

## **KURZPROTOKOLL FOREVER**

<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</math> 18 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. HER2/neu neg./PR pos.
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