Zentalis Pharmaceuticals Announces First Patient Dosed in Potentially Registrational Phase 2 Study of ZN-c3 in Patients with Uterine Serous Carcinoma

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NEW YORK and SAN DIEGO, Aug. 02, 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 first patient has been dosed in the Phase 2 trial of ZN-c3, the Company's oral WEE1 inhibitor product candidate, in adult women with recurrent or persistent uterine serous carcinoma (USC). Following an end-of-Phase 1 meeting, the U.S. Food and Drug Administration agreed in principle that ZN-c3 has the potential for an accelerated approval pathway based on the Phase 2 global study design in USC.

"This trial, with its potential accelerated approval pathway, underscores our potential ability to efficiently develop and advance promising therapeutic candidates in hopes of delivering them to patients quickly," commented Dr. Anthony Sun, Chairman and Chief Executive Officer of Zentalis. "Dosing the first patient in this Phase 2 trial is an important next step toward our goal of developing a safe and effective therapy for the thousands of women in the U.S. diagnosed with USC annually. Despite current treatment options, USC – a highly aggressive form of endometrial cancer – has an extremely poor prognosis, with survival rates ranging between 30-50%. We believe that our potentially first- and best-in-class oral WEE1 inhibitor, ZN-c3, represents one of the most promising clinical advances in DNA damage response and synthetic lethality to date, and if successfully developed and approved, has the potential to redefine the USC treatment landscape."

The Phase 2 trial (ZN-c3-004) is an open-label, multicenter study evaluating the clinical activity, safety, pharmacokinetics, and related biomarkers of ZN-c3 in patients with recurrent or persistent USC. The primary efficacy endpoint is a measure of the antitumor activity of ZN-c3 based on the objective response rate as defined by RECIST criteria. Secondary endpoints include duration of response and progression-free survival. More information about the trial is available at www.clinicaltrials.gov: NCT04814108.

About Uterine Serous Carcinoma

Uterine serous carcinoma (USC) 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 and 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 such as with chemotherapy in patients with advanced ovarian cancer. We also recently received orphan drug and rare pediatric disease designations by the FDA for pediatric osteosarcoma and expect to initiate a Phase 1/2 trial in combination with chemotherapy in 3Q 2021.

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 majority-owned 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 in the Unites States and globally, 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 March 31, 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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