patient (0.6%) on tam and 6 patients (1.9%) were receiving an AI with a moderate inhibitor. 24 patients (16.5%) on tam and 40 patients (12.4%) receiving an AI were receiving weak CYP2D6 inhibitors.

Conclusion: While infrequent, breast cancer patients receive medications that can have an adverse effect on tam therapy, primarily its metabolism and activation. Patients receiving AI therapy do receive medications that can interact with tam metabolism, and as such can be a challenge to manage if they have to change from an AI to tam if they cannot tolerate an AI. This is not an infrequent event as our centre has shown that up to 20% of breast cancer patients discontinue AI's due to side effects. Patients are frequently receiving moderate to weak inhibitors of CYP2D6, and these patients should be tested for their pharmacogenomic profile prior to initiating tam to determine if they are wild-type vs intermediate or poor metabolizers.

14 Poster

Influence of zoledronic acid on bone mineral density in premenopausal women with hormone receptor positive or negative breast cancer and neoadjuvant or adjuvant chemotherapy or endocrine treatment

P. Hadji[1], A. Kauka[1], M. Kalder[1], T. Bauer[1], U. Albert[1], M. Muth[2], M. Ziller[3]. *[1]Phillips-University Marburg, Department of Endocrinology Reproductive Medicine and Osteoporosis, Marburg, Germany; [2]Novartis Pharma GmbH, Oncology, Nuremberg, Germany; [3]Phillips-University Marburg, Department of Endocrinology Reproductive Medicine and Osteoporosis, Nuremberg, Germany*

Background: Depending on baseline bone mineral density (BMD), adjuvant chemotherapy or endocrine therapy of premenopausal breast cancer patients can lead to a substantially increased risk of osteoporotic fractures. Hereby, a significant decrease of BMD > 10% after 2 years of therapy has been reported. Adjuvant therapy with zoledronic acid (Zometa®) in early breast cancer was investigated in the ABCSG-12 and the Zo-Fast trial. Zoledronic acid 4 mg given every six months increased BMD in premenopausal and postmenopausal women receiving endocrine treatment. In addition, a significant increase in PFS could be observed in favor of zoledronic acid.

Material and Methods: The goal of the two monocentric, placebo-controlled, randomized studies Probone I and Probone II is to demonstrate that adjuvant therapy with zoledronic acid improves BMD in premenopausal women. Hormone receptor negative patients (Probone I) are treated with (neo)adjuvant chemotherapy, hormone receptor positive patients (Probone II) with endocrine treatment alone or in combination with (neo)adjuvant chemotherapy. Patients receive zoledronic acid or placebo i.v. every 3 months for 2 years. Primary objective is the change in BMD at the lumbar spine between baseline and month 24 (measured by DXA). Secondary objectives include disease free survival, BMD at total hip and os calcis, BMD measured by QUS at os calcis and phalanges, markers of bone turnover, pathologic fractures, safety and tolerability. BMD is measured at baseline, 12 and 24 months. QUS and markers of bone turnover are measured at baseline, 3, 6, 12 and 24 months.

Results: Recruitment has been finished in 2009 and 71 hormone receptor positive and 11 hormone receptor negative patients have been enrolled into the studies. 30 out of 82 patients have already finished treatment. The design of the study and demographic data of the enrolled patients will be presented.

Conclusion: Probone I/II are two ongoing studies to evaluate the effect of adjuvant zoledronic acid on BMD in premenopausal patients with breast cancer receiving chemotherapy and/or endocrine therapy. The results of these studies will be of great interest for daily practice because of the lack of approved treatments for the prevention of cancer treatment or aromatase inhibitor induced bone loss in patients with early breast cancer.

15 Poster

Five years of exemestane as initial therapy compared to tamoxifen followed by exemestane for a total of 5 years: the TEAM trial, a prospective, randomized, phase III trial in postmenopausal women with hormone receptor-positive early breast cancer

