Studientitel	Leiter/in	Mitarbeiter/in	Projektart	Dauer	Patientinnen-zahl mit 28.02.2014	Sponsor
ABCSG 8	Prof. Dr. Christian Singer	Ass. Prof. Dr. Daphne Gschwantler-Kaulich DGKS Ingeborg Brandl, BCN	§ 27	Bis 2019	119	ABCSG
ABCSG 12	Prof. Dr. Christian Singer	Ass. Prof. Dr. Daphne Gschwantler-Kaulich DGKS Ingeborg Brandl, BCN	§ 27	bis 30.11.2014	55	ABCSG
ABCSG 15 – IBIS II	Prof. Dr. Christian Singer	DGKS Ingeborg Brandl, BCN	§ 27	bis 12.2018	4	ABCSG
ABCSG 16 – SALSA	Prof. Dr. Christian Singer	Ass. Prof. Dr. Daphne Gschwantler-Kaulich DGKS Ingeborg Brandl, BCN	§ 27	bis 12.2019	94	ABCSG
ABCSG 18 - A randomized, double-blind, placebo-controlled, multi-center phase 3 study to determine the treatment effect of denosumab in subjects with non-metastatic breast, breast cancer receiving aromatase inhibitor therapy	Prof. Dr. Christian Singer	Dr. Anneliese Fink-Retter Ass. Prof. Dr. Daphne Gschwantler- Kaulich DGKS Ingeborg Brandl, BCN	§ 27	01.12.2006-31.12.2015	302	ABCSG
ABCSG 19 - Hera BO16348 Herceptin	Prof. Dr. Christian Singer	Dr. Arik Galid	§ 27	bis 08.2014	11	ABCSG
ABCSG 25 Study - Comparing biweekly and tailored epirubicin + cyclophosphamide	Prof. Dr. Christian Singer	Dr. Anneliese Fink-Retter DGKS Ingeborg Brandl,	§ 27	01.12.2007-31.12.2014	55	ABCSG

followed by biweekly tailored docetaxel versus three weekly epirubicin + cyclophosphamide, 5-flourouracil followed by docetaxel (FEC) in lymph node positive breast cancer patients - a continuation of the feasibility part of the SBG 2004-1 study		BCN				
ABCSG 26 – A phase III trial evaluating the role of continuous letrozole vs intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone-receptor positive, node positive early stage breast cancer - SOLE	Prof. Dr. Christian Singer	DGKS Ingeborg Brandl, BCN	§ 27	01.01.2011-31.12.2015	7	ABCSG
ABCSG 27 - Internationale multizentrische, zweiarmige open-label-Phase III Studie zur adjuvanten Therapie mit Bevacizumab beim dreifach negativem (triple-negative Mammakarzinom / BEATRICE	Prof. Dr. Christian Singer	Dr. Anneliese Fink-Retter DGKS Ingeborg Brandl, BCN	§ 27	01.11.2007-30.06.2019	11	ABCSG
ABCSG 28 Posytive – primary operation in synchronous metastasized invasive breast cancer, a multicenter prospective randomized study to evaluate the use of local therapy	Prof. Dr. Christian Singer	Prof. Dr. Michael Seifert Ass. Prof. Dr. Georg Pfeiler Dr. Muy-Kheng Tea DGKS Ingeborg Brandl	§ 27	01.09.2010-31.08.2014	1	ABCSG
ABCSG 30 BETH - A multicentre phase III randomized Study of adjuvant therapy for patients with HER-2-positive or high risk node-negative breast cancer comparing	Prof. Dr. Christian Singer	DGKS Ingeborg Brandl, BCN	§ 27	01.11.2008 31.05.2021	4	ABCSG

chemotherapy plus trastuzumab with chemotherapiy plus trastuzumab plus bevacizumab						
ABCSG 31 ALTTO – Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation Study EGF 106708 ALTTO: EGF 106708 ABCSG 31	Prof. Dr. Christian Singer	DGKS Ingeborg Brandl, BCN	§ 27	01.04.2009-31.03.2019	1	ABCSG
ABCSG 32 - Multicentre randomized phase II study for operable mammacarcinoma with neoadjuvant Trastuzumab plus Docetaxel with and without Bevacizumab and Trastuzumab plus Docetaxel plus non-pegylated liposome-encapsulated Doxorubicin (NPLD) with and without bevacizumab in HER2-positive early breast cancer – ML22765	Prof. Dr. Christian Singer	Dr. Muy-Kheng Tea DGKS Ingeborg Brandl, BCN	§ 27	01.04.2011-30.09.2013	7	ABCSG
ABCSG 34 – A prospective open, randomized, phase- II study of a therapeutic cancer vaccine (L-BLP25, Stimuvax) in the pre-operative treatment of women with primary breast cancer	Prof. Dr. Christian Singer	Dr. Christine Staudigl DGKS Ingeborg Brandl, BCN	§ 27	01.03.2012-28.02.2014	61	ABCSG
ABCSG 36 - Phase III study evaluating palbociclib (PD-0332991) a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neoadjuvant	Prof. Dr. Christian Singer	Prof. Dr. Georg Pfeiler DGKS Ingeborg Brandl, BCN	§ 27	2014-2018	Noch nicht begonnen	ABCSG

chemotherapy "PENELOPEB						
ABCSG 38 -	Prof. Dr. Christian Singer	Prof. Dr. Georg Pfeiler DGKS Ingeborg Brandl, BCN	§ 27	01.04.2014- 30.09.2016	Noch nicht begonnen	ABCSG
ABCSG 39 – A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer	Prof. Dr. Christian Singer	Dr. Muy-Kheng Tea DGKS Ingeborg Brandl, BCN	§ 27	01.05.2012- 31.12.2025	7	ABCSG
ABCSG 40 - Eine randominisierte, doppelblinde, placebo-kontrollierte Phase-II-Studie zu Letrozol mit und ohne BYL719 oder Buparlisib zur neoadjuvanten Behandlung postmenopausaler Frauen mit hormonrezeptorpositivem, HER2-negativem Brustkrebs	Prof. Dr. Christian Singer	Prof. Dr. Georg Pfeiler	§ 27	01.04.2014- 31.12.2016	Noch nicht begonnen	ABCSG
OHERA - An observational study of cardiac events in patients with HER-2postive early breast treated with Herceptin - BO20652	Prof. Dr. Christian Singer	Dr. Anneliese Fink-Retter Ass. Prof. Dr. Daphne Gschwantler-Kaulich DGKS Ingeborg Brandl, BCN	§ 27	01.12.2007- 31.10.2014	17	Fa. Quintiles
Prospektiv internationale Studie zur Beobachtung des Neutropenie und Anämiemanagements bei Patienten mit	Prof. Dr. Christian Singer	Dr. Christine Staudigl	§ 27	01.02.2008- 31.12.2014	38	Fa. AMGEN

soliden Tumoren, die eine myelotoxische Chemotherapie erhalten (Studie Nr. 20060445)						
TANIA - A phase III randomized study evaluating the efficacy and safety of continued and re-induced bevacizumab in combination with chemotherapy for patients with locally recurrent or metastatic breast cancer after first-line chemotherapy and bevacizumab treatment) Proj.Nr. TANIA-RO4876646	Prof. Dr. Christian Singer	Dr. Anneliese Fink-Retter	§ 27	01.01.2011-31.12.2013	1	Fa. Roche
PERUSE - A multicenter, open-label, single arm study of pertuzumab in combination with trastuzumab and a taxane in first line treatment of patients with HER2-positive advanced (metastatic or locally recurrent) breast cancer	Prof. Dr. Christian Singer	Prof. Dr. Michael Seifert Dr. Anneliese Fink-Retter DGKS Ingeborg Brandl, BCN	§ 27	15.03.2012-14.03.2019	3	Fa. Roche
A prospective Dose Intensity and Neutropenia Prophylaxis Evaluation Program in patients receiving myelosuppressive chemotherapy of high risk of febrile neutropenia for different types DIEPP Proj.Nr.: AMG20100088	Prof. Dr. Christian Singer	Dr. Christine Staudigl	§ 27	01.02.2011-30.06.2013	11	Fa. AMGEN
CIA-Study - A prospective, randomized, multicenter study to evaluate the impact of Ferric(III)-Carboxymaltose in comparison to a combination of Darbopoetin alpha and	Prof. Dr. Christian Singer	Dr. Christine Staudigl	§ 27	01.02.2011-31.07.2013	1	Fa. VIFOR

