

#### 439P Testing HR+ / HER2- patients with advanced or metastatic breast cancer for identification of tissue mutations in the PIK3CA gene: Results of a national program by the Hellenic Society of Medical Oncology (HeSMO)

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**Background:** PIK3CA mutations have been identified in approximately up to 40% of breast cancer cases and PIK3CA targeting has already been incorporated in treatment algorithms, especially in the second line of ER+/HER2- patients. HeSMO launched a national program to provide PIK3CA mutation testing, which is officially not reimbursed, with the aim to identify mutations in the PIK3CA gene, and, therefore, lead to more therapeutic options.

**Methods:** All HR+/HER2- patients with a diagnosis of metastatic breast cancer were eligible to participate in this program. The result of the test was obtained using the COBAS® PIK3CA method, a diagnostic test specifically designed to detect mutations in the PIK3CA gene in tumor tissue samples (FFPE) attained by biopsy or surgically, which detects 17 different mutations in the PIK3CA gene, including the most commonly occurring in Exons 9 and 20.

**Results:** From June 2022 to March 2023, 149 patients from across the country were tested within this program. Sixty one (61) patients (40.94%) were detected with mutation in PIK3CA gene and 88 (59.06%) without mutation (Table). 23 patients had Exon 9 mutations (37.70%), 33 in Exon 20 (54.10%), and 8 had mutations in the remaining Exons 1, 4 and 7 (13.11%). In 1 sample 4 mutations were detected: (Exon 7/9/20), and 2 mutations in another 2 samples (Exon 9: E545X, Q546X and Exons 1/20), while in all other samples just 1 mutation was detected in each.

Exon	Mutation	Samples	Mutation percentage in all patients detected with PIK3CA gene mutation (61)	Mutation percentage in all patients tested (149)
Exon 1	R88Q	2	3,28%	1,34%
Exon 4	N345K	3	4,92%	2,01%
Exon 7	C420R	3	4,92%	2,01%
Exon 9	E542K	7	11,48%	4,70%
Exon 9	E545X	12	19,67%	8,05%
Exon 9	Q546X	2	3,28%	1,34%
Exon 9	E545X, Q546X	1	1,64%	0,67%
Exon 9	E542K, E545X	1	1,64%	0,67%
Exon 20	H1047X	32	52,46%	21,48%
Exon 20	G1049R	1	1,64%	0,67%

**Conclusions:** In our series, 40.94% of the patients tested, were detected with mutations in PIK3CA gene, in accordance with published data. Apart from the significant implications for treatment possibilities in a substantial patients' population, these results provide valuable epidemiological data and strengthen our efforts for reimbursement of PIK3CA mutation testing in Greece.

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#### 440P Palliative radiotherapy in metastatic breast cancer: Does molecular subtype predict patient response to radiotherapy?

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**Background:** This study aimed to determine whether molecular subtype does impact patient response to palliative radiotherapy in metastatic breast cancer.

**Methods:** All metastatic breast cancer patients referred for palliative radiotherapy (either for pain-relief or spinal cord/nerve decompression), between 2017 and 2022, were included in this study. Patient response to radiotherapy was evaluated at 3 weeks from radiotherapy. Re-irradiation need was assessed. Radiotherapy outcomes were statistically analyzed with regards to breast cancer molecular subtypes.

**Results:** Data of 137 metastatic breast cancer patients were evaluated. Ductal cell carcinoma was the most common histological type. Patients' distribution according to molecular subtype was as follow: 17% of luminal A tumors, 72% of luminal B tumors, 6% of Her2 tumors and 5% of triple-negative tumors. All patients received single fraction palliative radiotherapy with a prescription dose of 8 Gy and 6 Gy respectively in 77 % and 13 % of cases. Forty-six patients were lost to follow-up and one patient didn't complete treatment. Complete response to radiotherapy was reported in 21%, 54% and 50% of cases, respectively for luminal A, luminal B and Her2 tumors. No complete response was found in the triple-negative breast cancer subgroup. The "no response to radiotherapy" rate for luminal A and luminal B tumors, was 21% and 20% respectively. Re-irradiation of the same metastatic subsite was performed in 8 patients, all with luminal B molecular subtype. Although not statistically significant, luminal tumors tended to respond better to palliative radiotherapy when compared to non-luminal tumors, with a complete response rate of 48% versus 30% respectively (p=0.3). No statistically significant correlation was found between breast cancer molecular subtype and radiotherapy outcomes.

**Conclusions:** This study suggests that breast cancer subtypes do exhibit differential responses to palliative radiotherapy. Yet molecular subtype failed to reliably predict radiotherapy outcomes and identify patients who would derive greater than average benefit from palliative radiotherapy. Further studies are needed to identify reliable biomarkers predictive of likely radiotherapy sensitivity.

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#### 441P Real-world efficacy of ribociclib (RIB) + aromatase inhibitor (AI)/fulvestrant (FUL) in subgroups of special interest: 5th interim analysis (IA) of the RIBANNA study

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**Background:** RIBANNA (CLEEO11ADE03) is a prospective, noninterventional study assessing the efficacy and safety of RIB+AI/FUL, or endocrine therapy (ET) or chemotherapy (CT) in pre-, peri- and postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor-2-negative (HER2-) advanced breast cancer (ABC) in a broad patient population. Real-world data on the efficacy of RIB in subgroups of special interest resulting from the 5<sup>th</sup> IA from the RIBANNA study will be presented at the conference.

**Methods:** Efficacy outcomes in subgroups of special interest will be determined. Adjusted progression-free survival (PFS) for 1L RIB will be separately analyzed for patients with visceral vs. non-visceral metastases (lung, liver, central nervous system), pre- vs postmenopausal patients, patients receiving AI vs FUL as Ribociclib combination partner, de novo vs. recurrent and endocrine-resistant vs. -sensitive disease. In addition, conditional PFS (this is, the probability of survival without progression for further months given a previous survival for a defined number of months) will be analyzed for patients without progression at 6, 12, and 24 months in the overall study population.