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Extended adjuvant neratinib in HER2+/HR+ early breast cancer in clinical routine: Final results from the multi-national, prospective, observational study ELEANOR

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Background

Neratinib is an oral, irreversible pan-HER tyrosine kinase inhibitor approved in Europe as extended adjuvant treatment for adult patients (pts) with HER2+/HR+ early breast cancer (eBC) who completed adjuvant trastuzumab-based therapy <1 year ago. In the phase III ExteNET study, neratinib significantly improved 2-year invasive disease-free survival (iDFS) (Δ4.5%, HR 0.49, 95% CI 0.30-0.78) with an iDFS rate of 95.3% for neratinib.

Methods

ELEANOR was a prospective, observational study in female pts with HER2+/HR+ eBC receiving neratinib according to label in Germany, Austria and Switzerland (NCT04388384). The primary objective was to assess adherence to neratinib (i.e., neratinib intake as planned by the physician on ≥75% of days).

Results

Of 298 pts enrolled from July 2020 to May 2023 at 66 sites, 285 qualified for the main analysis set (MAS; see table for baseline characteristics), 287 for the safety set (SAF), 279 for the compliance set (CS), and 82 for the patient-reported outcome set (PROS).Table: 299P

Baseline characteristics	MAS, N=285
Age (at inclusion) in years, median (IQR)	52 (44-60)
ECOG status (at inclusion), n (%)	
0	210 (73.7)
1	57 (20.0)
2	5 (1.8)
Missing	13 (4.6)
Menopausal status (at primary diagnosis), n (%)	
pre	131 (46.0)
peri	18 (6.3)
post	136 (47.7)
AJJC stage (clinical, at primary diagnosis), n (%)	

Baseline characteristics	MAS, N=285
Tis/N0/M0	2 (0.7)
I	113 (39.6)
II	130 (45.6)
III	31 (10.9)
Missing	9 (3.2)
Prior adjuvant/post-neoadjuvant anti-HER2 treatment, n (%)	
Trastuzumab	111 (38.9)
Trastuzumab + Pertuzumab	93 (32.6)
T-DM1	67 (23.5)
Other[§]	13 (4.6)
Missing	1 (0.4)

[§]Any other [combination] of trastuzumab, pertuzumab, and T-DM1, including switches of agents

Conclusions

Real-world effectiveness data on extended adjuvant neratinib in a cohort of pts with HER2+/HR+ eBC who completed contemporary anti-HER2 therapies appear to be consistent with previous data. Despite a slight and transient decrease in self-rated overall health within the first 3 months of neratinib treatment, the rate of adherent pts was high. No new safety signals were detected.

Clinical trial identification

NCT04388384.

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Legal entity responsible for the study

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Disclosure

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