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Health-related quality of life from HER2CLIMB-05: A phase 3 study of tucatinib versus placebo in combination with trastuzumab and pertuzumab as 1L maintenance therapy for HER2+ mBC

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Background

HER2CLIMB-05 demonstrated clinical benefits of tucatinib (Tuc) with trastuzumab (T) and pertuzumab (P) as 1L maintenance therapy in patients with HER2+ mBC. We report on patient-reported outcome (PRO) results from HER2CLIMB-05.

Methods

Patients with centrally confirmed HER2+ mBC were enrolled and randomized 1:1 to Tuc (300 mg) or placebo twice daily, in combination with T and P. PROs were completed at baseline, Day 1 of Cycles 2-4, and every 2 cycles until the first follow-up visit after end of treatment. Analyses included EORTC-QLQ-C30 (global health status/quality of life (GHS/QoL), role function (RF), physical function (PF)) and descriptive statistics (observed values and change from baseline). We ran analyses on time to deterioration (TTD) based on first PRO deterioration excluding clinical progression, as well as first (TTFD) and confirmed (TTCD; >2 consecutive assessments) deterioration analyses including clinical progression and/or death events in their definitions.

Results

Mean PRO changes from baseline showed a trend towards maintenance across treatment arms and high compliance rates throughout. Results reported median months (m). TTD for GHS/QoL was 11.8m with Tuc vs 18.7m with placebo (HR (95% CI) = 1.29 (1.03, 1.62)). TTFD was significantly improved with the addition of Tuc vs. placebo for PF (0.79 (0.65, 0.96); 10.6m vs 7.8m), groups were comparable for GHS/QoL and RF (GHS/QoL: 1.00 (0.83, 1.19); RF: 0.99 (0.83, 1.19)). TTCD was significantly improved with the addition of Tuc vs placebo for GHS/QoL (0.81 (0.67, 0.99); 14.6m vs 10.3m) and PF (0.73 (0.59, 0.89), 17.5m vs 10.6m). For RF, TTCD trended toward improvement (0.84 (0.69, 1.02); 12.4m vs 8.8m).

Conclusions

Adding Tuc to standard therapy maintained or improved patient-reported GHS/QoL, PF, and RF, with significant delays in composite deterioration events defined by PROs, clinical progression, and death. These findings demonstrate that the clinical efficacy of Tuc is accompanied by preservation of patient experience of health-related QoL, further supporting its use as a 1L maintenance therapy in patients with HER2+mBC.

Clinical trial identification

NCT05132582.

Legal entity responsible for the study

Pfizer Inc.

Funding

Pfizer Inc.

Disclosure

V.C. Dieras: Financial Interests, Personal, Advisory Board, Steering Committee, IDMC, consultant, Symposium, travel expenses: Roche Genentech; Financial Interests, Personal, Advisory Board, Advisory boards, Symposia and travel expenses: Novartis; Financial Interests, Personal, Advisory Board, Steering committee, Advisory boards, symposia, travel expenses: Pfizer; Financial Interests, Personal, Advisory Board, Advisory boards, Symposia,: Lilly; Financial Interests, Personal, Advisory Board, consulting, Symposia, travel expenses: Astra Zeneca; Financial Interests, Personal, Advisory Board, Advisory boards, consulting, Symposia,travel expenses+ program Daiichi Endeavour: Daiichi Sankyo; Financial Interests, Personal, Advisory Board, advisory boards, symposia,travel expenses: Gilead; Financial Interests, Institutional, Steering Committee Member: Roche Genentech, Pfizer; Non-Financial Interests, Leadership Role, President scientific committee: Société française de sénologie pathologie mammaire; Non-Financial Interests, Leadership Role, Breast group UCBG, ESME group scientific committee: UNICANCER. E.P. Hamilton: Financial Interests, Institutional, Advisory Board: Arivinas, Astra Zeneca, BeOne Medicines, BicycleTx, BioNTech, Boehringer Ingelheim, Boundless Bio, Bristol-Myers Squibb, Circle Pharma, Daiichi Sankyo, Gilead Sciences, Halda Therapeutics, Incyclix Bio, Janssen/Johnson & Johnson, Jazz Pharmaceuticals, Lilly, Mersana Therapeutics, Novartis, Pfizer, Precede Biosciences, Pyxis Oncology, Roche/Genentech, Samsung Bioepis, Shorla Pharma, Stemline Therapeutics; Financial Interests, Institutional, Research Funding: Pfizer, Accutar Biotechnology, Artios, Arvinas, AstraZeneca, AtlasMedx, BeiGene, BeOne Medicines, Bicycle Therapeutics, Biohaven Pharmaceuticals, BioNTech, Compugen, Cullinan, Daiichi Sankyo, Dantari, Day One Biopharmaceuticals, Duality Biologics, Ellipses Pharma, Elucida Oncology, Exelixis, FujiFilm, Genmab, Gilead Sciences, H3 Biomedicine, Iambic Therapeutics, Immunogen, Inspirna, InventisBio, Jacobio, Jazz Pharmaceuticals, K-Group Beta, Kind Pharmaceuticals, Lilly, Loxo Oncology, Mabspace Biosciences, Mabwell Bioscience, Marengo Therapeutics, MediLink Therapeutics, Merck, Mersana, Novartis, Olema, Orinove, Orum Therapeutics, Pionyr Immunotherapeutics, Prelude Therapeutics, Profound Bio, Regeneron, Relay Therapeutics, Rgenix, Roche/Genentech, SeaGen, Shattuck Labs, Simcha Therapeutics, Stemline Therapeutics, Sutro, Systimmune, Taiho, Tesaro, TheRas, Treadwell Therapeutics, Verastem, Xadcera Biopharmaceutical, Zymeworks. S. Thakkar: Financial Interests, Personal, Full or part-time Employment: Pfizer. J.S. McGinley: Financial Interests, Personal and Institutional, Full or part-time Employment: Vector Psychometric Group, LLC. Q. Shen: Financial Interests, Institutional, Full or part-time Employment: Pfizer Inc. A. Savord: Financial Interests, Personal and Institutional, Full or part-time Employment: Vector Psychometric Group, LLC. C. Seo: Financial Interests, Institutional, Full or part-time Employment: Pfizer Inc.; Financial Interests, Institutional, Stocks or ownership: AstraZeneca. M.X. Dunbar: Financial Interests, Personal and Institutional, Full or part-time Employment: Pfizer Inc. J. Cappelleri: Financial Interests, Institutional, Full or part-time Employment: Pfizer Inc. All other authors have declared no conflicts of interest.