PUBLICATIONS JONAS BERGH
A: PAPERS (443) B: ABSTRACTS (223)
C: CLINICAL TRIALS (64) D: VARIA (104)

A: PAPERS INCLUDING REVIEWS AND COLLABORATIVE GROUP PUBLICATIONS

1. Bergh J, Nilsson K, Zech L, Giovanella B. Establishment and characterisation of a continuous lung squamous cell carcinoma cell line (U-1752). Anticancer Res 1:317-322, 1981.

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B: ABSTRACTS (not complete)

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END ABSTRACT

C: CLINICAL TRIALS (not complete)

Phase I, II, III and IV studies. This list mainly includes trials, in which Jonas Bergh is responsible investigator or member of the executive committee, or as a local investigator.

1 A randomized study comparing aminoglutetemide versus medroxyprogesterone in advanced breast cancer.

2 Tolerance to and effects on various parameters of LS 2616 in cancer patients. A phase I dose-finding study. Responsible investigator: Jonas Bergh.

3 Protocol for a phase I-II study with tauromustin administered as single drug in a weekly schedule to patients with advanced malignant melanoma.

4 Open phase II-study of the efficacy and safety of Linomide in the treatment of renal cell carcinoma. Responsible investigator: Jonas Bergh.

5 A randomized study comparing two versus five years of post-operative tamoxifen.

6 Adjuvant post-operativ therapy of pre-menopausal women with lymph node positive breast cancer - A randomized study, CSB II:2.

7 A randomized study comparing MMM versus FEC.

8 Double-blind, controlled study of clodronate and placebo as an adjunct to conventional therapy in breast cancer in patients with recurrent disease and bone metastasis. Responsible investigator: Jonas Bergh.

9 Phase II trial of suramin in breast cancer. Responsible Swedish investigator: Jonas Bergh.

10 Adjuvant therapy of high risk patients with lymph node negative breast cancer in stage I and II - a multicentral trial.

11 Therapy of locally advanced breast cancer. Co-ordinator: Jonas Bergh.

12 Phase II-studies with intravenous and intratumoral, respectively, administration of 90-Yttrium labelled monoclonal antibody for therapy of malignant glioma. Responsible investigator: Jonas Bergh.

13 Studies with intravenous and intratumoral, respectively, administration of 111-Indium labelled monoclonal antibody for diagnosis of malignant glioma. Responsible investigator: Jonas Bergh.

14 High-dose chemotherapy + autologous stem cell transplantation compared with dose escalating chemotherapy in breast cancer with poor prognosis: A randomized study. Principle investigator: Jonas Bergh.

15 Vorozole versus aminogluthimide in the second line treatment of advanced post-menopausal breast cancer. (Multicenter trial, responsible Swedish investigator: Jonas Bergh)

16 Adjuvant therapy of post-menopausal women with lymph node positive and receptor negative breast cancer - A randomized study, CSB II:3. Responsible investigator: Jonas Bergh.

17 A phase II-study with dosescalated FEC with G-CSF support to patients with metastatic breast cancer. Responsible investigator: Jonas Bergh.

18 A phase II-study with therapy using the solvent Cremophor EL to patients with metastatic and anthracycline resistant breast cancer. Responsible investigator: Jonas Bergh.

19 RP 56976-V-286: A phase II trial of RP56976 in patients with advanced anthracycline resistant breast cancer. (Multicenter trial, responsible Swedish investigator: Jonas Bergh)

20 A phase II trial of RP 56976 as second line chemotherapy in patients with metastatic breast cancer. (Multicenter trial, responsible Swedish investigator: Jonas Bergh)

21 An open-label, singel arm study to determine the safety, tolerability and activity of epirubicin in combination with the multidrug resistance modulator SDZ PSC 833 in subjects with anthracycline-resistant advanced breast cancer. (Responsible Swedish investigator: Jonas Bergh)

22 A randomized, double-blind, placebo controlled, phase 3 trial comparing SMS 201-995 PA LAR plus tamoxifen versus tamoxifen plus placebo in women with locally recurrent or metastatic breast cancer. (Responsible Swedish investigator: Jonas Bergh)

23 A phase I study in patients with cutaneous or subcutaneous, recurrent breast carcinoma or melanoma using SCH 58500 (rAd/p53) administerad by single intratumoral dose. (Responsible Swedish investigator: Jonas Bergh)

24 Therapy of locally advanced breast cancer. Responsible investigator: Jonas Bergh.

25 ET-therapy on breast cancer patients - a phase II study. Responsible investigator: Jonas Bergh.

26 A phase I safety study of CHS 828 in patients with solid tumour malignancy. (Initially responsible investigator: Jonas Bergh)

27 NESP-980291. A randomised, double-blind, placebo-controlled, dose-finding study of novel erythropoesis stimulating protein (NESP) administered once every three weeks by subcutaneous (SC) injection for the treatment of anaemia in subjects with solid tumours receiving multicycle chemotherapy. Multicenter study.Responsible local investigator Jonas Bergh.

