Studienname	**OlympiaN** **Phase II, Multicentre, Open-Label Study to Assess the Efficacy and Safety of Olaparib Monotherapy and Olaparib Plus Durvalumab Combination as Neoadjuvant Therapy in Patients with BRCA Mutations and Early Stage HER2-Negative Breast Cancer**
Sponsor/ Studiencode	AstraZeneca D931CC00001
Setting	HER2 neg. eBC, neoadjuvante Therapie
Primäres Studienziel	pCR Rate
Studiendesign	There will be 2 cohorts: **Cohort** A will consist of a lower-risk population **Cohort B** will consist of a higher-risk population Participants will be allocated to receive 300 mg oral olaparib twice daily as monotherapy (**Cohort A)** or in combination with durvalumab 1500 mg via intravenous infusion every 4 weeks for a minimum of 4 and a maximum of six 28-day cycles before undergoing definitive surgery (**Cohort B**).
Einschluss-kriterien (Auswahl)	• HER2 neg. nicht metastasiertes/ frühes Mammakarzinom • ER-negativ oder low (≤ 10%) • cT1b-2 N0 oder cT1 N0 Clinical TNM staging (per AJCC 8th Edition) as follows: o T1b (>5 mm but ≤10 mm), N0, no known metastases (M0 or MX); OR o T1c (>10 mm but ≤20 mm), N0, no known metastases (M0 or MX); OR o T1 (>1 mm but ≤20 mm), N1, no known metastases (M0 or MX); OR o T2 (>20 mm but ≤50 mm), N0, no known metastases (M0 or MX).). • BRCA Mutation 1/ 2 • Erneute Biopsie vor Therapiestart
Ausschluss-kriterien (Auswahl)	• Maligne Vorgeschichte <5 Jahre • Kardiale Vorgeschichte • Autoinflammatorische Erkrankungen • Aktive Hepatitiserkrankung • For higher risk (Cohort B) participants only: Prior exposure to anti-PD1, anti-PD-L1, or anti-CTLA4 agents (ICIs); OR an agent directed to other co-inhibitory or co-stimulatory T-cell receptors • For higher risk (Cohort B) participants only: Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab.
Teilnehmende Zentren	➢ KEM Essen