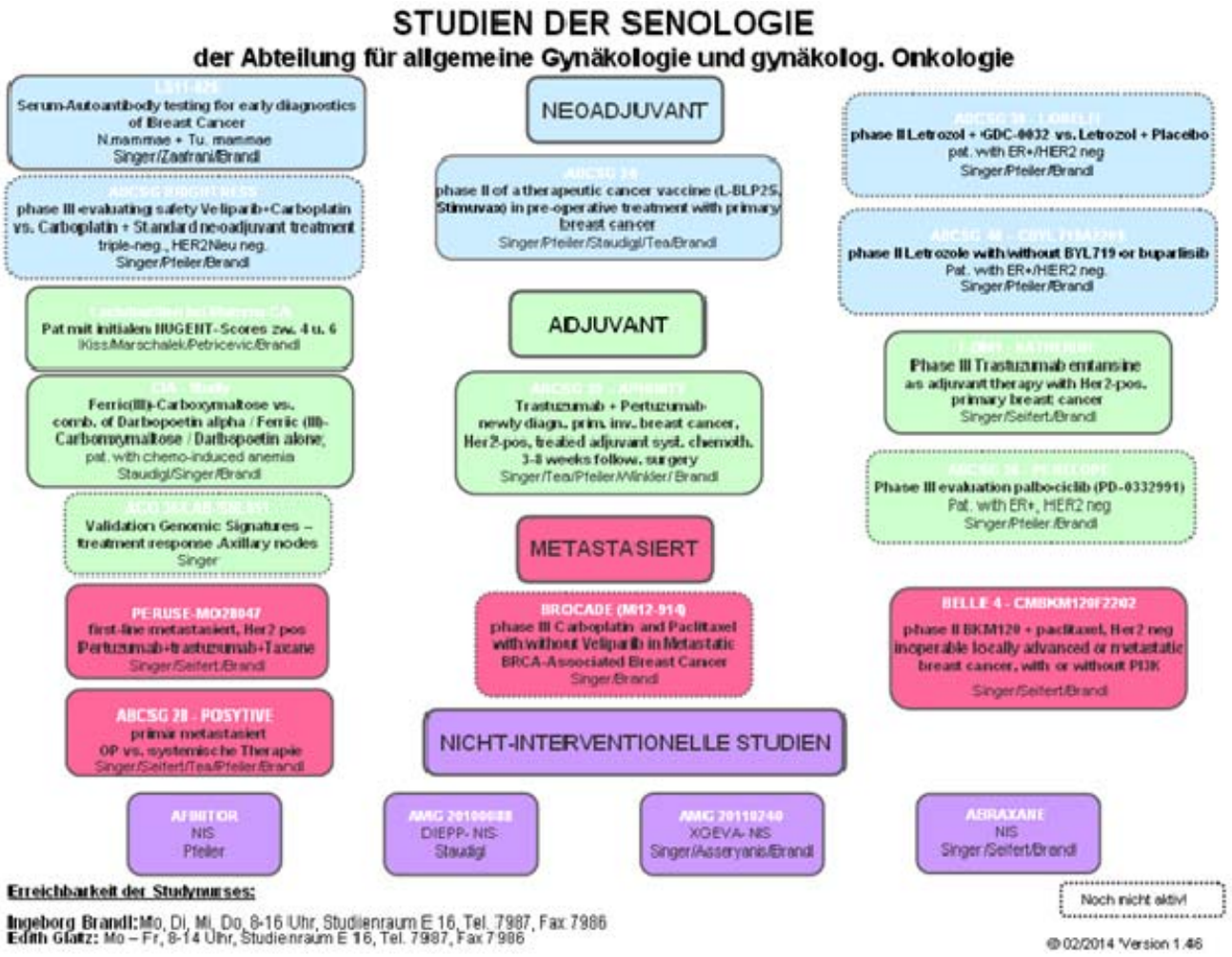
Ferric(III)-Carboxymaltose and to Darbopoetin alpha alone in patients with chemotherapy-induced anemia						
BELLE 4 – A randomized, double-blind, placebo controlled, phase II study of BKM120 plus paclitaxel in patients with Her2 negative inoperable locally advanced or metastatic breast cancer, with our without PI3K pathway activation	Prof. Dr. Christian Singer	Prof. Dr. Michael Seifert DGKS Ingeborg Brandl, BCN	§ 27	01.06.2012-31.03.2015	1	Fa. Novartis
A multicenter, single arm study of trastuzumab emtansine (T-DM1) in HER2 positive locally advanced or metastatic breast cancer patients who have received prior anti-her2 and Chemotherapy-based treatment	Prof. Dr. Christian Singer	Dr. Muy-Kheng Tea Dr. Elfriede Winkler-Dobrovits DGKS Ingeborg Brandl, BCN	§ 27	01.10.2012-30.06.2014	3	Fa. Roche
Serum-Autoantibody testing for early diagnostics of Breast Cancer Proj. Nr. LS11-026	Prof. Dr. Christian Singer	Dr. Sonia Zaafrani	§ 27	01.05.2012-30.04.2015	152	WWTF
AGO 35/LAB-SNL011 Prospective Validation of Genomic Signatures to Predict Treatment Response in the Axillary Nodes after Neoadjuvant Chemotherapy in Patients with HER2-negative Breast Cancer	Prof. Dr. Christian Singer	-	§ 27	2014 - 2017	Noch nicht begonnen	AGO - Austria
ABCSG BRIGHTNESS	Prof. Dr. Christian Singer	Ass.-Prof. Dr. Georg Pfeiler DGKS Ingeborg Brandl, BCN	§ 27		Noch nicht begonnen	ABCSG

BROCADE M12-914	Prof. Dr. Christian Singer	DGKS Ingeborg Brandl, BCN	§ 27		Noch nicht begonnen	AbbVie
Lactobazillen bei Mamma-CA – Klinische Studie mit einem Lactobazillenpräparat: Oral verabreichtes Probiotikum zur Verbesserung der Scheidenflora bei Frauen mit Mamma-Carzinom nach Chemotherapie – eine prospektiv randomisierte, placebokontrollierte Doppelblindstudie	Univ. Prof. Dr. Herbert Kiss	Dr. Julian Marschalek Ass. Prof. Dr. Ljubomir Petricevic DGKS Ingeborg Brandl, BCN	Amtsforschung	01.05.2013	11	MedUni Wien
ABRAXANE-MBC-1 – A non-interventional single arm observational study in subjects treated with nab-paclitaxel	Prof. Dr. Michael Seifert	DGKS Ingeborg Brandl	§ 27	01.07.2012-31.07.2014	3	Fa. Celgene
The ability of an orally administered preparation of four lactobacillus species to improve the quality of the vaginal flora of women with breast cancer and chemotherapy. A prospective randomized placebo controlled, double-blind trial	Prof. Dr. Herbert Kiss, MBA	Ass. Prof. Dr. Petricevic Dr. Julian Marschalek DGKS Ingeborg Brandl	Amtsforschung	01.05.2013-31.12.2013	11	MedUni Wien
Protexa versus TiLoopBra in der Sofortrekonstruktion der Brust	Prof. Dr. Christian Singer	Ass. Prof. Dr. Daphne Gschwantler-Kaulich	§ 27	01.04.2013-30.06.2015	50	AFS Medical GmbH
XGEVA –NIS: Prospektive Beobachtungsstudie zur Beurteilung der Behandlungspersitenz mit XGEVA® bei Patienten mit Knochenmetastasen aufgrund solider Tumoren zur Prävention von skelettbezogenen Ereignissen (SREs) in der klinischen Routinepraxis	Prof. Dr. Christian Singer	Ass. Prof. Dr. Ella Asseryanis DGKS Ingeborg Brandl, BCN	§ 27	01.10.2012-30.09.2015	10	Amgen

AFINITOR – NIS	Ass.-Prof. Dr. Georg Pfeiler	-	§ 27	01.04.2013 30.06.2015	3	Novartis
Zirkulierende Tumorzellen bei Hochrisikopatientinnen	Ass.-Prof. Dr. Georg Pfeiler	-	Amtsforschung	12.2012	10	MedUni Wien
Porth Studie (EK Nr 760/2011)	Ass.-Prof. Dr. Georg Pfeiler	-	Amtsforschung	12.2014	15	MedUni Wien
BMI und endokrine Therapie (EK Nr. 1114/2009)	Ass.-Prof. Dr. Georg Pfeiler	-	Amtsforschung	05.2015	87	MedUni Wien

Studien an der Senologie

- ABCSG 28
- ABCSG 34
- ABCSG 36 (PENELOPE)
- ABCSG 38
- ABCSG 39
- ABCSG 40
- T-DM1 (KATHERINE)
- PERUSE
- BELLE 4
- CIA-Study
- AGO 35/LAB-SNL011
- ABCSG Brightness
- BROCADE M12-914
- Lactobazillen bei Mamma-CA
- NIS XGEVA
- NIS ABRAXANE


STUDIEN DER SENOLOGIE
der Abteilung für allgemeine Gynäkologie und gynäkolog. Onkologie
Serum-Autoantibody testing for early diagnostics of Breast Cancer
N.mammae + Tu. mammae
Singer/Zaafrani/Brandl
phase III evaluating safety Veliparib+Carboplatin vs. Carboplatin + Standard neoadjuvant treatment
triple-neg., HER2Neu neg.
Singer/Pfeiler/Brandl
Pat mit initialen IHGENT-Scores zw. 4 u. 6
Kiss/Marschalek/Petricevic/Brandl
Ferric(III)-Carboxymaltose vs. comb. of Darbopoetin alpha / Ferric (III)-Carbomaltose / Darbopoetin alone;
pat. with chemo-induced anemia
Staudigl/Singer/Brandl
Validation Genomic Signatures – treatment response Axillary nodes
Singer
PERUSE-MO28047
first-line metastasiert, Her2 pos
Pertuzumab+trastuzumab+Taxane
Singer/Seifert/Brandl
ABCSG 28 - POSYTIVE
primär metastasiert
OP vs. systemische Therapie
Singer/Seifert/Tea/Pfeiler/Brandl
NEOADJUVANT
phase II of a therapeutic cancer vaccine (L-BLP25, Stimuvax) in pre-operative treatment with primary breast cancer
Singer/Pfeiler/Staudigl/Tea/Brandl
ADJUVANT
Trastuzumab + Pertuzumab
newly diagn., prim. inv. breast cancer, Her2-pos, treated adjuvant syst. chemoth.
3-8 weeks follow. surgery
Singer/Tea/Pfeiler/Winkler/Brandl
METASTASIERT
BROCADE (M12-914)
phase III Carboplatin and Paclitaxel with/without Veliparib in Metastatic BRCA-Associated Breast Cancer
Singer/Brandl
NICHT-INTERVENTIONELLE STUDIEN
AFINITOR
NIS
Pfeiler
AMG 20100088
DIEPP- NIS
Staudigl
AMG 20110240
XGEVA- NIS
Singer/Asseryanis/Brandl
phase II Letrozol + GDC-0032 vs. Letrozol + Placebo
pat. with ER+/HER2 neg
Singer/Pfeiler/Brandl
phase II Letrozole with/without BYL719 or buparlisib
Pat. with ER+/HER2 neg.
Singer/Pfeiler/Brandl
Phase III Trastuzumab emtansine
as adjuvant therapy with Her2-pos. primary breast cancer
Singer/Seifert/Brandl
Phase III evaluation palbociclib (PD-0332991)
Pat. with ER+, HER2 neg
Singer/Pfeiler/Brandl
BELLE 4 - CMBKM120F2202
phase II BKM120 + paclitaxel, Her2 neg inoperable locally advanced or metastatic breast cancer, with or without PI3K
Singer/Seifert/Brandl
ABRAXANE
NIS
Singer/Seifert/Brandl
Noch nicht aktiv!
Erreichbarkeit der Studynurses:
Ingeborg Brandl: Mo, Di, Mi, Do, 8-16 Uhr, Studienraum E 16, Tel. 7987, Fax 7986
Edith Glatz: Mo – Fr, 8-14 Uhr, Studienraum E 16, Tel. 7987, Fax 7986
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ABCSG 28 Primary Operation in SYnchronic meTastasized InVasivE breast cancer, a multicenter prospective randomized study to evaluate the use of local therapy

