETON monotherapy studies of azenosertib

Monotherapy data to be presented in the second half of 2024

Conference call to be held today, June 18, 8:00 am ET

SAN DIEGO, June 18, 2024 (GLOBE NEWSWIRE) -- Zentalis® Pharmaceuticals, Inc. (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 placed a partial clinical hold on the following studies of azenosertib: the Phase 1 ZN-c3-001 dose-escalation study in solid tumors, the Phase 2 ZN-c3-005 (DENALI) study in platinum-resistant ovarian cancer (PROC) and the Phase 2 ZN-c3-004 (TETON) study in uterine serous carcinoma (USC). This action follows two recent deaths due to presumed sepsis in the DENALI study.

“Patient safety is our top priority and any deaths that occur in the setting of clinical trials are unfortunate. We are working closely with the FDA to resolve this partial clinical hold as quickly as possible,” said Kimberly Blackwell, M.D., Chief Executive Officer of Zentalis. “Over 500 patients have been treated with azenosertib monotherapy to date, and we believe that our data indicate a favorable therapeutic index that could potentially offer meaningful benefits to women facing PROC and USC. We have completed enrollment for Cohort 1b of the DENALI study, where we’ve enrolled more than a hundred patients, further demonstrating the support we’ve seen for having a novel oral therapy like azenosertib. We look forward to sharing these results along with overall efficacy and safety data from DENALI Cohort 1b later this year.”

In addition to sharing topline results of Cohort 1b of DENALI, the Company remains on track to present results from the ZN-c3-001 and Phase 1/2 ZN-c3-006 (MAMMOTH) studies later this year. The Company will provide additional updates to the azenosertib clinical development and other data timelines following resolution of the partial clinical hold. Zentalis remains committed to the azenosertib development program and bringing this potentially practice-changing therapy to patients with gynecological malignancies.

Conference Call Details
Zentalis will host a live conference call and webcast today at 8:00 a.m. Eastern Time to provide a business update. To access the live conference call by telephone, please register at: https://register.vevent.com/register/BI24249bb9e5714044b9f4057f28565923. Upon registering, each participant will be provided with call details and access codes. The live webcast may be accessed by visiting the event link at: https://edge.media-server.com/mmc/p/y2wz6vv6. The webcast will also be made available on the Company's website at www.zentalis.com under the Investors & Media section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

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 and hematologic malignancies. 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 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 for anticipated azenosertib data readouts, and the timing and content thereof; sepsis as the presumed cause of two recent deaths; our belief that our data indicate a favorable therapeutic index that could potentially offer meaningful benefits to women facing PROC and USC; our plans to update provide additional updates to the azenosertib clinical development and other data timelines following resolution of the partial clinical hold; the potential benefits of azenosertib, including as a potentially practice-changing therapy to patients with gynecological malignancies; the potential for azenosertib to be first-in-class and best-in-class; the broad franchise potential of azenosertib; and our plans to explore enrichment strategies targeting tumors of high genomic instability and advance our research on protein degraders. The terms “believe,” “look forward,” “on track,” “potential,” “presumed,” “to be,” “strategy,” “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: the risk that the partial clinical hold may or may not be resolved in a timely manner, 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 our lead product candidates; 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.

Contact:
Elizabeth Pingpank Hickin
ehickin@zentalis.com
860-463-0469