A. Hasenburg[1], C.J.H. van de Velde[2], C. Seynaeve[3], D.W. Rea[4], J. Vannetzel[5], R. Paridaens[6], C. Markopoulos[7], Y. Hozumi[8], H. Putter[9], S.E. Jones[10]. *[1]University Medical Center, Gynecology, Freiburg, Germany; [2]University Medical Center, Surgery, Leiden, The Netherlands; [3]Erasmus Medical Center, Medical Oncology, Rotterdam, The Netherlands; [4]University of Birmingham, Cancer Studies, Birmingham, United Kingdom; [5]Institut du Sein Henri Hartmann, Medical Oncology, Neuilly sur Seine, France; [6]UZ Gasthuisberg, Medical Oncology, Leuven, Belgium; [7]University Medical School, Medical Oncology, Athens, Greece; [8]Jichi Medical Universiy, Medical Oncology, Shimotsuke, Japan; [9]University Medical Center, Med Statistics, Leiden, The Netherlands; [10]US Oncology Research, Medical Oncology, Houston, USA*

Background: Exemestane (E) is a steroidal Aromatase Inhibitor (AI) with an established role in early breast cancer after 2−3 years of Tamoxifen (T). Additionally, AIs have shown superiority to T as initial adjuvant therapy. The Tamoxifen Exemestane Adjuvant Multinational (TEAM) study has been prospectively designed to compare the role of E as initial adjuvant therapy with a sequential approach of T followed by E.

Methods: Postmenopausal patients with hormone receptor-positive early breast cancer were randomized to open-label E 25 mg/d or T 20 mg/d. All patients completed surgery and chemotherapy, if indicated. Data were collected and analyzed by the Central Data Center in Leiden, The Netherlands. The trial was initiated in 2001 with the primary objective being a comparison of disease-free survival (DFS) with T vs. E. In 2004, TEAM was modified in response to new data; all those initially receiving T were switched to E after 2.5−3 years. An additional 2500 patients were recruited and randomized at diagnosis to E or T followed by E for 5 years. The modified study design included 2 co-primary analyses: (1) DFS of T vs. E that was previously reported at 2.75 years follow-up and (2) DFS at 5 years follow-up of E vs. T followed by E.

Results: Between 2001 and January 2006, 9779 women were randomized to TEAM. In total, 99% of patients were ER+ and/or PgR+, 50% were node-negative, 44% underwent mastectomy, 68% received radiotherapy, and 36% received chemotherapy. Median follow-up is now 5.1 years. There were 712 DFS events in E vs 714 in T followed by E (locoregional or distant recurrence, second breast cancers, or death without recurrence); HR 0.97 (95% CI 0.88–1.08; p-value 0.60). There were 400 patients with distant metastases in E vs 420 in T followed by E; HR 0.93 (95% CI 0.81–1.07; p-value 0.30). No additional safety issues have emerged with longer follow-up.

Conclusion: Overall this trial shows that starting with E is not more effective than T followed by E in preventing breast cancer recurrence. The previously reported significant improvement in distant recurrence with E vs. T at 2.75 years has not been maintained with longer follow-up after switching from T to E. This suggests that for postmenopausal patients with endocrine sensitive early breast cancer the use of either 5 years of upfront E or T followed by E are appropriate treatment options.

16 Poster

Circulating tumour cells (CTCs) can be detected in peripheral blood of breast cancer (BC) patients two years after primary diagnosis

B. Rack[1], C. Schindlbeck[1], A. Schneeweiss[2], I. Schrader[3], K. Friese[4], M.W. Beckmann[5], K. Pantel[6], W. Lichtenegger[7], H. Sommer[4], W. Janni[8]. *[1]Ludwig-Maximilians-University, Department of Gynaecology, Muenchen, Germany; [2]University of Heidelberg, Department of Gynaecology, Heidelberg, Germany; [3]Henriettenstiftung, Department of Gynaecology, Hannover, Germany; [4]Ludwig-Maximilians-University, Department of Gynaecology, Muenchen, Germany; [5]University of Erlangen, Department of Gynaecology, Erlangen, Germany; [6]University Hamburg-Eppendorf, Institute for Tumor Biology, Hamburg, Germany; [7]Charité University Hospital, Department of Gynaecology, Berlin, Germany; [8]Heinrich-Heine University, Department of Gynaecology, Duesseldorf, Germany*

Background: Recent trials have demonstrated prognostic relevance of CTCs in metastatic BC. The SUCCESS trial evaluates the role of CTCs at primary diagnosis and after chemotherapy as well as two and five years after diagnosis in primary BC patients treated with chemotherapy and zoledronate.

Methods: We analyzed 23 ml of peripheral blood in N+ and high risk N− primary BC pts receiving 3×FEC (500/100/500)–3×Doc100 q3w vs. 3×FEC (500/100/500)–3×DocGemcitabine (75/1000 d1+8) chemotherapy