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NCT01259063: Phase I/II Study of RAD001 and Intravesical Gemcitabine in BCG-Refractory Primary or SecondaryCarcinoma In Situ of the Bladder: Statistical Analysis Plan

The primary endpoint was the proportion of patients who were disease free at one year following the start of therapy. A rate of 30% was considered promising for this trial. We have chosen a single-stage design and set the type 1 and type II error rates at 0.05 and 0.10, respectively. Secondary endpoints were to estimate the proportion of complete response at any time within the year following the start of therapy, with a binomial exact confidence interval. Kaplan-Meier methods were used to assess recurrence-free progression