Neratinib (HER2)- an irreversible pan-HER tyrosine kinase inhibitor, is used for the extended adjuvant treatment of patients with early-stage HER2-positive (HER2)-positive breast cancer following adjuvant trastuzumab-based therapy and for patients with HER2+ metastatic breast cancer in combination with capecitabine.1–7

In the ExteNET adjuvant trial, where no mandatory anti-diarrheal prophylaxis (loperamide alone or in combination with bile acids or colestipol) was implemented (DE), diarrhea reduced the rate, severity, and duration of grade 3-4 diarrhea compared with that observed in ExteNET.9

In DE1 (weekly dose escalation regimen), neratinib was administered on a 15-day schedule (days 1–15; 11.96 ± 1.64 weeks, range 9.17–15.33 weeks). In DE2 (bi-weekly dose escalation regimen), neratinib was administered 120 mg daily during Week 1, 160 mg daily during Week 2, and 240 mg daily starting with Week 3 (up to 1 year), and loperamide was given as needed (not to exceed 16 mg/day) throughout the course of the 1-year neratinib treatment.4

In DE2 (bi-weekly dose-escalation regimen), neratinib was administered 120 mg daily during Week 1, 160 mg daily during Week 2, and 240 mg daily starting with Week 3 (up to 1 year), and loperamide was given as needed (not to exceed 16 mg/day) throughout the course of the 1-year neratinib treatment.3

The authors would like to thank all patients and their families for participating in the CONTROL study. Funding support was provided by Puma Biotechnology Inc. Puma Biotechnology Inc. funded medical writing/editing assistance for this poster, which was provided by Miller Medical Communications Ltd.

In DE2, 7 (11.7%) and 9 (14.5%) patients, respectively, had received prior prophylaxis (6% and 3%, respectively, with loperamide, 10% and 6% with bile acids such as colestipol).4

In DE1 and DE2, 2 (3.3%) and 4 (6.5%) patients, respectively, discontinued neratinib because of diarrhea.4

The median treatment duration for DE1 was 11.96 ± 1.64 weeks, range 9.17–15.33 weeks. In the DE1 cohort, 55 (91.7%) patients experienced neratinib dose reduction to 240 mg on schedule, one patient (1.7%) experienced a 240 mg week 1 reduction to the planned schedule.4

The median treatment duration for DE2 was 11.96 ± 1.64 weeks, range 11.1–12.0 weeks. In the DE2 cohort, 55 (91.7%) patients experienced neratinib dose reduction to 240 mg on schedule, one patient (1.7%) experienced a 240 mg week 1 reduction to the planned schedule.4

In the DE1 cohort, 49 (77.4%) patients experienced dose reduction to 240 mg on schedule, two (3.2%) reduced to 240 mg to 1–2 weeks later than the planned schedule (cycle 1, n = 2), and 2 (2.2%) had not escalated to dose reduction, 240 mg and remain on treatment.5

Overall, 46% and 65% of patients in DE1 and DE2, respectively, had received prior prophylaxis (6% and 3%, respectively, with loperamide, 10% and 6% with bile acids such as colestipol).4

In DE2 (bi-weekly dose-escalation regimen), there were no grade 4 diarrhea events. The incidence of grade 3 diarrhea was 2.3% (2/86) in DE1 and 66% (5/80) in DE2 when grade 3 diarrhea in DE1 occurring in the first 2 weeks. The median time to first dose reduction or discontinuation due to diarrhea in DE1 was 2.3 days (range 1–7 days) for DE1 and 2.3 days (range 1–7 days) for DE2.4

In DE1 and DE2, 7 (11.7%) and 9 (14.5%) patients, respectively, had received prior prophylaxis (6% and 3%, respectively, with loperamide, 10% and 6% with bile acids such as colestipol).4

In DE1 and DE2, 8 (13.3%) and 16 (25.8%) patients, respectively, had received prior prophylaxis (6% and 3%, respectively, with loperamide, 10% and 6% with bile acids such as colestipol).4