# *KURZPROTOKOLL*
# *MONALEESA-7*

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| **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<br>- 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<br>- 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<br>- 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<br>- 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)<br>- 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<br>- 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)<br>- 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<br>- 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<br>- 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<br>- Patient is premenopausal or perimenopausal at the time of study entry<br>- Patients who received (neo) adjuvant therapy for breast cancer are eligible<br>- Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer<br>- Patient has HER2-negative breast cancer |

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| | - Patient must have either measurable disease or If no measurable disease is present, then at least one predominantly lytic bone lesion<br>- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1<br>- Patient has adequate bone marrow and organ function |
| **Ausschlusskriterien** | - Patient who has received a prior CDK4/6 inhibitor<br>- Patient is postmenopausal<br>- Patients who currently have inflammatory breast cancer at screening.<br>- 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.<br>- 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.<br>- Patient with CNS metastases.<br>- Patient has active cardiac disease or a history of cardiac dysfunction<br>- Patient is currently using other antineoplastic agents<br>- 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)<br>Ambulantes Onkologisches Zentrum<br>Starkenburgring 66<br>63069 Offenbach<br>n.a. Melanie Moschitz<br>Tel: 069 8405 5815<br>Fax: 069 8405 4486<br>Melanie.Moschitz@sana.de |
| **Sponsor** | Novartis Pharma (Hauptsponsor) |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT02278120 |