KURZPROTOKOLL
FOREVER

Öffentlicher Titel	Everolimus und Exemestan bei menopausalen Frauen mit ER-positivem, lokal fortgeschrittenem oder metastasiertem Brustkrebs
Wissenschaftl. Titel	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
Kurztitel	FOREVER
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	- Adult women (>= 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 - 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 - Postmenopausal women - Progressing following prior therapy with non steroidal aromatase inhibitors (NSAI) with or without direct switching to steroidal AI treatment with Exemestane - 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
Ausschlusskriterien	- HER2-overexpressing patients by local laboratory testing - Non stable or non pre-treated brain metastases - Patients with only non-measurable lesions other than bone metastasis - Previous treatment with mTOR inhibitors - Known hypersensitivity to mTOR inhibitors
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg./ER pos. HER2/neu neg./PR pos.
Prüfzentren	**Frauenheilkunde und Geburtshilfe** (Nachbeobachtung) Theodor-Stern-Kai 7 60590 Frankfurt am Main Claudia Plechatsch Tel: 069 6301-83632 Fax: 069 6301-86469 claudia.plechatsch@unimedizin-ffm.de
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