CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

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| **Studientitel** | **EPIK-B5: A Phase III, randomized, double-blind, placebo-controlled study of alpelisib (BYL719) in combination with fulvestrant for men and postmenopausal women with HR-positive, HER2-negative advanced breast cancer with a PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor** | |
| **EudraCT-Nummer** | **2021-001966-39** | |
| **ClinicalTrials.gov Identifier** | **NCT05038735** | |
| **Sponsor** | Novartis Pharmaceuticals | |
| **Ansprechpartner*in** | Dr. med. Caroline Neeb | |
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| **Wichtigste Einschlusskriterien** | • Participant is an adult ≥ 18 years old at the time of informed consent and has signed informed consent before any trial related activities and according to local guidelines.<br>• If female, then the participant must be in postmenopausal status. Postmenopausal status is defined either by: prior bilateral oophorectomy, age ≥60 or age <60 and amenorrheic for 12 or more months in the absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression and follicle-stimulating hormone (FSH) and estradiol in the postmenopausal range per local normal range.<br>• Participant has a histologically and/or cytologically confirmed diagnosis of ER+ and/or PgR+ breast cancer by local laboratory.<br>• Participant has HER2-negative breast cancer defined as a negative in situ hybridization test or an IHC status of 0, 1+ or 2+. If IHC is 2+, a negative in situ hybridization (Fluorescent in situ hybridization (FISH), Chromogenic in situ hybridization (CISH), or Silver-enhanced in situ hybridization (SISH)) test is required by local laboratory testing. | |

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| | • Participant has at least one measurable lesion as per RECIST v1.1 criteria as assessed by BIRC (a lesion at a previously irradiated site may only be counted as a target lesion if there is clear sign of progression since the irradiation).<br><br>• Participant has recurrence or progression of disease during or after combined AI (i.e. letrozole, anastrozole, exemestane) and CDK4/6 inhibitor therapy. The combined AI and CDK4/6 inhibitor therapy does not need to be the latest treatment regimen (including adjuvant setting).<br><br>• Participant has received ≤1 line of prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy).<br><br>• Participant must show the presence of a PIK3CA mutation(s) determined by tissue either by a local laboratory using only CE-marked IVD assays such as QIAGEN Therascreen® PIK3CA RGQ PCR test or by a Novartis designated laboratory. |