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. Prof. Dr. Georg Pfeiler
Prof. Dr. Michael Seifert
Dr. Muy-Kheng Tea
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Patients age > 18 years
- Synchronic metastasized invasive carcinoma of the breast with the primary tumour in situ
- The primary tumour must be identified and may be any size
- Invasive adenocarcinoma on histological examination
- The metastatic site must be identified by radiology; CT for brain metastases, CT scan of Thorax and Abdomen for liver and lung metastases (or US and chest-X ray), total bone scan with CT scan (or X-ray) for verification of bone metastases, CT scan or US for thyroid and adrenal metastases. A biopsy is not necessary
- Pat. With formerly treated non-metastasized breast cancer in history may be eligible
- Recurrent breast cancer with synchronic metastases are eligible
- Bilateral synchronic metastasized breast cancer are eligible

Ausschlusskriterien:

- Pat. who are not eligible for general anaesthesia and operations
- Pat. without metastatic breast cancer
- Pat. with a tumour marker value (CEA, CA 15-3) above normal levels without the radiological proven evidence of metastases (CCT, CT Thorax and Abdomen, bone scan, PET scan, US or X-ray) are not eligible for the study. Pat. with a second untreated malignancy
- Any previous malignancy treated with curative intent and the patient has not been disease-free for 5 years – exceptions are:
    - Carcinoma in situ of the cervix
    - Squamous carcinoma of the skin
    - Basal cell carcinoma of the skin
    - Breast cancer
- Any recurrent cancer disease except breast cancer
- Pregnant or lactating women
- Pat. are allowed to be part of a clinical trial except any surgical or local therapy trials
- Patients with synchronic metastases after resection of the primary

ABCSG 34 - A prospective, open, randomized, phase-II study of a therapeutic cancer vaccine (L-BLP25, Stimuvax) in the pre-operative treatment of women with primary breast cancer

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. Prof. Dr. Georg Pfeiler
Dr. Muy-Kheng Tea
Dr. Christine Staudigl
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Pre-and postmenopausal female patients with core-biopsied, early primary invasive breast cancer of any clinical and/or radiological tumor stage (except T4d, inflammatory breast cancer) scheduled to receive preoperative therapy
- Postmenopausal AND E+++ or (E++ and ki67<15%) AND G 1,2, x AND scheduled for endocrine therapy as institutional standard of care
- Triple negative or E- Or E+ or (E++ and ki67>15%) OR G3 or premenopausal status AND scheduled for anthracylin-taxan-based chemotherapy as institutional standard of care (Therapy B)
- No distant metastasis (M0) or secondary carcinoma as assessed clinically and radiologically (X-Ray or CT or MRI or PET)
- Age > 18
- WHO performance status 0 or 1
- No prior chemotherapy, radiotherapy, or endocrine therapy for invasive breast cancer
- Willingness to undergo Sin/ALND Procedure (Sentinel/Axillary Lymph node dissection)
- No medical and/or cardiologic contraindication to receive an anthracyclin-and taxan-containing chemotherapy or endocrine therapy regimen
- Adequate Hematologic function, as follows (< 14 days prior to randomisation):
  - Absolute neutrophil count (ANC) > 1.5 x 109/L
  - Leucocyte count > 3.0 x 109g/L
  - Platelet count > 140 x 109/L
  - Haemoglobin > 9 x g/dL
- Adequate renal function, as follows (< 14 days of randomization):
  - Creatinine < 1.5 x upper limit of normal (ULN)
- Adequate Hepatic function, as follows (< 14 days of randomization)
  - Aspartate aminotransferase (AST) < 2,5 x ULN
  - Alanine aminotransferase (ALT) < 2,5 x ULN
  - Total bilirubin < 1.5 x ULN
- Adequate cardiac function:
  - Normal cardiac function must be confirmed by LVEF (Echocardiography or MUGA scan) (Therapy B only)
  - The result must be above 50 % or above the lower criteria has to be met.
  - HYHA <III
  - No uncontrolled angina, arrhythmia, hypertension
  - No myocardial infarction over the last 6 months as confirmed by ECG
  - Negative pregnancy test max. 7 days prior to randomization for pre-menopausal patients, no pregnancy tests must be performed at the time, requested that a) FSH and estradiol are in postmenopausal range and/or b) the patient is amenorrhoeic for > 12 months with uterus still in situ and/or c) the patients is 61 years of age or older

Ausschlusskriterien:

- Her2 overexpression
- Past or current history of other neoplasms in the last 5 years, except basal cell cancer of the skin, non-melanoma skin cancer and in situ cancer of the cervix.
- Any medical condition rendering the patient unfit for standard of care preoperative therapy (chemotherapy or endocrine therapy in the respective SoC treatment strata)
- Concurrent or prior systemic antitumor therapy < 5 years
- Patients scheduled for any chemotherapy other than EC->T or T->EC
- Known liver disease as determined by the investigator and indicated by:
  - Aspartale aminotransferase (AST) > 2,5 x ULN
  - Alanine aminotransferase (ALT) > 2,5 x ULN
  - Total bilitrubin > 1,5 x ULN
- Known renal disease as determined by the investigator indicated by:
  - Creatinine > 2 x upper limit of normal (ULN)
- Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) < 1 year before randomization.
- Known autoimmune disease (e.g. rheumatoid, arthritis, systemic lupus erythematosus, ulcerative colitis, Chrohn's disease, multiple sclerosis, ankylosing spondylitis)
- Severely compromised heamatopoietic function
- Known immunodeficiency disease (cellular immunodeficiency, hypogammaglobulinaemia, dysgamaglobulinaemia)
- Known positive test(s) for human immunodeficiency virus (HIV) infection, hepatitis C virus, acute or chronic active hepatitis B infection.
- Active infection requiring systemic treatment or any uncontrolled infections < 14 days prior to randomization.
- Major surgery or significant traumatic injury occurring within 4 weeks prior randomization.
- Use of i.v. or s.c. immune modulators (Viscum album etc.)
- Pre-treatment of Stimuvax
- Pregnancy or breastfeeding. All female patients with reproductive potential must have a negative pregnancy test (serum or urine) prior to randomisation.
- Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that would impart in the judgment of the investigator.
- Known hypersensitivity against taxanes and/or Epirubicin and/or Cyclophosphamide or aromatase inhibitors in the respective SoC treatment groups.
- Concurrent treatment with corticosteroids except as use for the prophylactic medication regimen, inhalational use, prevention or treatment of acute hypersensitivity reactions, treatment of nausea/vomiting or chronic treatment (initiated > 6 months prior to study entry) at low dose (< 20 mg methylprednisolone or equivalent)

• Kontrollgruppe: Standardtherapie
1. CT konventionelle Sequenz (EC/T), 8 Zyklen
2. CT umgekehrte Sequenz (T/EC), 8 Zyklen
3. Endokrine Therapie mit Letrozol, ca. 24 Wochen

• Experimentelle Gruppe: Standardtherapie + L-BLP25
1. CT konventionelle Sequenz (EC/T), 8 Zyklen + L-BLP25
2. CT umgekehrte Sequenz (T/EC), 8 Zyklen + L-BLP25
3. Endokrine Therapie mit Letrozol, 24 Wochen + L-BLP25

ABCSG 36 – Phase III study evaluating palbociclib (PD-0332991) a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy "PENELOPE^{B}"

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. –Prof. Dr. Georg Pfeiler
Prof. Dr. Michael Seifert
DGKS Ingeborg Brandl, BCN

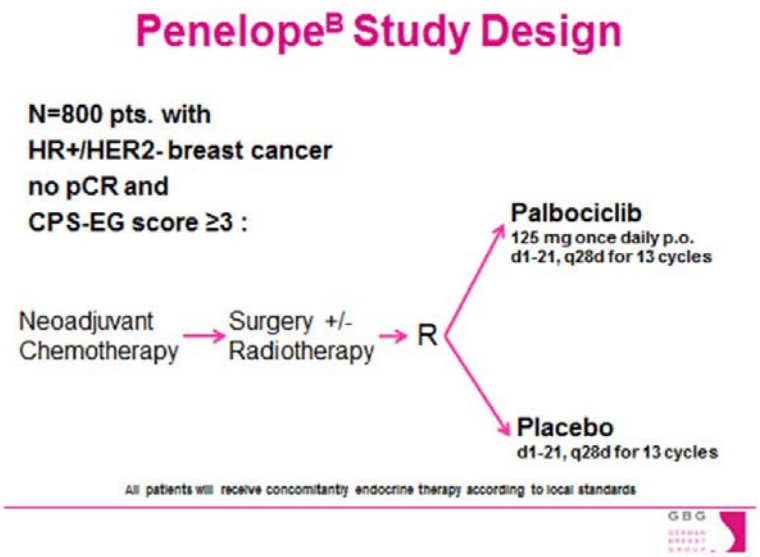
Einschlusskriterien:

- Histologically confirmed unilateral or bilateral primary invasive carcinoma of the breast.
- Residual invasive disease post-neoadjuvant either in the breast or as residual nodal invasion.
- Centrally confirmed hormone-receptor-positive (>=1% positive stained cells) and HER2-normal (IHC score 0-1 or FISH negative (in-situ hybridization (ISH) ratio <2.0 status assessed preferably on tissue from post-neoadjuvant residual invasive disease of the breast, or if not possible, of residual nodal invasion. In case of bilateral breast cancer status has to be confirmed for both sides.
- Centrally assessed Ki-67, pRB and Cyclin D1 status assessed preferably on post-neoadjuvant residual invasive disease of the breast, or if not possible, of residual nodal invasion.
- Patients must have received neoadjuvant chemotherapy of at least 6 cycles at a minimum duration of 16 weeks including a taxane. (Exception: Patients with progressive disease that occurred after at least 6 weeks of taxane-containing neoadjuvant treatment which will also be eligible).
- Adequate surgical treatment including resection of all clinically evident disease and ipsilateral axillary lymphnode dissection. Histologically complete resection (R_0) of the invasive and ductal in situ tumor is required in case of breast conserving surgery as the final treatment. No evidence of gross residual disease (R2) is required after total mastectomy (R1 resection is acceptable). Axillary dissection is not required in patients with a negative sentinel-node biopsy before (pN0, pN+(mic)) or after (ypN0, ypN+(mic) neoadjuvant chemotherapy.
- Less than 16 weeks interval since the date of final surgery and date of randomization (including the radiotherapy period.

