BREAST CANCER TREATMENT WITH EVEROLIMUS AND EXEMESTANE FOR ER+ WOMEN - RESULTS OF THE 2ND INTERIM ANALYSIS OF THE NON-INTERVENTIONAL TRIAL BRAWO


1Department of Gynecology and Obstetrics, University Hospital Erlangen, Erlangen, GERMANY
2Private Practice, Medical Center Onkologie Ravensburg, Ravensburg, GERMANY
3Department of Obstetrics and Gynecology, University Hospital Heidelberg, Heidelberg, GERMANY
4Private Practice, Medical Centre Hildesheim, Hildesheim, GERMANY
5Praxis für Gynäkologie & Geburtshilfe, Gynäkologische Onkologie & Palliativmedizin, Poliklinik GmbH Chemnitz, Chemnitz, GERMANY
6Department of Gynecology and Obstetrics, Technical University Dresden, Dresden, GERMANY
7Gynecology and Obstetrics, Medical Center Bonn, Bonn, GERMANY
8Breast Center, Department of Obstetrics & Gynecology, and Comprehensive Cancer Center, University of Munich, Munich, GERMANY
9Department of Obstetrics and Gynecology, St. Vincentius Kliniken Kehl, Kehl, GERMANY
10Department of Gynecology and Obstetrics, GRN-Klinik Weinheim, Weinheim, GERMANY
11Department of Gynecology and Obstetrics, University Hospital Schleswig-Holstein Campus Kiel, Kiel, GERMANY
12Department for Senology / Breast Center, Klinikum Essen Mitte, Essen, GERMANY
13Oncology, Novartis Pharma GmbH, Nuremberg, GERMANY
14Department of Sport Medicine, University of Cologne, Cologne, GERMANY
15Oncology Bethanien, Bethanien Hospital, Frankfurt a.M., GERMANY
16Department of Hematology, Oncology, and Tumor Immunology, Charité University Medicine, Campus Benjamin Franklin, Berlin, GERMANY
17Department of Obstetrics and Gynecology, Sana Klinikum Offenbach, Offenbach, GERMANY
18Department of Obstetrics and Gynecology, University of Tuebingen, Tuebingen, GERMANY

Aim: BRAWO is a German non-interventional study of 3000 patients (pts) with advanced or metastatic, hormone-receptor-positive and HER2-negative breast cancer treated with everolimus (EVE) and exemestane (EXE). Data is collected at about 400 sites. Main objectives are to extend the knowledge on a) the impact of physical activity on efficiency and quality of life, b) prophylaxis and management of stomatitis in clinical routine, and c) the sequence of therapy, when EVE is used in daily clinical practice. We report the results of the 2nd preplanned interim analysis (IA) which was defined to take place 12 months after the inclusion of the 500th patient into the documentation.

Methods: The 2nd interim analysis (data cut-off 08 Jul 2014) covers data of the first 500 documented patients (pts) and evaluated for the first time progression free survival (PFS). Furthermore, baseline data, safety data and the tumor status were analyzed.

Results: At the time of data cut-off, 409 pts had discontinued the study, 91 were still ongoing. Baseline characteristics: Median age: 66 yrs; median BMI: 25.9; ECOG 0-1: 377 (89.8%); visceral metastases: 53.7%; bone only metastases: 26.3%. 26.2% pts received EVE and EXE as first treatment (first line), 28.8% as second line, 18.8% as third line and 26.2% as fourth or later line in the advanced setting. Median PFS was 8.0 months (6.7; 9.1; 95% CI). For pts receiving EVE/EXE as first treatment in the advanced setting (N = 131) median PFS was 10.1 months (6.7; 17.6). 41.6% of these 500 pts had at least one stomatitis event: 19.8 % grade 1, 15.8% grade 2 and 3.4% grade 3. 86.8% of pts...