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 - Have disease that has demonstrated progression on or after an aromatase inhibitor alone or in combination with a CDK4/6 inhibitor - Must be deemed appropriate for treatment with endocrine therapy - If female, have a postmenopausal status by natural or surgical means or by ovarian function suppression - Have RECIST evaluable disease (measurable disease and/or nonmeasurable bone-only disease) - Have a performance status of 0 or 1 on the Eastern Cooperative Oncology Group scale (Oken et al. 1982) - Have adequate renal, hematologic, and hepatic organ function - 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 - Have visceral crisis, lymphangitic spread within the lung, or any evidence of leptomeningeal disease - Have symptomatic or untreated brain metastasis - Have serious preexisting medical conditions that, in the judgment of the investigator, would preclude participation in this study - 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** Wilhelm-Epstein-Straße 4 60431 Frankfurt am Main PD Dr. med. Marc Thill Tel: 069 95332228 Fax: 069 95332733 marc.thill@fdk.info
Sponsor	Eli Lilly and Company
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04975308 EudraCT 2021-000079-35
Links	Zu den Ein- und Ausschlusskriterien