Ausschlusskriterien:

- Known severe hypersensitivity reactions to compounds similar to palbociclib or palbociclib/placebo excipients or to endocrine treatments.
- Inadequate organ function including: Hemoglobin <9g/dL (90g/L) ANC < 1,500/mm^3 (< 1.5 x 10^9/L); Platelets <100,000/mm^3 (< 100 x 10^9/L); AST and/or ALT >3 upper normal limits (UNL); alkaline phosphatase > 2.5 x UNL, total serum bilirubin > 1.25 x UNL; serum creatinine > 1.25 x ULN or estimated creatinine clearance < 60 mL/min as calculated using the method standard for the institution, severe and relevant co-morbidity that would interact with the participation in the study
- QTc >480 msc or a family or a personal history of a long or short QT syndrome, Brugada syndrome or know history of QTc prologation, or Torsade de Pointes (TdP).
- Uncontrolled electrolyte disorders that can compound the effects of a QTc prolonging drug (e.g., hypocalcemia, hypoalemia, hypomagnesemia).
- Any of the following with 6 months of randomization: myocardial infarction, severe/unstable angina, ongoing cardiac dysrhythmias of NCl CTCAE version 4.0 Grade ≥2, atrial fibrillation of any grade, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, cerebrovascular accident including transient ischemic attack, or symptomatic pulmonary embolism.
- Major surgery within 2 weeks prior to randomization.
- Prior neoadjuvant endocrine treatment. Adjuvant endocrine treatment might have been started before randomization.
- Prior treatment with any CDK 4/6 inhibitor.

- Patients treated within the last 7 days prior to randomization with drugs known to be CYP3A4 inhibitors or inducers or drugs that are known to prolong the QT interval.



ABCSG 38 – A Phase II Randomized, Double-Blind, Parallel Cohort Study of Neoadjuvant Letrozole + GDC-0032 versus Letrozole + Placebo in Post-Menopausal Women with ER+/HER2- Primary Breast Cancer "LORELEI"

Ansprechpartner:

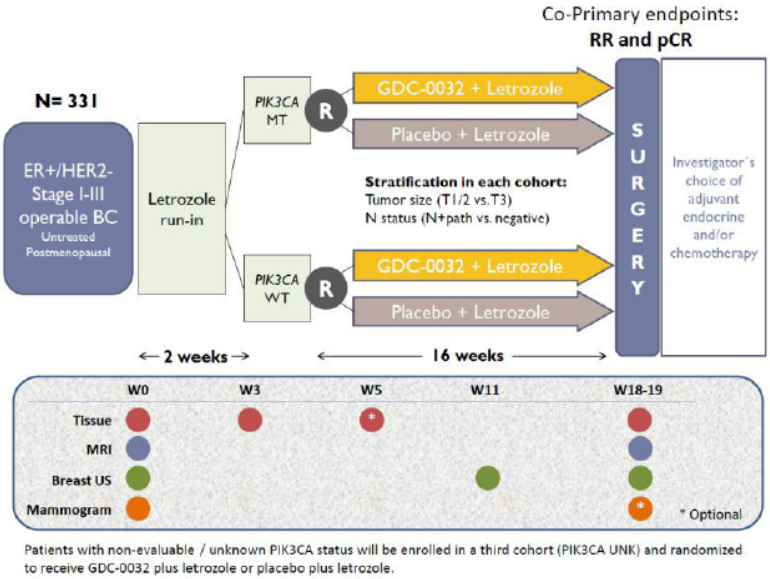
Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. –Prof. Dr. Georg Pfeiler
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Female woman, post-menopausal, ECOG 0-1.
- Newly diagnosed unilateral breast cancer, Tumor ≥2 cm, stage I-III (non-inflammatory) eligible for primary surgery.
- No prior systemic therapy.
- Available pre-treatment biopsy (FFPE and fresh-frozen)
- ER-positive and HER2-negative, as per local assessment.
- Adequate renal, hepatic and hematopoetic functions.

Ausschlusskriterien:

- Type 1 or 2 diabetes requiring antihyperglycemic medication
- Any prior treatment for primary invasive breast cancer
- Inoperable locally advanced or inflammatory (i.e., inoperable Stage III) or metastatic (stage IV) breast cancer
- Bilateral or multicentric invasive breast cancer.



Patients with non-evaluable / unknown PIK3CA status will be enrolled in a third cohort (PIK3CA UNK) and randomized to receive GDC-0032 plus letrozole or placebo plus letrozole.

ABCSG 39 – APHINITY
A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. Prof. Dr. Georg Pfeiler
Dr. Muy-Kheng Tea
DGKS Ingeborg Brandl, BCN

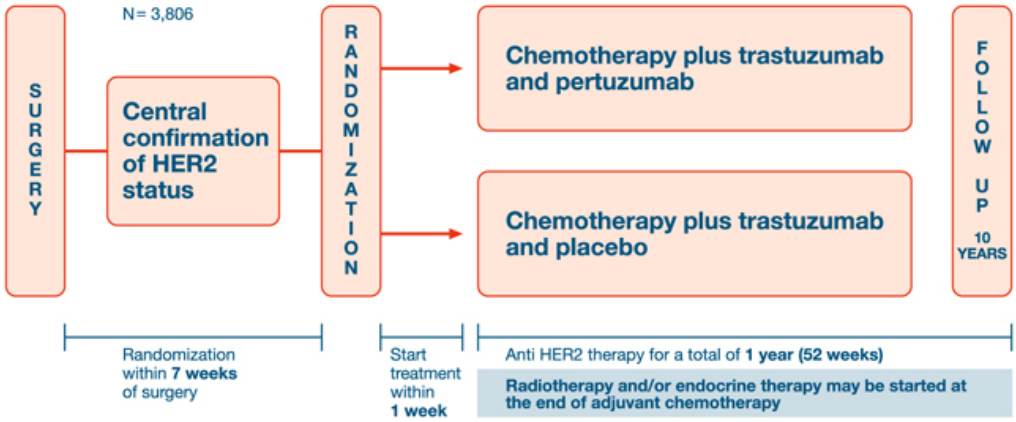
Einschlusskriterien:

- Age > 18 years
- ECOG performance status < 1
- Non-metastatic operable primary invasive carcinoma of the breast that is:
  a) histologically confirmed
  b) adequately excised
  c) PTNM staging
  - If a node positive (pN>1), any pT except T0.
  - If a node negative patient (pN0)
    Then tumour size must be > 1,0 cm OR in cases of a tumour size between > 0.5 cm and < 1.0 cm, at least one of the following features must be present: pathological grade 3; negative for ER and PgR; or patient age < 35 years)
- Known hormone receptor status (ER/PgR or ER alone)
- Baseline LVEF >50 % measured by echocardiography or MUGA scan.
- HER2-positive breast cancer confirmed by a central laboratory and defined as:
  - 3+ over expression by IHC or HER2 (c-erbB2) gene amplification by FISH
- Completion of all necessary baseline laboratory and radiologic investigations prior to randomization
- For patients of childbearing potential, agreement to use an “effective” forms of non-hormonal contraception or two patient and/or partner. Contraception must continue for the duration of study treatment and for at least 6 months after last dose of study treatment.

Ausschlusskriterien:

- History of any prior invasive breast carcinoma
- Past or current history of malignant neoplasms, except for curatively treated:
  - Basal and squamous cell carcinoma of the skin.
  - In situ carcinoma of the cervix.
- Any “clinical” T4 tumor, including inflammatory breast cancer
- Synchronous bilateral tumours
- Previous neo-adjuvant or adjuvant chemotherapy for breast cancer.
- Any prior radiation for the breast cancer
- Prior use of anti-HER2 therapy (e.g. lapatinib, neratinib or other TKI) for any reason or other prior biologic or immunotherapy for breast cancer.
- Concurrent anti-cancer treatment in another investigational trial, including hormone therapy, immunotherapy, and bisphosphonate therapy.
- Serious cardiac illness or medical conditions including but not confined to:
  - Documented LVEF <50 % in patients history
  - History of documented congestive heart failure (CHF)
  - High-risk uncontrolled arrhythmias
  - Angina pectoris requiring antianginal medication

  - Clinically significant valvular heart disease
  - Evidence of transmural infarction on ECG,
  - Poorly controlled hypertension
- Other concurrent serious diseases that may interfere with planned treatment including severe pulmonary conditions/illness.
- Any of the following abnormal laboratory tests immediately prior to randomization:
  - Serum total bilirubicin > 1.25 x upper limit of normal transferase (ASAT) >1.25 x ULN;
  - Alkaline amino transferase (ALAT) or aspartate amino transferase (ASAT) > 1.25 x ULN
  - Alkaline phosphatise (ALP) > 2.5 x ULN
  - Serum creatinine > 1.5 x ULN
  - Total white blood cell count (WBC) < 2,500 /mm^2
  - Absolute neutrophil count <1,500/mm^3
  - Platelets <100,00 / mm^3
- Pregnant or lactating women
- Women of childbearing potential or less than one year after menopause (unless surgically sterile) who are unable or unwilling to use the contraceptive measures required by this protocol during and 6 months after the last dose of study medication
- Sensitivity to any of the study medications or any of the ingredients or excipients of these medications, including sensitivity to benzyl alcohol.



ABCSG 40 – Eine randominisierte, doppelblinde, placebo-kontrollierte Phase-II-Studie zu Letrozol mit und ohne BYL719 oder Buparlisib zur neoadjuvanten Behandlung postmenopausaler Frauen mit hormonrezeptorpositivem, HER2-negativem Brustkrebs.

