# *KURZPROTOKOLL*
# *JZLC*

| | |
|---|---|
| **Öffentlicher Titel** | Phase III Studie zu LY3484356 als Zweitlinientherapie bei ER+/HER2- Brustkrebs |
| **Wissenschaftl. Titel** | EMBER-3: A Randomized, Open-Label, Phase 3 Study of LY3484356 vs Investigator's Choice of Endocrine Therapy, in Patients with Estrogen Receptor Positive, HER2 Negative Locally Advanced or Metastatic Breast Cancer Previously Treated with Endocrine Therapy |
| **Kurztitel** | JZLC |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig |
| **Studienphase** | Phase III |
| **Erkrankung** | Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher |
| **Einschlusskriterien** | - Have a diagnosis of ER+, HER2- locally advanced or metastatic breast cancer<br>- Have disease that has demonstrated progression on or after an aromatase inhibitor alone or in combination with a CDK4/6 inhibitor<br>- Must be deemed appropriate for treatment with endocrine therapy<br>- If female, have a postmenopausal status by natural or surgical means or by ovarian function suppression<br>- Have RECIST evaluable disease (measurable disease and/or nonmeasurable bone-only disease)<br>- Have a performance status of 0 or 1 on the Eastern Cooperative Oncology Group scale (Oken et al. 1982)<br>- Have adequate renal, hematologic, and hepatic organ function<br>- Must be able to swallow capsules/tablets |
| **Ausschlusskriterien** | - Have received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant, or any investigational-ER-directed therapy (including SERDs and non-SERDs), any PI3K-, mTOR- or AKT- inhibitor<br>- Have visceral crisis, lymphangitic spread within the lung, or any evidence of leptomeningeal disease<br>- Have symptomatic or untreated brain metastasis<br>- Have serious preexisting medical conditions that, in the judgment of the investigator, would preclude participation in this study<br>- Known allergic reaction against any of the components of the study treatment |
| **Alter** | 18 Jahre und älter |
| **Molekularer Marker** | HER2/neu neg./ER pos. |
| **Prüfzentren** | **Agaplesion Markus Krankenhaus**<br>Wilhelm-Epstein-Straße 4<br>60431 Frankfurt am Main<br>PD Dr. med. Marc Thill<br>Tel: 069 95332228<br>Fax: 069 95332733<br>marc.thill@fdk.info |
| **Sponsor** | Eli Lilly and Company |
| **Registrierung in anderen Studienregistern** | EudraCT 2021-000079-35 |

© Clinical Trial Center Network (CTCN) Zentrale am Universitätsklinikum Frankfurt
Ohne Gewähr für Richtigkeit oder Vollständigkeit