28 Randomized Phase II study of two different schedules of BMS-184476 in patients with previously treated metastatic breast cancer + amendment 1, 2 + 3. Local investigator: Jonas Bergh.

29 Individually dose-adjusted FEC compared to standard FEC as adjuvant chemotherapy for node positive or high-risk node negative breast cancer. Principal investigators: Carl Blomqvist, Mikael Andersson Jonas Bergh.

30 Phase III randomized Double-blind Evaluation of LY353381 compared with tamoxifen in women with locally advanced or metastatic breast cancer. (Multicenter trial, responsible Swedish investigator: Jonas Bergh)

31 p53 study. First prospective intergroup translational research trial assessing the potential predictive value of p53 using a functional assay in yeast in patients with locally advanced/inflammatory or large operable breast cancer prospectively randomised to a taxane versus a non taxane regimen. Principal investigator: Hervé Bonnefoi, co-investigators Richard Iggo, Martine Piccard, Jonas Bergh.

32 HERA. A randomised three-arm multi-centre comparison of 1 year and 2 years of Herceptin versus no Herceptin in women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy. (Multicenter trial, responsible Swedish investigator: Jonas Bergh).

33 Vaccine immunization with nucleic acid coding for the gene HER-2/neu together with low doses of GM-CSF (Leucomax®) as adjuvant in patients with metastatic breast carcinoma. Principal investigator: Jonas Bergh.

34 A phase 2, randomized,open-label study of single agemt CI-1033 in patients with metastatic breast cancer. (Multicenter trial, responsible Swedish investigator: Jonas Bergh).

35 SBG 2004-1. A phase II study continuing into a randomised phase III study. Comparison of safety, feasibility and efficacy of: dose dense and tailored and dose escalated epirubicin + cyclophosphamide followed by docetaxel (dEC→T) or dose dense epirubicin + cyclophosphamide followed by docetaxel (EC→T) or docetaxel + doxorubicin + cyclophosphamide (TAC) in lymph node positive breast cancer patients. Multicenter study. Principal investigator: Jonas Bergh.

36 FACT. Anastrozole monotherapy versus maximal oestrogen blockade with anastrozole and fulvestrant combination therapy: an open randomized, comparative, phase III multicentre study in postmenopausal women iwth hormone receptor positive breast cancer in first relapse after primary treatment of localised tumour. Multicenter study. Co-ordinating investigator: Jonas Bergh.

37 SBG 2004-1/ABCSG 25/GBG 53 (PANTHER) study. A randomised phase III study comparing biweekly and tilored epirubicin + cyclophosphamide followed by biweekly tailored docetaxel (dtEC→dtT) (A-arm) versus three weekly epirubicin + cyclophosphamide, 5-fluorouracil follwed by docetaxel (FEC→T) (B-arm) in lymph node positive breast cancer patients – a continuation of the feasibility part of the SBG 2004-1 study. Multicenter study. Principal investigator: Jonas Bergh.

38 A6181100. Exploratory evaluation of a sequential administration of docetaxel and SU011248 in women with advanced breast cancer. Responsible Swedish Investigator: Jonas Bergh.

39 Sutent A6181064. A randomised, phase 3 study of docetaxel in combination with sunitinib versus docetaxel in the first-line treatment of advanced breast cancer patients. Multicenter study. Principal investigator: Jonas Bergh.

40 Sutent A6181064. A randomised, phase 3 study of docetaxel in combination with sunitinib versus docetaxel in the first-line treatment of advanced breast cancer patients. Biopsy and PET substudy for Karolinska. Multicenter study. Principal investigator: Jonas Bergh.

41 RAD001. A phase Ib study investigating to combination of RAD001 with trastuzumab and vinorelbine in patients with HER2-overexpressing metastatic breast cancer. Multicenter study. Local investigator: Jonas Bergh.

42 BAY 43-9006/12444. A phase III randomised, double-blind, placebo-controlled Trial comparing Capecitabine plus Sorafenib versus Capecitabine plus Placebo in the Treatment of locally advanced or metastatic HER2- negative breast cancer. National co-ordinator: Jonas Bergh.

43 BAY 43-9006/12444. PET/CT- biopsy study for patients already accepted on the randomised, double-blind, phase III study with Capecitabine +/- Sorafenib in the treatment of advanced breast cancer. Principal Investigator: Jonas Bergh.

44 20050209/ABCSG18. A Study to Determine Treatment Effects of Denosumab in Patients With Breast Cancer Receiving Aromatase Inhibitor Therapy. A randomised, double-blind, placebo-controlled multicenter phase II study to determine the treatment effect of denosumab in subjects with non-metastatic breast cancer receiving aromatase inhibitor therapy. National Co-ordinator: Jonas Bergh.