Ansprechpartner:

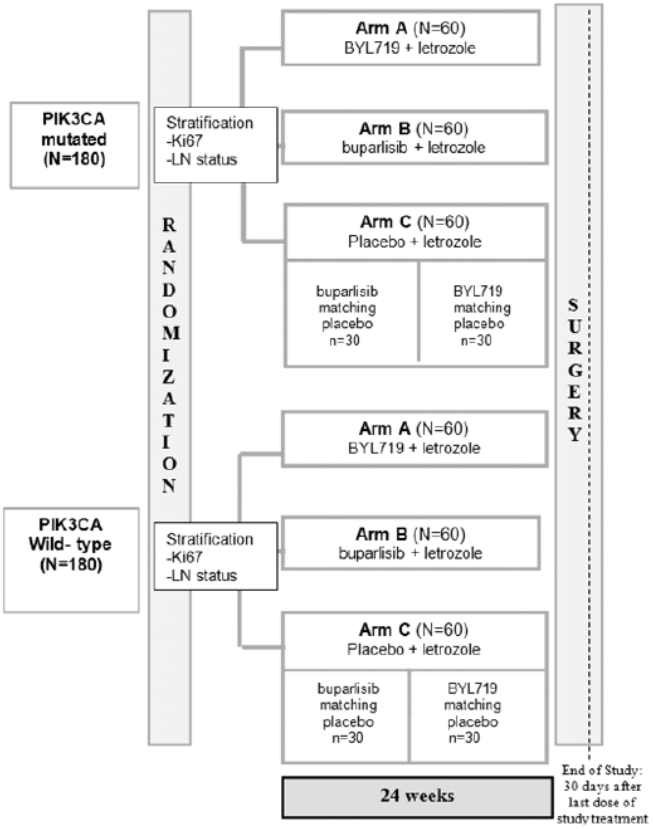
Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. –Prof. Dr. Georg Pfeiler
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Die Patientin hat T2-T3, keinen N, M0, operablen Brustkrebs
- Die Patientin muss über einen messbaren Tumor verfügen
- Die Patientin verfügt über eine diagnostische Biopsie für die Analyse von PIK3CA-Mutation und Ki67-Wert.
- Die Patientin leidet, gemäß den örtlichen Labortests, unter Östrogenrezeptor und/oder Progesteron positivem Brustkrebs
- Die Patientin leidet unter HER2-negativem Brustkrebs, definiert als negative In-situ-Hybridisierung oder einen ICH-Status von 0 oder 1+ gemäß den örtlichen Labortests
- Die Patientin weist, wie von dem von Novartis festgelegten Labor definiert, einen bekannten PIK3CA-Mutationsstatus auf (mutiert oder Wildtyp). (Patientinnen mit unbekannten PIK3CA-Mutationsstatus können nicht teilnehmen)
- Die Patientin bekommt ihren Ki67-Wertstatus zentral bestimmt
- Die Patientin weist einen Eastern Cooperative Oncology Group (ECOG) – Leistungsstatus von ≤ 1 auf, von dem der Prüfarzt zum Zeitpunkt des Screenings annimmt, das er stabil ist

Ausschlusskriterien:

- Die Patientin weist eine lokal rezidivierende oder metastasierende Erkrankung auf
- Die Patientin hat eine systemische Therapie (z.B. Chemotherapie, zielgerichtete Therapie, Immuntherapie) oder Strahlentherapie für gegenwärtige Brustkrebserkrankungen vor Aufnahme in die Studie erhalten.
- Patientinnen mit klinisch manifestiertem Diabetes mellitus (Nüchternglukose > 120mg/dl oder 6,7 mmol/l) oder dokumentiertem steroidinduziertem Diabetes mellitus
- Die Patientin hat ein Ergebnis von ≥ 12 im PHQ-9 Fragebogen
- Die Patientin wählt Antwort „1,2 oder 3“ bei Frage Nr. 9 im PHQ-9 Fragebogen bezüglich Potenzial für Suizidgedanken oder suizidale Ideen (unabhängig vom Gesamtergebnis des PHQ-9)
- Die Patientin hat ein GAD-7-Stimmungsskala-Ergebnis von ≥ 15
- Die Patientin hat in ihrer Vergangenheit eine medizinisch dokumentierte ausgeprägte depressive Episode, bipolare Störung (I oder II), Zwangsstörung, Schizophrenie, Suizidversuche oder –gedanken in der Vergangenheit oder homizidale Gedanken (z.B. das Risiko, sich oder andere zu verletzen) oder eine schwere Persönlichkeitsstörung (definiert gemäß DSM-IV). Anmerkung: Bei Patientinnen, dich sich bei Baseline in psychotropischer Behandlung befinden, sollte die Dosierung und der Plan in den 6 Wochen vor der ersten Einnahme des Studienmedikaments nicht verändert werden.
- Die Patientin hat ≥ CTCAE Grad 3-Angstzustände


PIK3CA mutated (N=180)
Stratification -Ki67 -LN status
Arm A (N=60) BYL719 + letrozole
Arm B (N=60) buparlisib + letrozole
Arm C (N=60) Placebo + letrozole
buparlisib matching placebo n=30
BYL719 matching placebo n=30
PIK3CA Wild- type (N=180)
Stratification -Ki67 -LN status
Arm A (N=60) BYL719 + letrozole
Arm B (N=60) buparlisib + letrozole
Arm C (N=60) Placebo + letrozole
buparlisib matching placebo n=30
BYL719 matching placebo n=30
RANDOMIZATION
SURGERY
24 weeks
End of Study: 30 days after last dose of study treatment

T-DM1 (KATHERINE)
A randomized, multicenter, open-label phase III study to evaluate the efficacy and safety of trastuzumab emtanisine versus Trastuzumab as adjuvant therapy for patients with Her2-positive primary breast cancer who have residual tumor present pathologically in the breast or axillary lymph nodes following pre-operative therapy (BO27938)

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Dr. Muy-Kheng Tea
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Her2-positive breast cancer
- Histologically confirmed invasive breast carcinoma
- Clinical stage T1-4, N0-3, M0
- Completion of preoperative systemic treatment consisting of at least 6 cycles with a total duration at least 16 weeks, including 9 weeks of HER2-directed therapy and 9 weeks of taxane-based chemotherapy
- Adequate excision: surgical removal of all clinically evident disease in the breast and lymph nodes as follows
    - Breast surgery: total mastectomy with no gross residual disease at the margin of resection, or breast-conserving surgery with histologically negative margins of excision
    - Lymph node surgery
        - In case of positive results from a fine-needle aspiration, core-biopsy, or sentinel node biopsy performed prior to preoperative therapy, additional surgical evaluation of the axilla following preoperative therapy is required.
        - If sentinel node biopsy performed before preoperative therapy was negative, no additional surgery evaluation of the axilla is required after preoperative therapy.
        - If the only sentinel node identified by isotope scan before preoperative therapy is in the internal mammary chain, surgical evaluation of the axilla is required after preoperative therapy.
        - If sentinel node biopsy performed after preoperative therapy is positive, additional surgical evaluation of the axilla is required.
        - If sentinel node evaluation after preoperative therapy is negative, no further additional surgical evaluation of the axilla is required.
        - Axillary dissection without sentinel node evaluation is permitted after preoperative therapy.
        - If the only sentinel node identified by isotope scan after preoperative therapy is in the internal mammary chain, surgical evaluation of the axilla is required after preoperative therapy.
- Pathologic evidence of residual invasive carcinoma in the breast or Axillary lymph nodes following completion of preoperative therapy.
- An interval of no more than 9 weeks between the date of surgery and the date of randomization.
- Known hormone receptor status (ER or PR) of the primary tumor.
- Signal written Informed Consent
- Age > 18 years
- ECOG performance status 0 or 1
- Life expectancy > 12 weeks from the first dose of study treatment

- Adequate organ function during screening, defined as:
  - Absolute neutrophil count > 1500 cells / mm^3
  - Platelet count > 100.000 cells / mm^3
  - Hemoglobin > 9.0 d/dL; patients may receive red blood cell transfusions to obtain this level
  - Serum creatinine < 1.5 x upper limit of normal (ULN)
  - International normalized ratio (INR) and activated partial thromboplastin time (apt) < 1.5 x ULN
  - Serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) < 1.5 x ULN
  - Serum total bilirubin < 1.5 x ULN, exept for patients with Gilbert's syndrome, for whom direct bilitrubin should be within normal range
  - Serum alkaline phosphatase < 1.5 x ULN
  - LVEF > 55% on ECHO or MUGA with no significant cardiac signs or symptoms duing or following preoperative therapy
    - LEV assessment may be repeated once up to 3 weeks following the initial screening assessment to assess eligibility
- For women of childbearing potential and men with partners of childbearing potential, agreement to use one highly effective form of non-hormonal contraception or two effective forms of non-hormonal contraception by the patient and/or partner and to continue its use for the durantion of study treatment and for 6 months after the last dose of study treatment
- Negative serum pregnancy test for pre-menopausal women and for women less than 12 months after the onset of menopause.

Ausschlusskriterien:

- Stage IV (metastatic) breast cancer
- History of any prior (ipsi- or contralateral) breast cancer except lobular CIS
- Evidence of clinically evident gross residual or recurrent disease following preoperative therapy and surgery
- Progressive diseasing during preoperative therapy
- Treatment with any anti-cancer investigational drug within 28 days prior to commencing study treatment
- History of other malignancy within the last 5 years except for appropriately treated CIS of the cervix, non-melanoma skin carcinoma, Stage I uterine cancer, or other non-breast malignancies with an outcome similar to those mentioned above
- Patients for whom radiotherapy would be recommended for breast cancer treatment but for whom it is contraindicated because of medical reasons (e.g., connective tissue disorder or prior ipsilateral breast radiation)
- Current NCI-CTCAE (v 4.0) Grade > 2 peripheral neuropathy
- History of exposure to the following cumulative doses of anthracyclines:
  - Doxorubicin > 240 mg/m^2
  - Epirubicin > 360 mg/m^2
  - For other anthracyclines, exposure equivalent to doxorubin > 240 mg/m^2
- Cardiopulmonary dysfunction as defined by any of the following:
  - Uncontrolled hypertension (systolic blood pressure > 180 mmHg and/or diastolic blood pressure > 100 mmHg)
  - Inadequately controlled angina or serious cardiac arrhythmia not controlled by adequate medication
  - LVEF > 500 % by either ECHO or MUGA
  - History of NCI CTCAE (v 4.0) Grade > 3 symptomatic CHF or NYHA criteria Class > II
  - History of a decrease in LVEF to < 40% or symptomatic CHF with prior trastuzumab treatment (e.g., during preoperative therapy)
  - Myocardial infarction within 6 months prior to randomization
  - Requirement for continuous oxygen therapy
- Current severe, uncontrolled systemic disease (eg., clinically significant cardiovascular, pulmonary, or metabolic disease; wound-healing disorders; ulcers)

- For female patients, current pregnancy and/or lactation
- Major surgical procedure unrelated to breast cancer or significant traumatic injury within approximately 28 days prior to randomization or anticipation of the need of major surgery during the course of study treatment.
- Concurrent, serious, uncontrolled infections or current known infection with HIV or active hepatitis B and/or hepatitis C
- History of intolerance, including Grade 3-4 infusion reaction or hypersensitivity to trastuzumab or murine proteins.
- Active, unresolved infections at screening
- Assessment by the investigator to be unable or unwilling to comply with the requirements of the protocol .

