Achieving Increasingly Stringent Clinical Disease Control Criteria is Associated with Greater Improvements in Patient-Centric Measures of Physical Function and Pain in Patients with Active PsA: 16-Week Results from Two Phase 3 Randomized, Placebo-Controlled Studies

CONTENT PROVIDED FOR SHAREHOLDERS, INVESTORS AND OTHER CAPITAL MARKET PARTICIPANTS ONLY

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Methods

Within each study, all patients who reached the following disease control criteria (BIO COMPLETE-NAIVE or BIOPROTECTIVE) at any time between Baseline and Week 16 were pooled:

- PASI50: at least 50% improvement from baseline in PASI score.
- DAS28<3.2: at least 30% improvement from baseline in DAS28 score.
- HAQ-DI<0.22: at least 22% improvement from baseline in HAQ-DI score.

- Patients who reached these criteria were assessed; it should be noted that BIO COMPLETE-NAIVE is a component of BIO COMPLETE-

- Associations between achievement of these criteria and improvements in patient-reported measures of physical function (HAQ-DI) or pain (MPAQ) (≥0) were assessed. It should be noted that MPAQ is a component of ACR, DAPO and MDA and HAQ-DI is a component of ACR and MDP.

- Observed case data are reported.

Results

Patients

- On-treatment patients, n=852 (279 placebo, BKZ n=423, ADA n=139; BE OPTIMAL: placebo n=279, BKZ n=423, ADA n=139; BE COMPLETE: placebo n=190, BKZ n=280, ADA n=193; BE PROTECTIVE: placebo n=279, BKZ n=423, ADA n=139).
- Baseline HAD-DI and MPAQ scores were similar between BE OPTIMAL-naive and TNPi-IR patients, indicating similar levels of disease burden (Table 1).

Association Between Disease Control and Patient-Reported Physical Function and Pain

- Patients achieving increasing numbers of disease control criteria demonstrated sequentially greater mean improvements from baseline in HAQ-DI score, irrespective of prior biologic treatment (Figure 1).

- Patients achieving MDA demonstrated greater improvements from baseline in HAQ-DI scores than those who achieved MoDA. For RSAS, sequentially greater mean improvements were observed in patients with MoDA and LDA/REM, irrespective of prior biologic treatment (Figure 2).

- Patients achieving improvements from baseline in PASI50 score generally reported greater improvements from baseline in HAQ-DI scores (Figure 3).

- Similar results were seen for pain, with patients achieving increasingly stringent disease control criteria also demonstrating sequentially greater improvements from baseline in MPAQ scores, irrespective of prior biologic treatment (Figure 4).

Conclusions

Patients with active PsA who achieved increasingly stringent disease control criteria at Week 16 reported sequentially greater improvements in physical function and reductions in pain, which would be expected to lead to improved quality of life, regardless of whether they were BIO COMPLETE-naive (BE OPTIMAL) or TNPi-IR (BE COMPLETE).