SUPPLEMENTAL MATERIALS

Progression-free survival Sensitivity Analysis - Cohort 1

The first PFS sensitivity analysis that included death or progression after one and only one missed radiologic assessment as PFS events, based on the independent radiology review in the intent-to-treat (ITT) population in Cohort 1, had consistent results with the primary analysis with a statistically significant improvement in progression-free survival, with a median of 112 days in the KLTi + gemcitabine group, substantially longer than the median progression-free survival (PFS) of 57.5 days in the gemcitabine group (HR 0.38; 95% CI: 0.17, 0.85), p = 0.0148. At one year, the percentage of patients in Cohort 1 who were progression free was 20.7% in the KLTi + gemcitabine group versus 8.3% in the gemcitabine group.

The second PFS sensitivity analysis that included deaths after at least one missed radiologic assessment as PFS events for patient without a radiologic PD, based on the independent radiology review in the intent-to-treat (ITT) population in Cohort 1, also had consistent results with the primary analysis with a statistically significant improvement in progression-free survival, with a median of 123.5 days in the KLTi + gemcitabine group, substantially longer than the median progression-free survival (PFS) of 57.5 days in the gemcitabine group (HR 0.32; 95% CI: 0.14, 0.72), p = 0.0041. At one year, the percentage of patients in Cohort 1 who were progression free was 23.1% in the KLTi + gemcitabine group versus 8.3% in the gemcitabine group.

The third PFS sensitivity analysis that censored patients at the start of other anti-cancer therapies, and included deaths as PFS events for patient without a radiologic PD, based on the independent radiology review in the intent-to-treat (ITT) population in Cohort 1, had consistent results as well with the primary analysis with a statistically significant improvement in progression-free

survival, with a median of 114 days in the KLTi + gemcitabine group, substantially longer than the median progression-free survival (PFS) of 57.5 days in the gemcitabine group (HR 0.33; 95% CI: 0.15, 0.75), p = 0.0058. At one year, the percentage of patients in Cohort 1 who were progression free was 22.7% in the KLTi + gemcitabine group versus 8.3% in the gemcitabine group.

Overall survival Sensitivity Analysis - Cohort 1

Results from OS sensitivity analyses that censored patients at the start of other anti-cancer therapies were consistent with the primary OS analysis, with a median OS of 286 days in the KLTi + gemcitabine group versus 162 days in the gemcitabine group, (HR 0.53; 95% CI: 0.22, 1.29), p = 0.1569. Gemcitabine patients who elected the open-label extension option and received Kanglaite Injection (n=1) were censored on the date they first started KLTi treatment in this analysis. Patients who started a new anti-cancer therapy were censored on the initiation date of the new therapy. At one year, the survival rate in Cohort 1 was 30.9% in the KLTi + gemcitabine group versus 21.2% in the gemcitabine group, with a difference of 9.7% [95% CI: -25.4%, 44.7%].

Cohort 2 Results

At one year, the survival rate in Cohort 2 was 14.0% in the KLTi + gemcitabine group versus 0% in the gemcitabine group, with a difference of 14.0% [95% CI: -11.2%, 39.2%]. In the intent-to-treat (ITT) analysis, the KLTi + gemcitabine group had a median progression-free survival of 60 days, versus 113.5 days in the gemcitabine group (HR 1.10; 95% CI: 0.32, 3.84); a median OS of 109 days was observed in the KLTi + gemcitabine group versus 283.5 days in the gemcitabine group (HR 1.42; 95% CI: 0.45, 4.47). The benefits of KLTi + gemcitabine versus gemcitabine

monotherapy were not observed in PFS or OS, likely due to baseline imbalance that overwhelmingly favored gemcitabine monotherapy. Specifically, KLTi +gemcitabine had more patients without prior surgery (16.7% vs 0) and fewer patients with 0-1 target lesions at baseline (8.3% vs 50% in gemcitabine only patients).

Progression-free survival - Cohort 3

In the progression-free survival by the independent radiologic assessment in the ITT population, 21 patients (80.8%) had disease progression or died, including 76.5% in the KLTi + gemcitabine group and 88.9% in the gemcitabine group. The median progression-free survival was 85 days in the KLTi + gemcitabine group, as compared with 78 days in the gemcitabine group (HR 0.88; 95% CI: 0.35, 2.17), p = 0.7751. At one year, the percentage of patients in Cohort 3 who were progression free was 0% in the KLTi + gemcitabine group and 0% in the gemcitabine group. Results from PFS sensitivity analyses were all consistent with the primary analysis.

