PSORIASIS

NETAKIMAB: 12-WEEK RESULTS FROM PLANETA STUDY, A PHASE III TRIAL OF A NOVEL IL-17 INHIBITOR IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

Bakulev Andrey [(1)] - Samtsov Aleksey [(2)] - Artemeva Antonina [(3)] - Chernyaeva Ekaterina [(3)] - Ivanov Roman [(3)]

Saratov State Medical University, Dermatology And Venereology, Saratov, Russian Federation [(1)] - Medical Military Academy, Dermatology And Venereology, Saint-petersburg, Russian Federation [(2)] - Jcs Biocad, Research And Development, Saint-petersburg, Russian Federation [(3)]

Introduction: netakimab, a novel anti-IL-17 inhibitor is studied in the phase 3 BCD-085-7/PLANETA trial (NCT03390101) in patients with moderate-to-severe plaque psoriasis. Results of the first 12 weeks are reported.

Objective: to compare the efficacy and safety of 120mg netakimab (NTK) in q4w, q2w regimens and placebo. Study was based on two independent hypotheses: NTK-q4w is non-inferior to NTK-q2w and NTK is superior to placebo.

Materials and Methods: 213 adult patients (PASI≥10, BSA≥10, sPGA≥3) were randomized in 2:2:1 into 3 arms: NTK-q2w, NTK-q4w, placebo. Therapy was blinded for 12 weeks. Arm1 received NTK at weeks 0, 1, 2, 4, 6, 8, 10. Arm2 received NTK at weeks 0, 1, 2, 6, 10 (placebo at weeks 4 and 8). Arm3 received placebo at weeks 0, 1, 2, 4, 6, 8, 10. On Week 12 the primary endpoint (PASI 75) was assessed. The secondary endpoints include sPGA(0-1) and other psoriasis evaluations.

Results: 83.3% and 77.7% patients from NTK-q4w, NTK-q2w arms achieved PASI75 at week12 ($p=0.46$ for NTK-q4w vs NTK-q2w) compared to 0% in placebo arm ($p<0.0001$), sPGA(0-1) was reached by 79.8%, 81.2% and 2.27% patients in NTK-q4w, NTK-q2w, placebo arms. Adverse events (AEs) were registered in: 17.7%, 16.7% and 18.2% patients in NTK-q4w, NTK-q2w, placebo arms ($p=1.0$). One therapy-related SAE (pneumonia) with grade3 (CTCAE 4.03) was registered in NTK-q4w arm. Grade3 neutropenia was observed in 1 patient from NTK-q2w, creatininemia was observed in 1 patient in placebo arm. Other AEs were mild or moderate (laboratory abnormalities were the most frequently), no local reactions in NTK groups. Binding anti-drug antibodies were found in one patient (1.18%, NTK-q2w arm). Neutralizing antibodies were not detected.

Conclusions: 120mg NTK-q4w was non-inferior to NTK-q2w and demonstrated superior efficacy at week12 compared to placebo in the treatment of moderate-to-severe plaque psoriasis. Positive safety profile and low immunogenicity were shown.