ABSTRACT: Subjects (923 ITT; 380 LR, 467 higher classification) were compared into two groups: LR vs HR. The AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry.

The study had 80% power and two risk patients (not shown), pre-screening/entry. AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry.

Methods: LI+SOC was compared to SOC and LI+CIZ+SOC was compared to SOC in low-risk subjects. The AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry.

In low-risk LR subjects, LI+CIZ+SOC was compared to SOC and LI+CIZ was compared to SOC in low-risk subjects. The AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry.

Conclusion: The LI target population can be defined according to the criteria 1 and 2 (below) to select at screening/entry.

• Localized patients with N0 nodal status (and no ECS), as determined by PET performed within 14 days of the AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry. Surgical downstaging rate was 38.7% vs 21.3%.

• Risk patients are defined as patients with AJCC Stage IV disease, AJCC Stage III disease with ECS or any AJCC Stage IV disease with ECS.

Methods: LI+CIZ+SOC was compared to SOC and LI+CIZ was compared to SOC in low-risk subjects. The AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry.

Conclusion: The LI target population can be defined according to the criteria 1 and 2 (below) to select at screening/entry.

1. Localized patients with N0 nodal status (and no ECS), as determined by PET performed within 14 days of the AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry. Surgical downstaging rate was 38.7% vs 21.3%.

2. Risk patients are defined as patients with AJCC Stage IV disease, AJCC Stage III disease with ECS or any AJCC Stage IV disease with ECS.

Conclusions: The LI target population can be defined according to the criteria 1 and 2 (below) to select at screening/entry. Surgical downstaging rate was 38.7% vs 21.3%.

1. Localized patients with N0 nodal status (and no ECS), as determined by PET performed within 14 days of the AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry. Surgical downstaging rate was 38.7% vs 21.3%.

2. Risk patients are defined as patients with AJCC Stage IV disease, AJCC Stage III disease with ECS or any AJCC Stage IV disease with ECS.

Conclusions: The LI target population can be defined according to the criteria 1 and 2 (below) to select at screening/entry. Surgical downstaging rate was 38.7% vs 21.3%.

1. Localized patients with N0 nodal status (and no ECS), as determined by PET performed within 14 days of the AJCC Stage classification was reflected in both AJCC Stage changenewAJCC Stage classification. Improved (I) analyses were performed between LR vs HR allowing differentiation of LR from HR at entry. Surgical downstaging rate was 38.7% vs 21.3%.

2. Risk patients are defined as patients with AJCC Stage IV disease, AJCC Stage III disease with ECS or any AJCC Stage IV disease with ECS. Surgical downstaging rate was 38.7% vs 21.3%.