

Zentalis Pharmaceuticals Announces FDA Clearance of IND Application for ZN-d5 for the Treatment of Hematologic Malignancies

April 30, 2020

ZN-d5 is the Company's fourth product candidate to receive IND clearance in five years

NEW YORK and SAN DIEGO, April 30, 2020 (GLOBE NEWSWIRE) -- Zentalis Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental pathways of cancers, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for ZN-d5, an oral selective inhibitor of B-cell lymphoma 2 (BCL-2) initially in development for the treatment of hematologic malignancies.

"The acceptance of this IND, our fourth cleared in only five years, highlights the capability and efficiency of our Integrated Discovery Engine in developing novel oncology therapies," commented Dr. Anthony Sun, Chairman and Chief Executive Officer at Zentalis Pharmaceuticals. "BCL-2 is as an important mediator in restoring the normal apoptotic process in tumor cells, making this protein a vital target for the treatment of cancer. ZN-d5, a BCL-2 inhibitor, may offer patients with hematologic and epithelial malignancies a differentiated therapy option, both as a monotherapy and in combination with other agents including our oral selective estrogen receptor degrader (SERD), ZN-c5. We are thrilled to explore this candidate's full potential as we advance toward clinical development."

About ZN-d5

ZN-d5 is an oral selective inhibitor of B-cell lymphoma 2 (BCL-2). BCL-2 is a protein that plays a critical role in the regulation of cell death. The overexpression of BCL-2 is frequently detected in numerous cancer types, which prevent apoptosis of cancer cells. We believe a BCL-2 inhibitor will restore the normal apoptosis process, making it an important target for cancer treatments. ZN-d5 is designed to have optimized potency, selectively and pharmacokinetics.

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. In addition to its lead program, ZN-c5, an oral selective estrogen receptor degrader (SERD) for estrogen-receptor-positive, HER2-negative breast cancer, the Company is developing a broad pipeline of oncology candidates, targeting areas of major unmet medical need. The Company has offices in New York and San Diego. For more information, please visit www.zentalis.com

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, commercialization, potential, safety, efficacy, and regulatory and clinical progress of our product candidates. 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 outbreak of the novel strain of coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials; 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 our lead product candidate; failure to identify additional product candidates and develop or commercialize marketable products; the early stage of our development efforts; 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 significant costs as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in our final prospectus under Rule 424(b)(4) filed with the Securities and Exchange Commission on April 6, 2020 could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. 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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