

Overall Survival Cox-regression Analyses of Phase III trials: IL0014 and IL0017 in First Line NSCLC Patients

*In all the models Treatment = 0 =Placebo and Treatment =1 = ZD1839

Overall Survival Study IL0014 - FDA Analysis (250 mg vs. Placebo)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.07086	0.09141	0.6009	0.4382	1.073	0.897 1.284

Overall Survival Study IL0014 - FDA Analysis (500 mg vs. Placebo)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.09350	0.09097	1.0563	0.3041	1.098	0.919 1.312

Overall Survival Study IL0014 - FDA Analysis (250mg + 500mg ZD1839 vs. Placebo)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.08291	0.07922	1.0952	0.2953	1.086	0.930 1.269

Overall Survival Study IL0017 - FDA Analysis (250 mg vs. Placebo)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.04177	0.09010	0.2150	0.6429	1.043	0.874 1.244

Overall Survival Study IL0017 - FDA Analysis (500 mg vs. Placebo)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	-0.03885	0.09147	0.1804	0.6710	0.962	0.804 1.151

Overall Survival Study IL0017 - FDA Analysis (250mg + 500mg ZD1839 vs. Placebo)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.00143	0.07838	0.0003	0.9855	1.001	0.859 1.168

Studies Combined - Overall Survival FDA Analysis (250 mg vs. Placebo stratified by study)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.05730	0.06426	0.7949	0.3726	1.059	0.934 1.201

Studies Combined - Overall Survival FDA Analysis (500 mg vs. Placebo stratified by study)

Variable	DF	Parameter Estimate	Standard Error	Chi-Square	Pr > ChiSq	Hazard Ratio	95% Hazard Ratio Confidence Limits
Treatment	1	0.02458	0.06461	0.1447	0.7036	1.025	0.903 1.163