**ABSTRACT**

The time course distributions of laboratory indices: a strategy for evaluating laboratory data from clinical trials. J Bruss1, E Antal1, B Hafkin1, B Cirincione2, S Sardella2, M Redman2, E Ludwig2, T Grasela2

**RESULTS** (continued)

- Twenty-seven linezolid patients and 11 comparator patients who developed at least 1 substantially low platelet count during the study period were included in the analysis (Figures 5-6). The median (SD) duration of therapy for these patients was 11.0 ± 4.0 days and 13.0 ± 4.0 days, respectively.
- The mean duration therapy for patients in both groups who developed at least 1 substantially low platelet count was longer than for patients in the overall population (13.0 ± 2.4 days).
- The median platelet count for linezolid patients who developed at least 1 substantially low platelet count was near the LLN, dropping below the LLN at EOT and rising back into the normal range at follow-up. The median platelet count for comparator patients remained below the LLN throughout the study period.
- A subsample of patients with a median platelet count was less than 150 thousand cells, but these values remained stable during the study period.

**RESULTS (continued)**

- The mean (SD) duration of therapy for patients who discontinued during the study period was similar to that seen in the overall population throughout the study period (Figure 8). Median count for patients who discontinued was similar to linezolid patients who discontinued.
- A subsample of patients who developed at least 1 substantially low platelet count defined as <75% of the lower limit of normal or <75% of baseline if abnormal at baseline based on normal reference ranges at the central laboratory. This subset included patients who developed substantially abnormal values – boxplots & scattergrams.

**RESULTS**

- Median platelet counts for patients rose from baseline but remained within the normal limits throughout the treatment and follow-up periods; this trend was similar to comparator patients as seen in Figures 1-4.
- There was a slight decrease in median platelet counts for linezolid treated patients who were treated more than 2 weeks as seen in Figure 1 and Figure 3.

**RESULTS (continued)**

- Overall, platelet and white blood cell counts provided a unique method of evaluating time-dependent trends in laboratory values to patients during and after therapy with linezolid or comparator. Median platelet counts for patients in both groups rose from baseline but remained within normal limits throughout the treatment and follow-up periods. The median platelet count for linezolid patients was similar to comparator patients as seen in Figure 1 and Figure 3.
- The median platelet count for patients who discontinued during the study period was similar to that seen in the overall population throughout the study period. Median count for patients who discontinued was similar to linezolid patients who discontinued.
- A subsample of patients with a median platelet count was less than 150 thousand cells, but these values remained stable during the study period.

**RESULTS (continued)**

- The mean (SD) duration of therapy for these patients was 11.0 ± 4.0 days and 13.0 ± 4.0 days, respectively. The median platelet count over time did not decline and remained within the normal range throughout the study period, regardless of increasing duration of therapy.

**RESULTS**

- In order to be consistent with comparator patients who discontinued during the study period, they were analyzed separately.
- The median platelet count for linezolid patients who discontinued during the study period was similar to that seen in the overall population throughout the study period (Figure 8). Median count for comparator patients who discontinued was similar to linezolid patients who discontinued.
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