Overall survival – Cohort 3

Overall Survival analysis in Cohort 3 was based on 20 deaths (76.9% of patients), including 12 in the KLTi + gemcitabine group (70.6%) and 8 in the gemcitabine group (88.9%). Patients who had not died at study termination were censored on 13JUN2014. In the ITT population, the median survival was 115 days [95% CI, 52 to 274] in the KLTi + gemcitabine group, as compared with 174 days [95% CI, 74 to 207] in the gemcitabine group (hazard ratio for death was 0.95; 95% CI: 0.38, 2.37), p = 0.9172. At one year, the survival rate in Cohort 3 was 22.0%

in the KLTi + gemcitabine group versus 0% in the gemcitabine group, with a difference of 22.0% [95% CI: -1.6%, 45.6%], p = 0.0682.

Results from OS sensitivity analyses that censored patients at the start of other anti-cancer therapies were consistent with the primary OS analysis, with a median OS of 115 days in the KLTi + gemcitabine group versus 174 days in the gemcitabine group, (HR 1.25; 95% CI: 0.44, 3.58), p = 0.6715. Patients who started a new anti-cancer therapy post study cut-off date were censored on 13Jun2014. At one year, the survival rate in Cohort 3 was 29.7% in the KLTi + gemcitabine group versus 0% in the gemcitabine group, with a difference of 29.7% [95% CI: 0.9%, 58.5%].

Objective Response Rate – Cohort 3

The Objective Response Rate by independent radiologic assessment in the ITT population in Cohort 3 was 17.6% (3/17) in the KLTi + gemcitabine group versus 0% (0/9) in the gemcitabine group. Disease stabilization rate (CR+PR+SD) in the ITT population was 47.1% [95% CI, 23.0 to 72.2] in the KLTi + gemcitabine group versus 55.6% [95% CI, 21.2 to 86.3] in the gemcitabine group. Similarly, in the Efficacy Evaluable (EE) population, the Objective Response Rate was 27.3% in the KLTi + gemcitabine group versus 0% in the gemcitabine group. Disease stabilization rate (CR+PR+SD) in the EE population was 72.7% [95% CI, 39.0 to 94.0] in the KLTi + gemcitabine group versus 55.6% [95% CI, 21.2 to 86.3] in the gemcitabine group.

Progression-free survival Sensitivity Analysis - Cohort 1+3

The first PFS sensitivity analysis that included death or progression after one and only one missed radiologic assessment as PFS events, based on the independent radiology review in the

intent-to-treat (ITT) population in Cohort 1+3, had consistent results with the primary PFS analysis with a statistically significant improvement in progression-free survival, with a median of 111 days in the KLTi + gemcitabine group, substantially longer than the median progression-free survival (PFS) of 58 days in the gemcitabine group (HR 0.58; 95% CI: 0.32, 1.06), p = 0.0720. At one year, the percentage of patients in Cohort 1+3 who were progression free was 12.3% in the KLTi + gemcitabine group versus 0% in the gemcitabine group.

The second PFS sensitivity analysis that included deaths after at least one missed radiologic assessment as PFS events for patient without a radiologic PD, based on the independent radiology review in the intent-to-treat (ITT) population in Cohort 1+3, also had consistent results with the primary PFS analysis with a statistically significant improvement in progression-free survival, with a median of 112 days in the KLTi + gemcitabine group, substantially longer than the median progression-free survival (PFS) of 58 days in the gemcitabine group (HR 0.54; 95% CI: 0.30, 0.98), p = 0.0404. At one year, the percentage of patients in Cohort 1+3 who were progression free was 16.1% in the KLTi + gemcitabine group versus 0% in the gemcitabine group.

The third PFS sensitivity analysis that censored patients at the start of other anti-cancer therapies, and included deaths as PFS events for patient without a radiologic PD, based on the independent radiology review in the intent-to-treat (ITT) population in Cohort 1+3, had consistent results as well with the primary PFS analysis with a statistically significant improvement in progression-free survival, with a median of 112 days in the KLTi + gemcitabine group, substantially longer than the median progression-free survival (PFS) of 58 days in the gemcitabine group (HR 0.57; 95% CI: 0.31, 1.05), p = 0.0688. At one year, the percentage of patients in Cohort 1+3 who were

progression free was 18.2% in the KLTi + gemcitabine group versus 9.5% in the gemcitabine group.

Overall survival Sensitivity Analysis - Cohort 1+3

Results from OS sensitivity analyses for Cohort 1+3 that censored patients at the start of other anti-cancer therapies were consistent with the primary OS analysis, with median OS of 178 days in the KLTi + gemcitabine group versus 162 days in the gemcitabine group, (HR 0.78; 95% CI: 0.39, 1.55), p = 0.2577. Gemcitabine patients who elected the open-label extension option and received Kanglaite Injection (n=2) were censored on the date they first started KLTi treatment in this analysis. Cohort 3 patients with last known alive date or anti-cancer therapies start date post study cut-off date were censored on 13JUN2014. At one year, the survival rate in Cohort 1+3 was 29.3% in the KLTi + gemcitabine group versus 15.6% in the gemcitabine group, with a difference of 13.7% [95% CI: -12.8%, 40.2%].