Comparision of efficacy of Biosimilar Adalimumab therapy in Ankylosing Spondylitis patients - 6 months Vs 1 year

S. Bandyopadhyay1, A. Ray2, R.N. Sarkar 3, S. Dash 1, S. Mondal1

1. Medicine, Apollo Gleneagles Hospital
2. Medicine, Fortis Hospital, Kolkata
3. Medicine, Calcutta Medical College, Kolkata,, India

Published in: APLAR/International Journal of Rheumatic Disease, October/2017/20(1)
Objective & Methods

• This retrospective analysis reports real life data of bADA in AS patients.

• Medical records of 52 patients who received bADA therapy, 40 mg s/c twice a month for at least 24 weeks and up to 48 weeks, were evaluated for standard AS outcome-measurement scores.
## Result

### Table: AS outcome-measurement scores at Week 24 and Week-48 of post biosimilar adalimumab therapy

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<tr>
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<tbody>
<tr>
<td>ESR</td>
<td>49.73±19.67</td>
<td>14.77±9.61**</td>
<td>25.08±10.27 £#,**</td>
<td>13.1</td>
</tr>
<tr>
<td>CRP</td>
<td>20.47±13.06</td>
<td>3.03±3.13**</td>
<td>5.27±5.32**</td>
<td>1.97±0.88</td>
</tr>
<tr>
<td>BASDAI</td>
<td>7.49±0.92</td>
<td>2.54±0.49**</td>
<td>2.43±0.53**</td>
<td>2.14±0.40 ##, **</td>
</tr>
<tr>
<td>BASFI</td>
<td>8.02±1.21</td>
<td>2.90±0.60**</td>
<td>2.57±0.54**</td>
<td>2.4±0.50##, **</td>
</tr>
<tr>
<td>HAQ (Pain)</td>
<td>67.88±6.74</td>
<td>27.21±8.06**</td>
<td>28.33±9.16**</td>
<td>16.07±5.58##, **</td>
</tr>
<tr>
<td>HAQ (Health)</td>
<td>60.96±7.79</td>
<td>27.11±7.88**</td>
<td>25.62±10.56**</td>
<td>21.25±6.02##, **</td>
</tr>
</tbody>
</table>

**P <0.0001 AND *P <0.01 as compared to baseline
## P<0.0001 AND # P <0.001 as compared to week 24; £ rise in levels

Efficacy of Exemptia in children with JIA
Result

- Treatment with bADA for 24 weeks was associated with significant reductions in ESR, CRP, BASDAI, BASFI, and HAQ scores in all patients.
- 28 patients continued to receive bADA therapy, resulting in further significant reductions of all outcome scores at week 48 (Table.1).
- For rest 28 patients who received only 24 weeks of treatment, BASDAI and BASFI scores did not deteriorate despite discontinuation of bADA treatment; however, rise in biomarkers was observed. There were no reported adverse drug reaction causing discontinuation.
Conclusion

- The real life safety and efficacy analysis of bADA in AS patients shows continued effectiveness post 24 weeks treatment despite bADA stoppage. Continued bADA use for 48 weeks is associated with improved biomarker and clinical parameter.
Abridged Prescribing Information

**COMPOSITION:** Exemptia™ (Adalimumab) 40 mg /0.8 mL single use pre filled syringe and 20 mg /0.4 mL single use pre filled syringe

**DESCRIPTION:** EXEMPTIATM (Adalimumab) is a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF-α). EXEMPTIATM is supplied as a sterile, preservative-free solution of Adalimumab for subcutaneous administration. The solution of EXEMPTIATM is clear and colorless.

**MECHANISM OF ACTION:** Adalimumab binds specifically to TNF-α and blocks its interaction with the p55 and p75 cell surface TNF-α receptors. Adalimumab also lyses surface TNF expressing cells in vitro in the presence of complement.

**INDICATIONS & DOSAGE:**

- **Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis:**
  - The recommended dose of EXEMPTIATM for adult patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), or ankylosing spondylitis (AS) is 40 mg subcutaneously administered every other week.
  - Methotrexate (MTX), other non-biologic DMARDs, glucocorticoids, nonsteroidal anti-inflammatory drugs (NSAIDs), and/or analgesics may be continued during treatment with EXEMPTIATM.

- **Juvenile Idiopathic Arthritis:** Exemptia™ dosing in JIA is based on weight; for 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg s.c. every other week.
  - Followed by 20 mg s.c. every other week for 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg s.c. every other week.
  - For ≥ 30 kg (66 lbs): 40 mg s.c. every other week.

- **Crohn's Disease:**
  - For weight 17 kg (37 lbs) to < 40 kg (88 lbs): Initial dose (Day 1): 80 mg s.c.
  - Followed by 40 mg every other week starting from week one after initial dose.

**Special Warnings and Precautions:**

- **Hypersensitivity to the active substance or to any of the excipients**, **Moderate to severe heart failure**, **Active tuberculosis or other severe infections such as sepsis and opportunistic infections**.

**SPECIAL WARNINGS AND PRECAUTIONS:**

- **Serious and fungal infections:** Do not start EXEMPTIATM during an active infection. If an infection develops, monitor carefully, and stop EXEMPTIATM if infection becomes serious. **Anaphylaxis or serious allergic reactions may occur**.

- **HEPATITIS B VIRUS REACTIVATION:** Monitor HBV carriers during and several months after therapy. Stop EXEMPTIATM if reactivation occurs.

**CONTRAINDICATIONS:**

- Hypersensitivity to the active substance or to any of the excipients.
- **Moderate to severe heart failure.**
- **Active tuberculosis or other severe infections such as sepsis and opportunistic infections.**

**UNDESIRED EFFECTS:**

- The most serious adverse reactions include the following: **Serious Infections**, **Tuberculosis and Opportunistic Infections**, **Malignancies**.

**STORAGE CONDITION:** Store between +2 °C and +8 °C, in the carton to protect from light. Do not freeze Exemptia™. Do not use Exemptia™ if frozen, even if it has been thawed. Keep out of reach of children. PRESENTATION: a) Injection: 40 mg/0.8 mL in a single-use prefilled syringe b) Injection: 20 mg/0.4 mL in a single-use prefilled syringe.
Please consult full Prescribing Information before prescribing.

Zydus Cadila does not recommend the use of any product in any different manner than as described in the prescribing information.

Further information is available on request from:

Cadila Healthcare Limited
Zydus Corporate Park
Nr. Vaishno Devi Circle,
SG Highway,
Ahmedabad – 382 481
Gujarat, India.
PHONE: +91-79-71800000

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Thank you