PERUSE – MO28047
A multicenter, open-label, single arm study of pertuzumab in combination with trastuzumab and a taxane in first line treatment of patients with HER2-positive advanced (metastatic or locally recurrent) breast cancer

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Prof. Dr. Michael Seifert
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Female patients aged 18 years or over
- Histologically or cytologically confirmed and documented adenocarcinoma of the breast with metastatic or locally recurrent disease not amenable to curative resection
- HER 2-positive (defined as either IHC 3+ or in situ hybridization (ISH) positive) as assessed by local laboratory on primary tumor and/or metastatic site if primary tumor not available (ISH positivity is defined as a ratio of 2.0 or greater for the number of HER 2 gene copies to the number of signals for CEP17, or for single probe tests, a HER 2 gene count greater than 4
- At least one measurable lesion and/or non-measurable disease evaluable according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1
- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2
- LVEF of at least 55 %
- Negative serum pregnancy test in women of childbearing potential (WOCBP), premenopausal or less than 12 months of amenorrhea post-menopause, and who have not undergone surgical sterilization)
- For WOCBP and male patients with partners of CBP who are sexually active, agreement to use a highly effective, non-hormonal form of contraception or two effective forms of non-hormonal contraception during and for at least 6 months post-study treatment
- Life expectancy of at least 12 weeks

Ausschlusskriterien:

- Previous systemic non-hormonal anticancer therapy for the metastatic or locally recurrent disease
- Disease-free interval from completion of adjuvant or neoadjuvant systemic non-hormonal treatment to recurrence within 6 months
- Previous approved or investigative anti-HER 2 agents in any breast cancer treatment setting, except trastuzumab and/or lapatinib in the adjuvant or neoadjuvant setting
- Disease progression while receiving trastuzumab and/or lapatinib in the adjuvant or neoadjuvant setting.
- History of persistent Grade 2 or higher haematological toxicity resulting from previous adjuvant or neoadjuvant therapy
- Radiographic evidence of central nervous system (CNS) metastases as assessed by computed tomography (CT) or magnetic resonance imaging (MRI)
- Current peripheral neuropathy of Grade 3 or greater
- History of other malignancy within the last 5 years prior to 1st study drug administration (dosing), except for carcinoma in situ of the cervix or basal cell carcinoma
- Serious uncontrolled concomitant disease that would contraindicate the use of any of the investigational drugs used in this study or that would put the patient at high risk for treatment-related complications.
- Inadequate organ function, evidenced by the following laboratory results
    - Absolute neutrophil count <1,500 cells/mm^3
    - Platelet count < 100,000 cells/mm^3
        - Hemoglobin <9g/dL

  - Total bilirubin greater than the upper limit of normal (ULN; unless the patient has documented Gilbert's syndrome)
  - AST (SGOT) or ALT (SGPT) > 2.5 x ULN
  - AST (SGOT) or ALT (SGPT) > 1.5 x ULN with concurrent serum alkaline phosphatise >2.5 x ULN; Serum alkaline phosphatise may be > 2.5 x ULN only if bone metastases are present and AST (SGOT) and ALT (SGPT) < 1.5 x ULN
- Uncontrolled hypertension or clinically significant cardiovascular disease: cerebrovascular accident/stroke or myocardial infarction within 6 months prior to first study medication, unstable angina, congestive heart failure (CHF) or serious cardiac arrhythmia requiring medication.
- Current known infection with HIV, Hep B or Hep C virus
- Dyspnoea at rest due to complications of advanced malignancy, or other disease requiring continuous oxygen therapy.
- Major surgical procedure or significant traumatic injury within 28 days prior to 1st study drug administration (dosing) or anticipation of need for major surgery during the course of study treatment.
- Receipt of intravenous antibiotics for infection within 14 days prior to enrolment
- Current chronic daily treatment with corticosteroids, excluding inhaled steroids
- Known hypersensitivity to any of the study medications or to excipients of recombinant human or humanized antibodies.
- History of receiving any investigational treatment within 28 days prior to 1st study drug administration.
- Assessed by the Investigator to be unable or unwilling to comply with the requirements of the protocol.
- Concurrent participation in any interventional clinical trial.

Pertuzumab basierende Therapie
(1-armig, keine Randomisierung)

Bis zum Progress, inakzeptable Toxizität, Patientenwiderruf oder Tod

Pertuzumab + Trastuzumab + Taxane (Docetaxel, Paclitaxel)

(Arzt wählt Taxane)

BELLE 4 – BKM120F2202
A randomized, double-blind, placebo controlled, phase II study of BKM120 plus pacltaxel in patients with HER2 negative inoperable locally advanced or metastatic breast cancer, with or without PI3K pathway activation

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Dr. Muy-Kheng Tea
Prof. Dr. Michael Seifert
Dr. Elfriede Winkler-Dobrovits
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

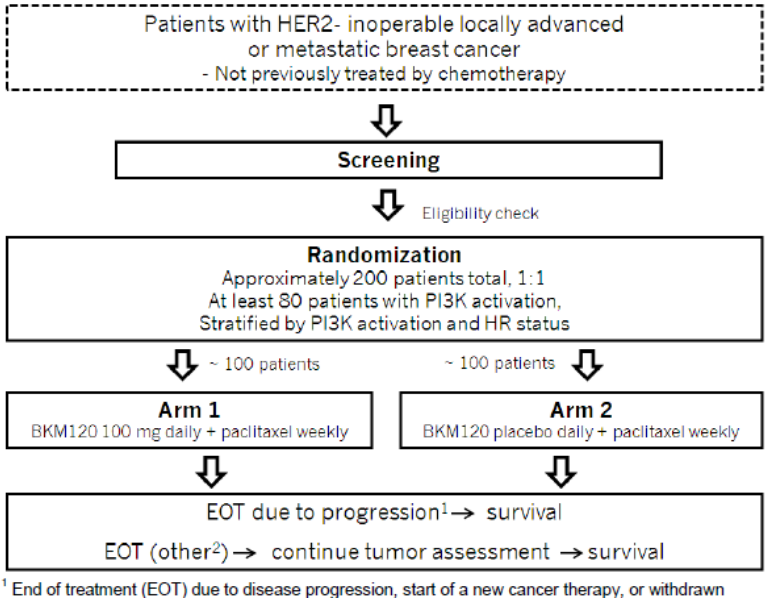
- Age > 18 years
- Patient has histologically and/or cytologically confirmed diagnosis of breast cancer
- Patient has radiologic evidence of inoperable locally advanced (recurrent or progressive) or newly diagnosed metastatic breast cancer
- Patient has HER2 negative disease (based on most recently analysed biopsy) defined as a negative SISH/CISH/FISH test or an IHC status or 0, 1+ or 2+ (if IHC 2+, a negative SISH/FISH/CISH test is required) by local laboratory of treatment.
- Patient has known PI3K status (activated or wild type) based on results from a Novartis designated laboratory prior to the start of treatment.
    - A representative archival of fresh tumour biopsy must be shipped to a Novartis designated laboratory for profiling and results obtained for successful randomization through IVRS
    - Note: one block or a > 20 unstained slide is required to determine the PI3K activation status
- Patient has measurable and/or non-measurable disease according to RECIST 1.1 criteria
- Patient has an ECOG performance status < 1 which the investigator believes is stable at the time of screening
- Patient has adequate bone marrow and organ function as defined by the following laboratory values
    - Absolutely Neutrophil Count > 1.5 x 10^9/L
    - Platelets > 100 x 10^9/L
    - Hemoglobin > 9.0 g/dL
    - INR < 1.5
    - Potassium and calcium within normal limits for the institution
    - Srum Creatinine < 1.5 x ULN and/or creatinine clearance > 45 mL/min
    - Total Serum Bilirubicin within normal range
    - Alanine aminotransferase (AST) and aspartale aminotransferase (ALT) within normal rage (or < 3.0 x ULN if liver metastases are present)
    - Fasting plasma glucose (FPG) < 150 mg/dL or < 8.3 mmol/L
    - HbA_{1c} < 8 %
- Patient is able to swallow and retain oral medication

Ausschlusskriterien:

- Patient has received previous treatment with a PI3K inhibitor
- Patient has received any prior systemic therapies (except endocrine therapy for the inoperable locally advanced (recurrent or progressive) or metastatic disease. Study treatment in this study must be the patient's first systemic therapy treatment for inoperable locally advanced or metastatic disease). Any number of endocrine therapies is permitted.
- Patient has symptomatic CNS metastases

  - Patients with asymptomatic CNS metastases may participate in this trial. The patient must have completed any prior local treatment for CNS metastases > 28 days prior to the start of study treatment (including radiotherapy and/or surgery)
- Patient has a concurrent malignancy or malignancy within 3 years of study enrolment, (with the exception of adequately treated, basal or squamous cell carcinoma, non-melanomatous skin cancer or curatively resected cervical cancer)
- Patient has been treated with any hematopoietic colony-stimulating growth factors (e.g.; G-CSF, GM-CSF) < 2 weeks prior to starting study drug. Erythropoietin or darbepoetin therapy, if initiated before enrolment, may be continued
- Patient who has received wide field radiotherapy < 4 weeks or limited field radiation for palliation < 2 weeks prior to starting study drug or who have not recovered to grade 1 or better from related side effects of such therapy (exceptions include alopecia, bone marrow and organ functions (limits described below))
- Patient is currently receiving increasing or chronic treatment (>5 days) with corticosteroids or another immunosuppressive agent
- Patient is currently receiving warfarin or other coumarin derived anti-coagulant, for treatment, prophylaxis or otherwise. Therapy with heparin, low molecular weight heparin (LMWH), or fondaparinux is allowed
- Patient is currently receiving treatment with drugs known to be moderate or strong inhibitors or inducers of isoenzyme CYP3A. The patient must have discontinued strong inducers for at least one week and must have discontinued strong inducers for at least one week and must have discontinued strong inhibitors before the treatment is initiated. Switching to a different medication prior to starting study treatment is allowed. A list of strong and moderate inhibitors and inducers of CYP3A4 will be provided in the final protocol.
- Patient has a known hypersensitivity to paclitaxel or other products containing Cremophor
- Patient has a contraindication to use the paclitaxel standard pre-treatment such as corticosteroids
- Patient has had major surgery within 14 days prior to starting study drug or has not recovered from major side effects.
- Patient has a score > 10 on the PHQ-9 questionnaire
- Patient selects a response of (1,2 or 3 to questions number 9 on the PHQ-9 questionnaire regarding potential for suicidal thoughts or ideation
- Patient has a GAD-7 mood scale score > 15
- Patient has a medically documented history of or active major depressive episode, bipolar disorder (I or II), obsessive-compulsive disorder, schizophrenia, a history of suicidal attempt or ideation, or homicidal ideation
- Patient has > CTCAE grade 3 anxiety
- Patient has active cardiac disease or a history of cardiac dysfunction including any of the following:
  - Unstable angina pectoris within 6 months prior to study entry
  - Symptomatic pericarditis
  - Documented myocardial infarction within 6 months prior to study entry
  - History of documented congestive heart failure
  - Documented cardiomyopathy
- LVEF < 50 % as determined by MUGA scan or ECHO
- Patient has any of the following cardiac conduction abnormalities
  - Ventricular arrhythmias except for benign premature ventricular contractions
  - Supraventricular and nodal arrhythmias requiring a pacemaker
  - Other cardiac arrhythmia not controlled with medication
- Patient has a QTcF > 480 msec on the screening ECG
- Patient is currently receiving treatment with medication that has a known risk to prolong the QT interval or inducing Torsades de Pointes, and the treatment cannot be discontinued or switched to a different medication prior to starting study drug. A list of prohibited drugs will be provided in the final protocol.
- Patient has impairment of gastrointestinal function or GI disease that may significantly alter the absorption of BKM120

