KURZPROTOKOLL
MONALEESA-7

Öffentlicher Titel	Phase III Studie zu sdf LEE011 mit Tamoxifen und Goserelin oder NSAI und Goserelin bei HER2 negativem fortgeschrittenem Brustkrebs
Wissenschaftl. Titel	A Phase III Randomized, Double-blind, Placebo-controlled Study of LEE011 or Placebo in Combination With Tamoxifen and Goserelin or a Non-steroidal Aromatase Inhibitor (NSAI) and Goserelin for the Treatment of Premenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer
Kurztitel	MONALEESA-7
Studienart	multizentrisch, Therapiestudie, randomisiert, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Ziele	- Progression Free Survival (PFS) [Time Frame: Up to approximatley 25 months] [Designated as safety issue: No] PFS, defined as the time from the date of randomization to the date of the first documented progression or death due to any cause and assessed according to RECIST 1.1 - Overall survival (OS) [Time Frame: Up to approximately 69 months] [Designated as safety issue: No] Time from date of randomization to the date of death from any cause - Clinical Benefit Rate (CBR) [Time Frame: Up to approximately 25 months] [Designated as safety issue: No] Proportion of patients with complete response (CR) or partial response (PR) or stable disease (SD) lasting 24 weeks or longer as defined in RECIST 1.1 - Safety and Tolerability of LEE011 [Time Frame: Up to approximately 26 months] [Designated as safety issue: Yes] Safety and tolerability will be determined by type, frequency and severity of adverse events and laboratory abnormalities per Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 - Time to Response (TTR) [Time Frame: Up to approximately 25 months] [Designated as safety issue: No] Time from randomization to the first documented and confirmed response (complete response or partial response) - Duration of Response (DOR) [Time Frame: Up to approximately 25 months] [Designated as safety issue: No] Time from the first documented response (CR or PR) to the first documented progression or death due to underlying cancer - Time to definitive deterioration of the ECOG PS from baseline [Time Frame: Baseline, up to approximately 25 months] [Designated as safety issue: Yes] Time to deterioration of Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) - Time to 10% deterioration in the global health status/QOL scale score of the EORTC QLQ-C30 [Time Frame: Up to approximately 25 months] [Designated as safety issue: No] Patient reported outcomes for health related quality of life - Change from baseline in the global health status/QOL scale score of the EORTC QLQ-C30 [Time Frame: Up to approximately 25 months] [Designated as safety issue: No] Patient reported outcomes for health related quality of life - Overall Response Rate (ORR) [Time Frame: Up to approximately 25 months] [Designated as safety issue: No] Proportion of patients with the best overall response of complete response (CR) or partial response (PR) according to RECIST 1.1.
Einschlusskriterien	- Patient has advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy - Patient is premenopausal or perimenopausal at the time of study entry - Patients who received (neo) adjuvant therapy for breast cancer are eligible - Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer - Patient has HER2-negative breast cancer

	- Patient must have either measurable disease or If no measurable disease is present, then at least one predominantly lytic bone lesion - Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 - Patient has adequate bone marrow and organ function
Ausschlusskriterien	- Patient who has received a prior CDK4/6 inhibitor - Patient is postmenopausal - Patients who currently have inflammatory breast cancer at screening. - Patients who received any prior hormonal anti-cancer therapy for advanced breast cancer, except for 14 days of tamoxifen or NSAI ± goserelin for advanced breast cancer prior to randomization. - Patient has a concurrent malignancy or malignancy within 3 years of randomization, with the exception of adequately treated basal cell skin carcinoma, squamous cell skin carcinoma, non-melanomatous skin cancer or curatively resected cervical cancer. - Patient with CNS metastases. - Patient has active cardiac disease or a history of cardiac dysfunction - Patient is currently using other antineoplastic agents - Patient is pregnant or nursing or physiologically capable of becoming pregnant and not using highly effective contraception
Alter	18 - 59 Jahre
Molekularer Marker	HER2/neu neg.
Fallzahl	660
Prüfzentren	**Sana Klinikum Offenbach** (Geschlossen) Ambulantes Onkologisches Zentrum Starkenburgring 66 63069 Offenbach n.a. Melanie Moschitz Tel: 069 8405 5815 Fax: 069 8405 4486 Melanie.Moschitz@sana.de
Sponsor	Novartis Pharma (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02278120