were switched to APR at Week 16 (early escape) or Week 24. Duration of morning stiffness and severity, assessed by subjects’ reported categories of stiffness (none, mild, moderate, moderately severe, severe), was reported. In the post hoc analysis, changes in morning stiffness severity and effect on pain, physical function and PtGA from baseline to Week 16 were compared between treatment arms. An analysis of covariance model adjusting the baseline value was used in the analysis, where missing values were imputed using the last-observation-carried-forward approach.

Results: A total of 219 subjects were randomized (APR: n=110; PBO: n=109), and 192 remained in the study through Week 16. APR and PBO groups were balanced with respect to baseline tender joint count (mean [SD]: 17 [13] vs. 18 [14]), swollen joint count (mean [SD]: 9 [5] vs. 10 [6]) and severity of morning stiffness (moderate to very severe: 87% vs. 80%), as well as previous use of DMARD (67% vs. 72%), baseline use of non-steroidal anti-inflammatory drug (69% vs. 68%) and oral corticosteroid use (12% vs. 13%). Mean [SD] duration of morning stiffness at baseline was shorter with APR vs. PBO (48 [48] vs. 72 [127] minutes). Baseline PIGA (mean [SD]: 5.9 [2.1] vs. 6.1 [2.0]), Patient’s Pain Numeric Rating Scale (NRS; mean [SD]: 6.1 [1.9] vs. 5.8 [2.2]), Health Assessment Questionnaire-Disability Index (HAQ-Di; mean [SD]: 1.3 [0.6] vs. 1.2 [0.6]), Short-Form Health Survey version 2 (SF-36v2) Physical Component Summary (mean [SD]: 32.4 [9.2] vs. 33.9 [8.3]), SF-36v2 Physical Functioning subscale (mean [SD]: 33.2 [11.2] vs. 34.2 [10.1]) and SF-36v2 Bodily Pain domain (mean [SD]: 35.4 [7.6] vs. 37.4 [7.6]) scores were similar in the APR and PBO groups, respectively. As early as Week 2, a significantly greater proportion of APR vs. PBO subjects experienced morning stiffness severity improvements (≥1 category improvement) (43% vs. 21%; P=0.0007). Significant improvements in morning stiffness severity were sustained through Week 16 in APR vs. PBO subjects (46% vs. 26%; P=0.0015). Subjects with improvements in morning stiffness severity in the APR and PBO groups showed consistent improvements in pain, physical function and PIGA at Week 16 (Table). In patients with unchanged stiffness severity, greater improvements were observed across outcome measures in the APR vs. PBO group, although the change from baseline was less than the improved stiffness group. Worsened morning stiffness was associated with lack of improvement in other patient-reported outcome measures.

Conclusion: Psoriatic arthritis (PsA) subjects treated with APR for 16 weeks, improvement in morning stiffness severity was evident as early as Week 2 and associated with improvements in pain, physical function and PIGA response.

Disclosure of Interests: Ana-Maria Orbai Grant/research support from: AbbVie, Celgene, Horizon Pharma, Janssen, Lilly, and Novartis, Consultant for: Lilly, Janssen, Novartis, Pfizer, and UCB, Jessica A. Walsh Grant/research support from: AbbVie, Celgene, Horizon Pharma, Janssen, Lilly, and Novartis, Consultant for: Lilly, Janssen, Novartis, Pfizer, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Lichen Teng Employee of: Celgene Corporation, Benoit Guedem, Employee of: Celgene Corporation, Rieke Alten Grant/research support from: Bristol-Myers Squibb, Speakers bureau: Bristol-Myers Squibb

Scientific Abstracts

Efficacy of Gusekumab in Psoriatic Arthritis With Involvement of the Scalp, Nails, Hands, and Feet: A POOLED ANALYSIS FROM 2 PIVOTAL PHASE 3 PSORIASIS STUDIES

Joseph F. Merola1, Soumya D. Chakravarty2,3, Yin You1, Shelly Kafka4, Chetan Karyekar5, Ana-Maria Orbai,6 Chetan Karyekar6,7,8,9
1Brigham and Women’s Hospital, 2Harvard Medical School, Boston, United States of America; 3Janssen Scientific Affairs, LLC, Horsham, United States of America; 4Drexel Univ College of Med, Philadelphia, United States of America; 5Janssen Research and Development, LLC, Horsham, United States of America; 6Johns Hopkins U School of Medicine, Baltimore, United States of America

Background: VOYAGE 1 & 2 were the pivotal Phase III GUS trials for plaque psoriasis (PsO).

Objectives: Here we compare efficacy of GUS vs PBO & vs adalimumab (ADA) on PsO involving scalp, nail & palmoplantar (palmoplantar pustular PsO excluded per protocol) in a a subgroup of pts with self-reported psoriatic arthritis (PsA), given the association between these distinct PsO phenotypes & PsA.

Methods: VOYAGE 1 (n=837) & VOYAGE 2 (n=992) enrolled adult pts who had plaque PsO for ≥6 months. An Investigator Global Assessment (IGA) score ≥3, PASI score ≥12, ≥10% BSA involvement at baseline (BL), & were candidates for phototherapy or systemic treatment for PsO. Pts were randomized to GUS, PBO or ADA at BL, w/PBO crossover to GUS at wk18. This post hoc analysis used observed pooled efficacy data for scalp-specific Investigator Global Assessment (ss-IGA), Physician’s Global Assessment (PGA) of Hands &/or Feet (h-PGA), Finger nail PGA (f-PIGA), & Nail Psoriasis Area & Severity Index (NAPSI) in subset of pts self-reporting PsA.