- Patient has peripheral sensory neuropathy with functional impairment
- Patient has any other concurrent severe and/or uncontrolled medical condition that would, in the investigator's judgement contraindicate patient participation in the clinical study
- Patient has a history of non-compliance to medical regimen or inability to grant consent
- Patient has a known of HIV infection
- Pregnant or nursing (lactating) women



[1] End of treatment (EOT) due to disease progression, start of a new cancer therapy, or withdrawn

CIA-STUDY

A prospective, randomized, multicenter study to evaluate the impact of Ferric(III)-Carboxymaltose in combination with Darbepoetin alfa in comparison to Darbepoetin Alfa and Ferric (III)-Carboxymaltose alone in patients with chemotherapy-induced anemia

Ansprechpartner:
Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Dr. Christine Staudigl
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Age > 18 years
- Negative pregnancy test
- Subjects must have a confirmed adenocarcinoma of the breast and receive neoadjuvant or adjuvant multicycle chemotherapy
- Subjects must have Haemoglobin levels ranging from 8-10 g/dL prior to last chemotherapy
- Subjects must have iron levels of ferritin < 800ng/mL and transferrin saturation < 20 %

Ausschlusskriterien:

- Haemoglobin levels < 7,9 d/dL or > 10,1 g/dL
- Subjects with absolute iron deficiency, defined as ferritin < 30 ng/mL and transferrin saturation < 15 %.
- Subjects with known haemoglobinopathy or haemochromatose
- History of arterial or venous thrombosis, including transient ischemic attack (TIA), within 1 year prior to randomization
- Active infection
- Known HIV virus infection, hepatitis B or hepatitis C
- Uncontrolled hypertension as defined a systolic blood pressure > 150 mmHg and diastolic pressure > 90mmHg. Anti-hypertensive medications are allowed if the subject is stable on their dose at the time of randomization
- Known hypersensitivity to FCM or to any other iron preparation
- Any condition which in the investigator's opinion makes the subject unsuitable for study participation
- Pregnant or lactating
- Use of recombinant human erythropoietins 3 weeks prior to screening
- Known hypo- or hyperthyroidism
- Intake of i.v. or oral iron preparation within 4 weeks prior to screening
- Subject previously has entered this study
- Inability to comply with protocol and/or not available for follow-up assessments

AGO35 – LAB-SLN011: Prospective Validation of Genomic Signatures to Predict Treatment Response in the Axillary Nodes after Neoadjuvant Chemotherapy in Patients with HER2-negative Breast Cancer

Ansprechpartner:
Leitung: Univ. Prof. Dr. Christian Singer, MPH

Einschlusskriterien:

- Patients consented to have additional needle biopsy for evaluation of tumor at MD Anderson, USA
- Clinical status of lymph nodes must be available
- Sonographical status of lymph nodes must be available
- Patients must consent to documentation of cancer treatment
- Histologic diagnosis of invasive breast cancer, clinical stage T1-4, M0 (non-inflammatory T4c)
- Patients scheduled for neoadjuvant chemotherapy (e.g. palpable tumor mass that measures at least 20 mm in diameter, unfavourable breast size: tumor size, clinically suspicious regional lymph node, or known high grade invasive breast cancer).
- Treatment with a 3-weekly FEC or AC regimen (3-4 cycles) followed by 3-4 cycles of q3 weekly docetaxel or paclitaxel.
- Loval HER2 status of tumor biopsy must be negative.

Ausschlusskriterien;

- The patient has a prior history of invasive or metastatic breast cancer.
- The patient had prior excisional biopsy of the primary invasive breast cancer.
- The patient had prior ipsilateral sentinel axillary lymph node biopsy for breast cancer.
- The patient cannot safely or feasibly undergo biopsy of the primary tumor.
- The patient has a diagnosis of Stage IV (distant metastatic) breast cancer.
- The patient has proven HER2-positive breast cancer, defined as a pathology report of amplification of the gene or 3+ score for immunohistochemical staining.

ABCSG Brightness – A randomized. Placebo-controlled, double-blind Phase III Study evaluating safety and efficacy of the addition of Veliparib plus Carboplatin versus the addition of Carboplatin to standard neoadjuvant chemotherapy versus standard neoadjuvant chemotherapy in subjects with early stage triple negative breast cancer (TNBC)

Ansprechpartner:
Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass. Prof. Dr. Georg Pfeiler
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Women ≥ 18 years of age
- Histologically confirmed invasive breast cancer by core needle or incisional biopsy (excisional biopsy is not allowed). Clinical stage T2-4 N0-2 or T1 N1-2. At the time of presentation, subjects must be candidates for potentially curative surgery by surgeon`s assessment. Inflammatory breast cancer or neuroendocrine carcinoma is not allowed. If multiple (up to 2) suspicious lesions are present, each must be biopsied to evaluate for invasive disease and all invasive lesions in the same breast must be triple-negative as defined below. Subjects with synchronous bilateral invasive breast cancers are not eligible.
- Documented BRCA germline mutation testing. All subjects regardless of BRCA mutation status (i.e.; wildtype BRCA or germline BRCA mutation) are eligible for study participation. If testing has been performed by a laboratory other than the Sponsor core laboratory, subjects may be enrolled but must be re-tested by Sponsor core laboratory for confirmation of BRCA 1 and/or BRCA 2 germline mutation. Subjects who complete informed consent and screening procedures will not be denied protocol therapy due to delays in BRCA testing results. For those subjects who meet other enrolment criteria but have not received BRCA germline mutation testing results at the completion of the screening period, randomization to a treatment group based on other stratification factors will be permitted. Subjects will be analysed according to results of BRCA testing as described in the statistical methods.
- ER-, PR- and HER2-negative (triple-negative) cancer of the breast. Randomization based on local results will be permitted and all results will be confirmed by central pathology reading. Triple-negative tumors are defined as:
    - For ER- and PR-negative: less than or equal to 1% tumor staining by immunohistochemistry (IHC).
    - HER2-negative disease, defined as IHC 0 -1+ OR HER2-neu negative according to ASCO-CAP guideline recommendations.
- ECOG Performance status of 0 to 1.
- Adequate organ function as follows:
    - Bone Marrow: Absolute neutrophil count (ANC) ≥ 1500/mm³ (1.5 x 10^9/L); Platelets ≥ 100,000/mm³ (100 x 10^9/L); Hemoglobin ≥ 9.5 g/dL (1.4 mmol/L); Leukocytes > 3,000/mm³;
    - Renal Function: Calculated reatinine clearance ≥ 50mL/min/1.73 m² by the Cockroft-Gault formula;
    - Hepatic Function: Aspartate aminotransferase (AST) or alanine transaminase (ALT) ≤ 2.5 x upper limit of normal (ULN); bilirubin ≤ 1.5 x ULN. Subjects with Gilbert`s syndrome may have a bilirubin > 1.5 x ULN, if no evidence of biliary obstruction exists.
    - Activated Partial Thromboplastin Time (APTT) must be ≤ 1.5 x ULN and international normalized ratio (INR) < 1.5 x ULN. Subjects on anticoagulant therapy will have an appropriate APTT and INR as determined by the Investigator;
    - Adequate cardiopulmonary reserve to undergo surgery with general anaesthesia.
    - Left ventricular ejection fraction greater than or equal to 50% by MUGA or echocardiogram.
- Women must be determined to be not of childbearing potential (surgically sterile or postmenopausal defined as amenorrheic for at least 12 months) by the Investigator OR they must have a negative serum pregnancy test prior to randomization. Women of childbearing potential must agree to use adequate

contraception (one of the following listed below) prior to study entry, while receiving study treatment and for 90 days following completion of therapy.
  - Total abstinence from sexual intercourse as the preferred lifestyle of the subject; periodic abstinence is not acceptable;
  - Sexual intercourse with only vasectomized partner;
  - Double-barrier method (condoms, contraceptive sponge, diaphragm or vaginal ring with spermicidal jellies or cream);
  - Intra-Uterine Device (IUD)
- Capability of understanding and complying with parameters as outlined in the protocol and able to sign and date the informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to initiation of any screening or study-specific procedures.

Ausschlusskriterien:

- Previous anti-cancer treatment (cytotoxic chemotherapy, immunotherapy, biologic therapy, radiotherapy or investigational agents) with therapeutic intent for current breast cancer.
- Previous treatment with carboplatin, paclitaxel, doxorubicin or cyclophosphamide.
- Prior therapy with a Poly- (ADP-ribose)-Polymerase (PARP) inhibitor.
- Concurrent treatment with an ovarian hormonal replacement therapy or with hormonal agents such as raloxifene, tamoxifen or other selective estrogen receptor modulator (SERM). Subjects must have discontinued use of such agents prior to beginning study treatment.
- A history of seizure within 12 months prior to study entry.
- Pre-existing neuropathy from any cause in excess of Grade 1.
- Known history of allergic reactions to cremophor-containing medications.
- Clinically significant unctrolled condition(s):
  - Active infection:
  - Symptomatic congestive heart failure;
  - Unstable angina pectoris or cardiac arrhythmia;
  - Myocardial infarction within last 6 months;
  - Contraindications to surgery with general anesthetic or regional radiotherapy;
  - Psychiatric illness/social situations that would limit compliance with study requirements; or
  - Any medical condition which in the opinion of the Investigator places the subject at an unacceptably high risk for toxicities.
- A previous or concurrent cancer that is distinct in primary site or histology from the cancer under study, except cervical carcinoma in situ, non-melanoma carcinoma of the skin, or in situ carcinoma of the bladder. Any cancer curatively treated greater than 3 years prior to entry is permitted.
- Pregnant or breastfeeding.

