**METHODS**

- **ASSET** was an investigator-initiated, multicenter double-blind, randomized placebo-controlled trial.
- Eligible subjects were randomized in a 1:1 ratio to either 12 months 125 mg CTLA4Ig, abatacept (ABA), or placebo (PBO).
- 88 subjects (44 ABA, 44 PBO) were randomized; 63 (25 complete datasets with estimates, standard errors, and p-values) were used for the final analysis.
- Treatment differences, adjusted for duration of dcSSc (≤18 vs >18 months) and late disease (>18-36 months), were statistically significant (p=0.01).
- For 0-18 month disease duration, the correlations were significant for most variables, except HAQ-DI and PTGA, with the CRISS (p<0.05).
- Table 2: Comparison of ABA and PBO using CRISS index (0.0-1.0) at 12 months

**RESULTS**

- There is evidence of improved CRISS scores on ABA compared to the PBO at month 12 and the difference was statistically significant (p=0.01).
- Most variables, except HAQ-DI and PTGA, had statistically significant correlations with the CRISS (p<0.05).
- For 0-18 month disease duration, the correlations were significant for CRSS and MDGA and for >18-36 months, it was driven by treatment differences, adjusted for duration of dcSSc.

**CONCLUSIONS**

- The current data suggest that CRISS is more sensitive to clinically meaningful treatment changes than the mRSS endpoint.
- We provide further validation of CRISS as an independent primary endpoint for early diffuse scleroderma clinical trials.

**REFERENCES**


**DISCLOSURES**

- D. Khanna Grant/research support from: NIH/NIAMS and NIH/NIAD, Bayer, BMS, Pfizer
- Consultant for: Actelion, Bayer, BMS, Boehringer Ingelheim, Genentech/Roche, Sanofi-Aventis, GSK, Corbus, Cytori, EMD Serono
- Stock Options: Eicos Sciences, Inc
- C. Spinolo Consultant for: Eicos Sciences, Inc

**BACKGROUND**

- Treatment with CTLA4Ig, abatacept (ABA), in early diffuse cutaneous systemic sclerosis (dcSSc; the Phase 2 ASSET trial) showed evidence of improvements in modified Rodnan skin score (mRSS) and secondary outcome measures at month 12 (2018 ACR abstract # 900).
- The CRSS index, a composite outcome measure for trials in SSC1, is a 2-step process that assigns a probability of improvement for each subject ranging from 0.0 (no improvement) to 1.0 (marked improvement).
- Step 1 assesses clinically meaningful decline in cardio-pulmonary-renal involvement with a probability of 0.0.
- For remaining subjects, probability of improvement is based on 5 variables: changes from baseline to month 12 in FVC%, mRSS, patient (PTGA) and physician global assessments (MDGA), and HAQ-DI.
- We assessed the performance of CRSS, a secondary outcome measure, in ASSET at month12.

** METHODS**

- ASSET was an investigator-initiated, multicenter double-blind, randomized placebo-controlled trial.
- Eligible subjects were randomized in a 1:1 ratio to either 12 months 125 mg subcutaneous ABA or matching placebo, stratified by duration of dcSSc (≤18 vs >18 months).
- Investigators reported SSC end organ involvement (Step 1 for CRSS) prospectively.
- These and all AE and SAEs were reviewed for cardio-pulmonary and renal involvement by the study PI.
- Step 2 calculated the CRSS index as previously defined.

**RESULTS**

- 88 subjects (44 ABA, 44 PBO) were randomized; 63 (72%) had complete data for all relevant outcomes at month 12.
- 5 PBO and 5 ABA subjects met the pre-defined definition of worsening cardio-pulmonary-renal involvement (Table 1) and were given a score of 0.0.

**REFERENCES**


**DISCLOSURES**

- D. Khanna Grant/research support from: NIH/NIAMS and NIH/NIAD, Bayer, BMS, Pfizer
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