

## ABCSG 41/ OlympiA: Adjuvant Olaparib improves 3-year-survival in patients with BRCA1- or BRCA2-mutated breast cancer

Vienna, 7 June, 2021. The ABCSG 41/ BIG 6-13/ OlympiA study ([OlympiA NCT02032823](#), [BIG 6-13, NSABP B-55](#)) is an international project to evaluate the efficacy and safety of the study drug olaparib in HER2-negative high-risk breast cancer patients with BRCA 1/2 germline mutations (gBRCA-P/LP variants - pathogenic/probable pathogenic variants) who have completed local treatment and (neo)adjuvant chemotherapy.

The project is led by study sponsor AstraZeneca and was globally enrolled as of May 28, 2019. A total of 1836 patients participated in the international study. The database closure date for the intended interim analysis was set at 165 invasive distant free survival (iDFS) cases reported in the database and triggered on March 27, 2020. Based on the IDMC decision that the OlympiA trial met the primary endpoint (iDFS) in the course of interim analysis, the overall database analysis was continued. Now, the 3-year survival data have been published in the New England Journal of Medicine under the title "Adjuvant Olaparib for Patients with BRCA1 or BRCA2 Mutated Breast Cancer."<sup>1</sup>

It was shown that in patients with HER2-negative high-risk early breast cancer and gBRCA-P/LP variants (germline BRCA-P pathogenic/probable pathogenic variants), adjuvant olaparib treatment after completion of local treatment and (neo)adjuvant chemotherapy significantly improves both invasive disease-free survival (iDFS) and distant disease-free survival (D-DFS) with limited impact on patient-reported quality of life.

Prof. Michael Gnant, President of the ABCSG, is delighted about this success: *"The great results for a patient group with very particular challenges show the innovative power of worldwide clinical research, to which the ABCSG was again able to make a significant contribution."*

In detail, the analysis showed that 3-year iDFS was 85.9% in the olaparib group and 77.1% in the placebo group (Diff. 8.8%; 95% CI 4.5%, 13.0%, hazard ratio (HR) for iDFS 0.58; 99.5% (CI), 0.41, 0.82; p<0.0001). The 3-year DFS was 87.5% in the olaparib group and 80.4% in the placebo group (Diff. 7.1%; 95% CI 3.0%, 11.1%; HR for DFS 0.57; 99.5% CI 0.39, 0.83; p<0.0001). Olaparib was associated with

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<sup>1</sup> **Adjuvant Olaparib for Patients with BRCA1 or BRCA2 Mutated Breast Cancer**

Andrew N J Tutt et. al. for the OlympiA Clinical Trial Investigators

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fewer deaths than placebo (59 versus 86); HR for overall survival was 0.68 (99% CI 0.44, 1.05,  $p=0.024$ ), not statistically significant at an interim analysis cutoff of  $p<0.01$ . Safety data were consistent with known toxicities of olaparib, with no excess of serious adverse events.

Prof. Christian Singer, National Coordinating Investigator of the ABCSG 41/ OlympiA study in Austria, comments: *"The results of the study undoubtedly represent a milestone in the therapy of BRCA-associated early breast cancer. At the same time, however, the study result also confronts us with enormous logistical challenges: Genetic testing for BRCA1 and BRCA2 mutations in the blood will become routine for high-risk patients with early HER2-negative breast carcinoma - and will therefore also have to be available quickly, at low cost and throughout Austria."*

### **ABCSG (Austrian Breast & Colorectal Cancer Study Group)**

For more than 30 years, Austria's largest academic study group, Austrian Breast & Colorectal Cancer Study Group (ABCSG), has independently conducted clinical trials on breast and colorectal cancer as well as pancreatic cancer. The results have received the greatest scientific recognition internationally and have contributed significantly to improving patients' chances of cure and survival. In Austria alone, the ABCSG works with numerous centers and hundreds of investigators; worldwide, the number of international collaborations is several thousand. To date, more than 29,000 patients have participated in ABCSG clinical trials.

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