Results: In VOYAGE 1 & 2 combined, 335 (18.3%) Pts self-reported PsA (GUS 76, GUS 153, ADA 106). Baseline demographics were generally comparable across all 3 treatment groups, with history of methotrexate use: PBO 64.5%, GUS 70.6%, ADA 61.3%. A significantly greater proportion of GUS-treated pts achieved a ss-IGA score of 0/1 (absent/very mild) at wk16 vs PBO, & at wk24 vs ADA (Figure A). Significantly higher proportions of GUS-treated pts achieved a h-PIGA score of 0/1 (clear/almost clear) vs PBO at wk16 with numerically greater differences at wk24 vs ADA (Figure B). At wk16, proportions of pts achieving a IGA score of 0/1 (clear/mild) were 47.6% for GUS vs 17.0% for PBO (p<0.001). The proportions of pts achieving an IGA score of 0/1 for GUS vs ADA were comparable at wk16 (47.6% vs 46.4%) & wk24 (67.0% vs 60.9%), but were higher for GUS by wk48 (82.5% vs 57.5%, Table). Mean (SD)% improvement from BL in NAPSI score was significantly higher for GUS vs PBO [39.5 (48.9) vs 6.5(47.5), p<0.001] at wk16 & was comparable for GUS vs ADA at wk24 [58.0 (51.3) vs 59.9 (40.4)]. By wk48, mean% improvement from BL in NAPSI score was higher for GUS vs ADA (70.8% vs 61.3%, Table). Conclusion: GUS-treated PsA pts with self-reported PsA showed clinical meaningful improvements vs ADA in ss-IGA & h-PIGA scores at wk16 & 24. Although improvements in 1-PIGA & NAPSI were similar in pts treated with GUS vs ADA at earlier timepoints, numerically greater differences were observed with GUS by wk48, likely requiring the additional duration to discriminate between treatments in this slow-growing cutaneous disease.

Disclosure of Interests: Ana-Maria Orbai Grant/research support from: AbbVie, Celgene, Horizon Pharma, Janssen, Lilly, and Novartis, Consultant for: Lilly, Janssen, Novartis, Pfizer, and UCB, Jessica A. Walsh Grant/research support from: AbbVie, Celgene, Horizon Pharma, Janssen, Lilly, and Novartis, Consultant for: Lilly, Janssen, Novartis, Pfizer, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Lichen Teng Employee of: Celgene Corporation, Benoit Guedem, Employee of: Celgene Corporation, Rieke Alten Grant/research support from: Bristol-Myers Squibb, Speakers bureau: Bristol-Myers Squibb

Table. Fingernail (f)-PGA score of clear (0) or minimal (1) in Psoriasis Patients with Self-reported PsA at Week 48

<table>
<thead>
<tr>
<th>Guenkelumb</th>
<th>Adalimumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>PsO Patients randomized at Week 0; n</td>
<td>329</td>
</tr>
<tr>
<td>PsO Patients with Self-reported PsA; n</td>
<td>64</td>
</tr>
<tr>
<td>Patients with f-PGA score &gt;2 at baseline</td>
<td>40</td>
</tr>
<tr>
<td>f-PGA score of clear (0)</td>
<td>20 (50.0%)</td>
</tr>
<tr>
<td>f-PGA score of clear (0) or minimal (1)</td>
<td>33 (82.5%)</td>
</tr>
</tbody>
</table>

Percent improvement from baseline in NAPSI Scores in Psoriasis Patients with Self-reported PsA at Week 48


AB0773

PSORIATIC ARTHRITIS IMPACT OF DISEASE QUESTIONNAIRE SCORES ARE CORRELATED WITH DISEASE ACTIVITY, AS MEASURED BY cDAPSA, IN PATIENTS WITH PSORIATIC ARTHRITIS

Disclosure of Interests: Ana-Maria Orbai 1, Klaus Krueger 1, Frank Behrens 2, Uta Kitz 2, Benoit Guerette 3, Lillian Mellars 4, Michele Brunori 5, Jurgen Wollenhaupt 6.

REFERENCES


AB0774

PREDICTORS OF SWITCHING IN A RETROSPECTIVE ITALIAN COHORT OF PSORIATIC ARTHRITIS PATIENTS RECEIVING BIOTECNOLOGICAL DRUGS FOR AT LEAST 3 YEARS

Disclosure of Interests: Augusta Ortolan: Pamela Polito, Federico Benetti, Maria Felicetti, Mariagrazia Lorenzin, Roberta Ramonda. Rheumatology Unit, Department of Medicine DIMED, University of Padova, Padova, Italy

BACKGROUND: Psoriatic Arthritis (PsA) is a chronic inflammatory disease typically treated, in its moderate-severe form, with biologic disease-modifying antirheumatic drugs (bDMARDs). However, refractory patients are not infrequent, and they are commonly managed by switching from one bDMARD to another. Since the chance of observing a good clinical response decreases according to line of treatment, it would be important