BROCADE M12-914 – A Phase III randomized placebo-controlled trail of Carboplatin and Paclitaxel with or without the PARP Inhibitor Veliparib (ABT-888) in metastatic or locally advanced unresectable BRCA-associated breast cancer

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH

Mitarbeit: DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Men and women ≥ 18 years of age
- Histologically or cytologically confirmed breast cancer that i seither locally advanced or metastatic. Locally advanced breast cancer must not be amenable to surgical resection or radiation with curative intent.
- Suspected deleterious or deleterious BRCA 1 and/or BRCA 2 germline mutation.
- If HER2-positive (HER2 3+ by immunohistochemistry or amplification by FISH > 2), subjects must be considered refractory for all available HER2-directed therapies. Subjects for whom available HER2-targeted therapies are contraindicated ma also be considered eligible.
- Measurable or non-measurable (but radiologically evaluable) disease per RECIST version 1.1 on computed tomography (CT) scan(within 28 days of C1D1) with at least one lesion outside previously irradiated areas.
- ECOG Performance status of 0 to 2 (within 28 days of C1D1)
- Adequate hematologic, renal and hepatic function as follows:
    - Bone Marrow; Absolute neutrophil count (ANC) ≥ 1500/mm³ (1.5 x 109/L); Platelets ≥ 100,000/mm³ (100 x 109/L); Hemoglobin ≥ 9.5 g/dL (1,4 mmol/L); Leukocytes > 3,000/mm³
    - Renal Function: Serum creatinine ≤ 1.5 x upper limit of normal (ULN) range OR creatinine clearance ≥ 50 mL/min/1.73 m² for subjects with creatinine levels above institutional normal;
    - Hepatic Function: Aspartate aminotransferase (AST) and alanine transaminase (ALT) ≤ 2.5 x institutional upper limit of normal; bilirubin ≤ 1.5 x the ULN range. For subjects with liver metastases, AST and ALT < 5 x ULN range. Subjects with Gilbert`s Syndrome may have a bilirubin ≥ 1.5 x the ULN range if no evidence of biliary obstruction exists;
    - Activated Partial Thromboplastin Time (APTT) must be ≤ 1.5 x the ULN range and international normalized ratio (INR) < 1.5. Subjects on anticoagulant therapy will have an appropriate APTT and INR as determined by the investigator.
    -
- Women of childbearing potential and men must agree to use adequate contraception prior to study entry, for the duration of study participation and for 90 days following completion of therapy. Women of childbearing potential must have a nergative serum pregnancy test within 7 days prior to initation. To be considered of non-child bearing potential, postmenopausal women must be amenorrheic for at least 24 months or subjects must be surgically sterile.
- Capable of understanding and complying with parameters as outlined in the protocol and able to sign and date the informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to initiation of any screening or study-specific procedures.

Ausschlusskriterien:

- Received anticancer agent(s) or an investigational agent within 21 days prior to C1D1 or radiotherapy within 28 days prior to C1D1. Prior treatment with palliative local breast or bone lesion radiation (other than pelvis) can occur, if administered at least 14 days prior to C1D1.Subjects experiencing a significant adverse effect or toxicity (Grade 3 or Grade 4), causally attributed to previous anticancer treatment that has not recovered to at least Grade 2 are excluded. Anticancer hormonal therapy must be stopped 7 days before starting C1D1. Subjects receiving bisphosphonates or denosumab are eligible.
- More than 2 prior lines of cytotoxic chemotherapy (e.g., gemcitabine, doxorubicin, capecitabine) for metastatic disease.*

  - Regimes received in the adjuvant/ neoadjuvant setting or for locally advanced breast cancer within the past 6 months will also be considered toward die maximum of 2 prior lines of therapy.
  - Previous treatments with hormonal therapy (tamoxifen, aromatase inhibitors) and signal transduction agents are allowed and are not counted towards the prior line of therapy.
- More than one prior line of platinum therapy for breast cancer. Subjects who have progressed on platinum therapy or recurred within 12 months of platinum therapy will be excluded.
- Prior therapy with PARP inhibitors.*
- Prior taxane therapy administered for the treatment of metastatic breast cancer with the below exceptions.*
  - Prior taxane therapy for metastatic breast cancer is allowed if the patient received ≤ 1 full cycle (i.e., within 4 weeks for subjects receiving weekly paclitaxel or Abraxane; within 3 weeks for subjects receiving paclitaxel or docetaxel every 3 weeks) in the abscene of progression or if taxane therapy for metastatic disease was > 12 months prior to C1D1.
  - Use of taxanes as adjuvant therapy or to treat locally advanced disease is permitted, if given more than 6 months prior to C1D1.

In all cases, the subject must be an appropriate candidate for paclitaxel therapy as per standard practice and per the investigator´s discretion.

- Subjects with active brain metastases or leptomeningeal disease.
  - Subjects with symptoms to suggest central nervous sytem (CNS) metastases should have a brain MRI within 28 days of enrollment to confirm the abscene of CNS metastases. Contrast CT is acceptable for subjects who are unable to undergo a brain MRI.
  - Subjects with known brain metastases must have clinically controlled neurologic symptoms, defined as surgical excision and/or radiation therapy with stable neurologic function and no evidence of Central Nervous System (CNS) scan or magnetic resonance imaging (MRI) scan performed during screening to a prior scan performed at least 4 weeks earlier and provided that the subject is asymptomatic, has no evidence of cavitation or hemorrhage and does not require corticosteroids.
- A history of uncontrolled seizure disorder; including focal or generalized seizure within the past year.
- Pre-existing neuropathy from any cause in excess of Grade 1.
- Major surgery within 3 weeks of the start of study treatment.
- Known history of allergic reactions to cremophor-paclitaxel or known contraindications to carboplatin.
- Clinically significant uncontrolled condition(s).
- A previous or concurrent cancer that is distinct in primary site or histology from breast cancer, except cervical carcinoma in situ, non-melanoma carcinoma of the skin or in situ carcinoma of the bladder. Any cancer curatively treated greater than 3 years prior to entry is permitted. For these subjects, metastases must be histologically or cytologically confirmed to be breast cancer.
- Pregnant or breastfeeding.

***** Note: For prior chemotherapy, treatment for 1 full cycle or less will not be considered as prior therapy unless the patient experienced progression of disease while on that therapy.

Lactobazillen bei Mamma-CA – Klinische Studie mit einem Lactobazillenpräparat: Oral verabreichtes Probiotikum zur Verbesserung der Scheidenflora bei Frauen mit Mamma-Karzinom nach Chemotherapie – eine prospektiv randomisierte, Placebo-kontrollierte Doppelblindstudie

Ansprechpartner:

Leitung: Univ. Prof. Dr. Herbert Kiss
Mitarbeit: Dr. Julian Marschalek
Ass. Prof. Dr. Ljubomir Petricevic
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

- Alter über 18 Jahren
- Nicht therapiebedürftige mikrobielle vaginale Besiedelungen
- Abwesenheit einer vaginalen Blutung
- Abwesenheit einer antimikrobiellen Therapie oder Prophylaxe in den letzten 4 Wochen
- Abwesenheit einer Lactoseintoleranz
- Eine unterschiebene Einverständniserklärung

NIS-XGEVA – Prospektive Beobachtungsstudie zur Beurteilung der Behandlungspersitenz mit XGEVA® bei Patienten mit Knochenmetastasen aufgrund solider Tumoren zur Prävention von skelettbezogenen Ereignissen (SREs) in der klinischen Routinepraxis

Ansprechpartner:

Leitung: Univ. Prof. Dr. Christian Singer, MPH
Mitarbeit: Ass.-Prof. Dr. Ella Asseryanis
DGKS Ingeborg Brandl, BCN

Einschlusskriterien:

Patienten, die in Übereinstimmung mit der aktuellen Fassung der Fachinformationen mit Denosumab (XGEVA®) behandelt wurden;

Der Arzt muss vor der Erwägung der Aufnahme der Patienten in die Beobachtungsstudie frei über die Behandlung mit XGEVA® entschieden haben. Deshalb erfolgt die Verabreichung der Therapie unabhängig und getrennt von der Teilnahme an der Studie. Die Verfügbarkeit für die Aufnahme in diese Studie wird keinen Einfluss auf die klinische Praxisentscheidung für die einzelnen Patienten haben.

Die Entscheidung für die Behandlung mit XGEVA®, erste Verabreichung von XGEVA®, Einholung der schriftlichen Einwilligungserklärung (den Bestimmungen des jeweiligen Landes entsprechend) und Aufnahme in die Studie können jedoch beim gleichen Besuch stattfinden, um zusätzliche Patientenbesuche zu vermeiden und die landesspezifische klinische Routinepraxis nicht zu stören.

Die entsprechende schriftliche Einwilligungserklärung wurde eingeholt, falls zutreffend.

Ausschlusskriterien:

- Diagnose von Multiplem Myelom
- Der Patient wurde in klinischen Studien oder in der klinischen Routine zuvor für mehr als 6 Monate mit Biophosphonaten oder einer anderen antiresorptiven Therapie für Knochenmetastasen behandelt.
- Zuvor mit Radionukliden, behandelte Patienten (z.B. Strontium-98, Samarium-153, Radium-223).
- Patienten, die derzeit an einer Prüfmedikament-Studie zur Behandlung/Prävention von Knochenmetastasten und SREs teilnehmen (Patienten in einer Behandlungsstudie zu ihrem zugrunde liegenden Krebsleiden oder in Langzeit-Nachbeobachtungsstudien sind für diese Beobachtungsstudie geeignet)
- Kontraindikationen für die Behandlung mit XGEVA® in Übereinstimmung mit der aktuellsten Fachinformation

NIS ABRAXANE MBC-1 – nab-Paclitaxel
Einsatz von nab-Paclitaxel (Abraxane) beim metastasierten Mammakarzinom unter Praxisbedingungen

Ansprechpartner:
Leitung: Univ. Prof. Dr. Michael Seifert
Mitarbeit: DKGS Ingeborg Brandl, BCN

Einschlusskriterien:
- Unterschriebene Einverständniserklärung
- Alter > 18 Jahre
- Metastasiertes Mammakarzinom

Ausschlusskriterien:
- Schwangere oder stillende Frauen
- Jeder Zustand der Patientin, einschließlich abnormaler Labordaten, die die Patientin einem nicht akzeptablen Risiko durch die Teilnahme an der NIS aussetzt.
- Bekannte Überempfindlichkeit gegen nab-Paclitaxel oder dessen Bestandteile
- Patientinnen mit einem Ausgangswert der Neutrophilenzahl von $<1{,}5 \times 10^9/l$