Evexta Bio Reports Progress towards Clinical Development of Rupitasertib in Advanced Breast Cancer

- **Feedback from FDA following Type B meeting enables Evexta Bio to move forward in clinical development of rupitasertib in advanced breast cancer (ABC)**
- **Phase 2 clinical trial on track to start in Q4 2024**
- **New preclinical efficacy data strengthen rationale to develop rupitasertib, in combination with elacestrant, in *ESR1*mt ER+ HER2- ABC**
- **Evexta Bio to present at 10th LSX World Congress taking place in London, April 29-30, 2024**

Paris, France, April 22, 2024 - Evexta Bio SA, a clinical-stage biotechnology company focused on developing first-in-class therapies in oncology, today provided an update on the clinical development of its lead asset, rupitasertib, a selective oral inhibitor of S6K and AKT1/AKT3.

Following a Type B meeting held on March 13, 2024, the U.S. Food and Drug Administration (FDA) provided Evexta Bio with valuable input on various aspects of rupitasertib development, including CMC, preclinical and clinical topics, enabling the company to proceed with the Phase 2 study in advanced breast cancer.

The Phase 2 trial is expected to start enrolling patients in Q4/2024. This Phase 2, open label study will evaluate the safety and efficacy of rupitasertib + elacestrant (ORSERDU®) in patients with ER+[1] HER2-[2] advanced breast cancer with detectable mutation/s of the estrogen receptor 1 gene (*ESR1*mt).

Rupitasertib is a selective oral inhibitor of S6K and AKT1/AKT3 designed to efficiently block the PI3K/AKT/mTOR (PAM) pathway while controlling the compensatory AKT feedback loop. In a Phase 1 trial (*Tsimberidou et al 2021*) involving heavily pretreated patients with various solid tumors, including those with *ESR1*mt, rupitasertib was shown to have a favorable safety profile along with preliminary signs of efficacy.

Recent preclinical studies in *ESR1*mt breast cancer models have shown compelling synergistic effects of rupitasertib administered in combination with elacestrant. These data support the preliminary clinical efficacy observed in the Phase 1 study and warrant the development of rupitasertib in *ESR1*mt ER+ HER2- advanced breast cancer patients.

Scott Filosi, CEO of Evexta Bio, said: *"The feedback we have received from the FDA on the clinical development plan for rupitasertib, along with the new preclinical efficacy data generated in estrogen-resistant breast cancer models, is enabling us to move forward with strong confidence to initiate our Phase 2 study. Advanced breast cancer patients with ESR1*

[1] Estrogen Receptor-positive.
[2] Human Epidermal growth factor Receptor 2 negative.

mutations who progressed on or after a CDK4/6 inhibitor have limited treatment options, and our goal is to provide them with an effective and well-tolerated therapy choice."

Dominique Bridon, CSO of Evexta Bio, added: "*Patients with ER+ HER2- breast cancer often develop resistance to first-line treatment with the acquisition of ESR1 mutations, and the prognosis for these patients is poor. In addition, S6K has been shown to be closely associated with the emergence of cancer resistance, particularly in breast cancer, through ER modulation. Rupitasertib, which inhibits S6K while controlling the AKT compensatory feedback loop, could be a major advance to better treat these patients who are in need of alternative therapies."*

Upcoming meeting

Evexta Bio will present at the LSX World Congress in London, April 29-30, 2024.

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About Evexta Bio (https://www.evextabio.com)

EvextaBio is a clinical-stage biopharmaceutical company exploring the new frontiers of oncology in search of daring novel therapeutic approaches with the potential to save lives. The company is currently developing two proprietary therapeutic assets with novel mechanisms of action across several indications:

- Rupitasertib, an optimized S6K inhibitor with efficient AKT1/AKT3 control of the compensatory AKT feedback loop. The oral anti-tumor agent is expected to enter a Phase 2 clinical trial in *ESR1*mt ER+ HER2- advanced breast cancer later in 2024.
- EVX020, a sole-in-class KIF20A kinesin inhibitor that has shown potent preclinical efficacy in hematological and solid tumor models. Two strategies are under assessment - development of EVX020 as a prodrug and as an antibody-drug conjugate (ADC) payload.

Founded by Truffle Capital and supported by Merck KGaA (Darmstadt, Germany) as a shareholder, Evexta Bio has forged alliances with leaders in academia and industry, including CNRS, Paoli-Calmettes Institute (Marseille, France) and Merck KGaA. The company is supported by a seasoned management team, board of directors and medical advisory board.

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