45 B1271003. An open, Phase 1b and phase 2 study of PF-04691502 in combination with letrozole compared with letrozole alone in the treatment of patients with oestrogen receptor positive HER2 negative breast cancer. Local Investigator: Jonas Bergh.

46 APHINITY (BIG 4-11/BOER126/TOC493G). A randomised, multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in the treatment of patients with operable HER2 positive primary breast cancer. Multicenter study. National Coordinator: Jonas Bergh.

47 BEVPAC. A prospective randomized Phase II study to identify predictive biomarkers and mechanisms of therapy resistance in patients with HER2-negative metastatic breast cancer (MBC) treated with the combination of bevacizumab and paclitaxel. Study Director: Jonas Bergh.

48 TailorDose. A clinical evaluation of a new measuring method for determination of individual in vivo dose of drugs/active components at chemotherapy. Principal investigator: Jonas Bergh.

49 Optitrain. Optimizing of training with muscle biopsy for women with breast cancer receiving adjuvant chemotherapy. Randomized. National Coordinator: Jonas Bergh.

50 BI BrEEast. A phase Ib/II randomized study of BI836845 in combination with examestane and everolimus versus examestane and everolimus alone in women with locally advanced or metastatic breast cancer. National Coordinator and Steering Committee: Jonas Bergh.

51 COBC. Cardio-Oncology Breast Cancer study: an open, randomized study comparing difference and frequence of cardiotoxity between regular cancer treatment and addition with cardiologic risk evaluation and early intervention at chemotherapy. Study Director: Jonas Bergh.

52 PREDIX HER2. A Neoadjuvant response-guided treatment of HER2 positive breast cancer. Part of a set of translational phase II trials based on molecular subtypes. Study Director: Jonas Bergh.

53 KATHERINE. A randomized, open phase III study of multicenter type with trastuzumab emtansine versus trastuzumab. Post-neoadjuvant standard anti-HER2 therapy. Local

investigator: Jonas Bergh.

54 Kamilla, TDM1 Breast. A non-randomized study with trastuzumab emtansine for patients with remaining cancer after standard anti-HER2 based therapy. Local investigator: Jonas Bergh.

55 BOLERO 6. A 3-armed, randomized, open label, phase II study of everolimus in combination with examestane versus everolimus alone versus Capecitabine for postmenopausal women with estrogen receptor positive, locally advanced, recurrent or metastatic breast cancer after recurrence or progression on prior letrozole or anastrozole. Local investigator: Jonas Bergh.

56 BIG 6-13, OlympiA. A phase III study with olaparib versus placebo for BRCA mutated high-risk HER2-negative breast cancer. Local investigator: Jonas Bergh.

57 SHERsig. A prospective phase II study to evaluate alternations in molecular biomarkers in HER2-positive metastatic breast cancer together with assessement of trastuzumab use beyond progression after initial exposure to trastuzumab-taxane based treatment. Member of the Steering Committee: Jonas Bergh.

58 Belle-3. A phase III randomized, double blind, placebo controlled study of BKM120 with fulvestrant, in postmenopausal women with hormone receptor-positive HER2-negative AI treated, locally advanced or metastatic breast cancer who progressed on or after mTOR inhibitor based treatment. Local investigator: Jonas Bergh.

59 GO29058/Sandpiper. A phase III double blind, placebo controlled randomized study of taselisib plus fulvestrant compared with placebo plus fulvestrant at postmenopausal women with oestrogene receptor positive and HER2 negative loccaly advanced or metastatic breast cancer that during or after treatment with aromatise inhibitor have had a relapse or progression. National coordinator: Jonas Bergh.

60 MK3475 Triple negative breast cancer. A randomised open-label phase III study of single agent pembrolizumab versus treatment of physician’s choice cof monotherapy for metastatic triple negative breast cancer (mTNBC). National coordinator: Jonas Bergh.

61 PREDIX LuminalA. Neoadjuvant response-guided treatment of slowly proliferating hormone receptor positive tumors. Study director: Jonas Bergh.

62 PREDIX LuminalB. Neoadjuvant response-guided treatment of estrogen receptor positive tumors with high proliferation or slow proliferation with metastatic nodes. Part of a platform of translational phase II trials based on molecular subtypes LumB. Study director: Jonas Bergh.

63 PASIPHAE. A phase 2, international, multicenter, open-labeled, randomized trial of PAlbociclib and fulvestrant vs. Standard oral capecitabine In Patients with Hormone receptor positive / HER2 negative Advanced breast cancer and documented Endocrine resistance. Study director: Jonas Bergh.

64 KEYNOTE-522. A Phase III Study, Pembrolizumab Plus Chemotherapy vs Placebo Plus Chemotherapy as Neoadjuvant Therapy followed by Pembrolizumab vs Placebo as Adjuvant Therapy for locally advanced Triple Negative Breast Cancer (TNBC). JB local investigator at Karolinska and member of the international steering committee.

March 7 2019

END CLINICAL TRIALS

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