Press Release

Zionexa announces FDA acceptance of New Drug Application (NDA) for FES (Fluoroestradiol F18), a biomarker for targeted imaging in Metastatic Breast Cancer (MBC)

New York, N.Y (USA) and Paris (France), May 21, 2019 – Zionexa, a radiopharmaceutical company specialized in the development and commercialization of innovative molecular imaging companion diagnostics (CDx) for targeted therapies in oncology, today announced that the U.S. Food and Drug Administration (FDA) has accepted its recently submitted New Drug Application (NDA) for FES for filing. FES is a new Positron Emission Tomography (PET) diagnostic drug for the characterization of estrogen receptor status in metastatic breast cancer.

"We are pleased the FDA has accepted our NDA filing and we are looking forward to working in collaboration with the administration during the review process. Filing the NDA for FES represents a key milestone for our young and promising company. Metastatic breast cancer (MBC) is a real health issue with more than 40,000 MBC-related deaths expected in the U.S. in 2019. With prompt and proper treatment, many metastatic breast cancers can be controlled, and mortality deferred. With FES, we look forward to making available to clinicians a non-invasive and qualitative way to find the optimal treatment for the patient with MBC," said Peter Webner, CEO Zionexa U.S. Corp.

About Metastatic Breast Cancer (MBC)

Metastatic breast cancer is the most advanced stage of breast cancer. Also called stage IV or advanced breast cancer, MBC means that the cancer has spread beyond the breast to other parts of the body. More than 154,000[1] women in the U.S. have MBC.

About FES[2], a biomarker for targeted diagnostic in metastatic breast cancer

FES is a new biomarker which is at the moment only approved for clinical use in France (EstroTep®) for identification of estrogen receptor status in patients with metastatic breast cancer.

About Zionexa – www.zionexa.com

Zionexa is an international and innovative company developing and commercializing molecular imaging solutions, companion diagnostics (CDx) for targeted therapies in oncology, to improve patients' pathway and provide them a better quality of life.

1 Mariotto AB, Etzioni R, Hurlbert M, PenberthyL, Mayer M. Estimation of the number of women living with metastatic breast cancer in the United States. Cancer Epidemiol Biomarkers Prev. 26(6):809-815, 2017.
2 FES is NOT FDA cleared for use in the U.S. and is only to be used in a physician sponsored clinical trial. For French prescribing information please contact infomed@zionexa.com

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