Zentalis Pharmaceuticals Announces Fast Track Designation Granted by the U.S. FDA to ZN-c3 for the Treatment of Uterine Serous Carcinoma

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Potentially registrational Phase 2 trial of ZN-c3 in USC is underway, with initial enrollment and safety update expected in 2H 2022

NEW YORK and SAN DIEGO, Nov. 17, 2021 (GLOBE NEWSWIRE) -- Zentalis Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ZN-c3, the Company's oral WEE1 inhibitor product candidate, for the treatment of recurrent or persistent uterine serous carcinoma (USC) in adult women.

"USC is a devastating endometrial cancer marked by low survival rates and high rates of recurrence. Receiving Fast Track designation for ZN-c3 is an important milestone, as it underscores the need for novel, effective treatment options for this aggressive and often fatal disease," commented Dr. Anthony Sun, Chairman and Chief Executive Officer of Zentalis. "ZN-c3, our potentially first- and best-in-class oral WEE1 inhibitor, is a notable clinical advancement in DNA damage response and synthetic lethality and is currently being evaluated in a potentially registrational Phase 2 trial in USC. We are grateful for the opportunity to have more frequent interactions with the FDA as we continue to quickly advance the development of this promising candidate for patients in need."

Fast Track designation aims to facilitate the development and accelerate the review of new therapeutics that are intended to treat serious or life-threatening conditions and that potentially address an unmet medical need. Drugs that are granted this designation are given the opportunity for more frequent interactions with the FDA, as well as potential pathways for expedited approval.

About Uterine Serous Carcinoma

Uterine serous carcinoma is an aggressive variant of endometrial cancer that accounts for less than 10% of all endometrial cancers, yet 80% of endometrial cancer–related deaths. In the U.S., ~6,500 women are diagnosed annually, with ~70% presenting with Stage III or IV disease at diagnosis. Currently, the standard of care for treating USC is staging surgery together with chemotherapy or radiotherapy; yet, the recurrence rates post-surgery are extremely high and result in low patient survival rates. There remains an urgent medical need for transformative therapies that target the USC pathway.

About ZN-c3

ZN-c3 is a potentially first-in-class and best-in-class oral inhibitor of WEE1 in development for the treatment of advanced solid tumors. The inhibition of WEE1, a DNA damage response protein, aims to generate sufficient DNA damage in cancer cells, causing cell death, thereby preventing tumor growth and potentially causing tumor regression. ZN-c3 has broad potential as a monotherapy and in combination. We are currently evaluating this candidate in several ongoing and planned studies, including two potentially registrational monotherapy trials in USC and a biomarker-driven setting, as well as combination studies, including in combination with chemotherapy in patients with advanced ovarian cancer. We also received orphan drug and rare pediatric disease designations from the FDA for pediatric osteosarcoma and have initiated a Phase 1/2 trial in combination with chemotherapy.

About Zentalis Pharmaceuticals

Zentalis Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. The Company is developing a broad pipeline of potentially best-in-class oncology candidates, all internally discovered, which include ZN-c3, a WEE1 inhibitor for advanced solid tumors, ZN-c5, an oral selective estrogen receptor degrader (SERD) for ER+/HER2- breast cancer, ZN-d5, a BCL-2 inhibitor for hematologic malignancies, and ZN-e4, an EGFR inhibitor for non-small cell lung carcinoma (NSCLC). Zentalis has licensed ZN-c3, ZN-c5 and ZN-d5 to its joint venture, Zentera Therapeutics, to develop and commercialize these candidates in China. Zentalis has operations in both New York and San Diego.

For more information, please visit www.zentalis.com. Follow Zentalis on 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 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 without limitation statements regarding our expectations surrounding the development, potential, safety, efficacy, and regulatory and clinical progress of our product candidates, including without limitation ZN-c3, in the Unites States and globally, potential eligibility of ZN-c3 for a rare pediatric disease priority voucher and plans and timing for the initiation of and the release of data from our clinical trials and our ability to meet other key milestones. 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 important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 filed 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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