

**KURZPROTOKOLL  
FOREVER**

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| <b>Öffentlicher Titel</b>                        | Everolimus und Exemestan bei menopausalen Frauen mit ER-positivem, lokal fortgeschrittenem oder metastasiertem Brustkrebs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Wissenschaftl. Titel</b>                      | A phase IIIb, multi-center, openlabel study for menopausal women with estrogen receptor positive locally advanced or metastatic breast cancer treated with everolimus (RAD001) in combination with exemestane                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Kurztitel</b>                                 | FOREVER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Studienart</b>                                | multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Studienphase</b>                              | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Erkrankung</b>                                | Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Adult women (<math>\geq 18</math> years of age) with metastatic or locally advanced breast cancer not amenable to curative treatment by surgery or radiotherapy or any other non-systemic treatment</li><li>- Histological or cytological confirmation of estrogen receptor positive (ER+) and/or progesterone receptor positive (PgR+), human epidermal growth factor receptor 2 (HER2) - negative breast cancer</li><li>- Postmenopausal women</li><li>- Progressing following prior therapy with non steroidal aromatase inhibitors (NSAI) with or without direct switching to steroidal AI treatment with Exemestane</li><li>- Patients must have: 1. At least one lesion that can be accurately measured or 2. Bone lesions: lytic or mixed (lytic + sclerotic) in the absence of measurable disease</li></ul> |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- HER2-overexpressing patients by local laboratory testing</li><li>- Non stable or non pre-treated brain metastases</li><li>- Patients with only non-measurable lesions other than bone metastasis</li><li>- Previous treatment with mTOR inhibitors</li><li>- Known hypersensitivity to mTOR inhibitors</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Alter</b>                                     | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Molekularer Marker</b>                        | HER2/neu neg./ER pos.<br>HER2/neu neg./PR pos.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Prüfzentren</b>                               | <b>Frauenheilkunde und Geburtshilfe (Nachbeobachtung)</b><br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Claudia Plechatsch<br>Tel: 069 6301-83632<br>Fax: 069 6301-86469<br><a href="mailto:claudia.plechatsch@unimedizin-ffm.de">claudia.plechatsch@unimedizin-ffm.de</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Sponsor</b>                                   | Novartis Pharma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Förderer</b>                                  | Novartis Pharma                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Registrierung in anderen Studienregistern</b> | EudraCT 2011-006111-62                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |