

T14.3.1.1

Overall Summary of Treatment-Emergent Adverse Events (TEAEs)

Safety Population Set

\s3	\s3 T + C N=127	\s3 P + C N=126	\s3 Total N=253
\s4 Patients with at Least One TEAE	\s4 127 (100.0)	\s4 124 (98.4)	\s4 251 (99.2)
\s4 Any Study Treatment Component Related TEAEs	\s4 124 (97.6)	\s4 117 (92.9)	\s4 241 (95.3)
\s4 Drug XYZ/Placebo Related TEAEs	\s4 94 (74.0)	\s4 79 (62.7)	\s4 173 (68.4)
\s4 Any Chemotherapy Component Related TEAEs	\s4 124 (97.6)	\s4 116 (92.1)	\s4 240 (94.9)
\s4 TEAEs of Grade 3 or Higher	\s4 101 (79.5)	\s4 93 (73.8)	\s4 194 (76.7)
\s4 Any Study Treatment Component Related TEAEs of Grade 3 or Higher	\s4 88 (69.3)	\s4 77 (61.1)	\s4 165 (65.2)
\s4 Drug XYZ/Placebo Related TEAEs of Grade 3 or Higher	\s4 46 (36.2)	\s4 32 (25.4)	\s4 78 (30.8)
\s4 Any Chemotherapy Component Related TEAEs of Grade 3 or Higher	\s4 82 (64.6)	\s4 77 (61.1)	\s4 159 (62.8)
\s4 Serious TEAEs	\s4 60 (47.2)	\s4 47 (37.3)	\s4 107 (42.3)
\s4 Any Study Treatment Component Related Serious TEAEs	\s4 36 (28.3)	\s4 23 (18.3)	\s4 59 (23.3)
\s4 Drug XYZ/Placebo Related Serious TEAEs	\s4 29 (22.8)	\s4 11 (8.7)	\s4 40 (15.8)
\s4 Any Chemotherapy Component Related Serious TEAEs	\s4 25 (19.7)	\s4 21 (16.7)	\s4 46 (18.2)

\s5 Source: ADSL, ADAE. Data cutoff: DDMMYY. Data extraction: DDMMYY.

\s5 Percentages were based on N.

\s5 Adverse event grades were evaluated based on NCI-CTCAE (version 4.03).

\s5 A TEAE is defined as an AE that had an onset date or a worsening in severity from baseline (pre-treatment) on or after the first dose of study drug up to 30 days following study drug discontinuation or initiation of new anti-cancer therapy, whichever occurs first.

\s5 For each row category, a patient with two or more adverse events in that category was counted only once. Treatment-Related TEAEs include TEAEs that were considered by the Investigator to be related to study drug or TEAEs with a missing causality.

\s5 The death event due to disease progression of ESCC is requested to be reported as an AE if the death event occurred \leq 30 days after the last dose of study drug per protocol. Those events are not included as TEAE leading to Death.

\s5^a The types of dose modification include dose delay, infusion interruption, infusion rate decreased and dose reduction for chemotherapy; dose delay, infusion interruption and infusion rate decreased for Drug XYZ/placebo.

\s5^b The types of dose interruption include dose delay and infusion interruption.

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Overall Summary of Treatment-Emergent Adverse Events (TEAEs) Safety Population Set

\s3	\s3 T + C N=127	\s3 P + C N=126	\s3 Total N=253
\s4 TEAEs Leading to Death	\s4 6 (4.7)	\s4 6 (4.8)	\s4 12 (4.7)
\s4 Any Study Treatment Component Related TEAEs Leading to Death	\s4 2 (1.6)	\s4 1 (0.8)	\s4 3 (1.2)
\s4 Drug XYZ/Placebo Related TEAEs Leading to Death	\s4 2 (1.6)	\s4 0 (0.0)	\s4 2 (0.8)
\s4 Any Chemotherapy Component Related TEAEs Leading to Death	\s4 1 (0.8)	\s4 1 (0.8)	\s4 2 (0.8)
\s4 TEAEs Leading to Any Treatment Discontinuation	\s4 40 (31.5)	\s4 26 (20.6)	\s4 66 (26.1)
\s4 TEAEs Leading to Discontinuation of Drug XYZ/Placebo	\s4 17 (13.4)	\s4 9 (7.1)	\s4 26 (10.3)
\s4 TEAEs Leading to Discontinuation of Any Chemotherapy Component	\s4 38 (29.9)	\s4 25 (19.8)	\s4 63 (24.9)
\s4 TEAEs Leading to Any Dose Modification ^a	\s4 100 (78.7)	\s4 88 (69.8)	\s4 188 (74.3)
\s4 TEAEs Leading to Dose Modification of Drug XYZ/Placebo	\s4 72 (56.7)	\s4 50 (39.7)	\s4 122 (48.2)
\s4 TEAEs Leading to Dose Modification of Any Chemotherapy Component	\s4 97 (76.4)	\s4 84 (66.7)	\s4 181 (71.5)
\s4 TEAEs Leading to Any Dose Interruption ^b	\s4 72 (56.7)	\s4 50 (39.7)	\s4 122 (48.2)

\s5 Source: ADSL, ADAE. Data cutoff: DDMMYYYY. Data extraction: DDMMYYYY.

\s5 Percentages were based on N.

\s5 Adverse event grades were evaluated based on NCI-CTCAE (version 4.03).

\s5 A TEAE is defined as an AE that had an onset date or a worsening in severity from baseline (pre-treatment) on or after the first dose of study drug up to 30 days following study drug discontinuation or initiation of new anti-cancer therapy, whichever occurs first.

\s5 For each row category, a patient with two or more adverse events in that category was counted only once. Treatment-Related TEAEs include TEAEs that were considered by the Investigator to be related to study drug or TEAEs with a missing causality.

\s5 The death event due to disease progression of ESCC is requested to be reported as an AE if the death event occurred \leq 30 days after the last dose of study drug per protocol. Those events are not included as TEAE leading to Death.

\s5 ^a The types of dose modification include dose delay, infusion interruption, infusion rate decreased and dose reduction for chemotherapy; dose delay, infusion interruption and infusion rate decreased for Drug XYZ/placebo.

\s5 ^b The types of dose interruption include dose delay and infusion interruption.

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Overall Summary of Treatment-Emergent Adverse Events (TEAEs) Safety Population Set

\s3	\s3 T + C N=127	\s3 P + C N=126	\s3 Total N=253
\s4 TEAEs Leading to Dose Interruption of Drug XYZ/Placebo	\s4 72 (56.7)	\s4 50 (39.7)	\s4 122 (48.2)
\s4 TEAEs Leading to Dose Interruption of Any Chemotherapy Component	\s4 0 (0.0)	\s4 0 (0.0)	\s4 0 (0.0)

\s5 Source: ADSL, ADAE. Data cutoff: DDMMYYYY. Data extraction: DDMMYYYY.

\s5 Percentages were based on N.

\s5 Adverse event grades were evaluated based on NCI-CTCAE (version 4.03).

\s5 A TEAE is defined as an AE that had an onset date or a worsening in severity from baseline (pre-treatment) on or after the first dose of study drug up to 30 days following study drug discontinuation or initiation of new anti-cancer therapy, whichever occurs first.

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\s5 The death event due to disease progression of ESCC is requested to be reported as an AE if the death event occurred \leq 30 days after the last dose of study drug per protocol. Those events are not included as TEAE leading to Death.

\s5^a The types of dose modification include dose delay, infusion interruption, infusion rate decreased and dose reduction for chemotherapy; dose delay, infusion interruption and infusion rate decreased for Drug XYZ/placebo.

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