



# Efficiency and Safety of Adalimumab Biosimilar (Exemptia) in Ankylosing Spondylitis

**S. Bandyopadhyay<sup>1</sup>, A. Ray<sup>2</sup>, R. Sarkar<sup>3</sup>**

*1. Apollo Gleneagles Hospital Medicine Kolkata India,*

*2. Fortis Hospital Rheumatology Kolkata India,*

*3. Calcutta Medical College Medicine Kolkata India*

**Presented at: APLAR, Shanghai, China in SEP 2016**

# Objective & Methods

- To evaluate efficacy and safety of adalimumab biosimilar (Exemptia approved in India) in newly diagnosed Ankylosing Spondylitis (AS) patients.
- Between January to July 2015, data of AS patients with BASDI and BASFI > 4 who had received Adalimumab biosimilar SC 40 mg fortnightly for 24 weeks was analyzed.
- Effectiveness at week 24 was evaluated using observed standard outcome-measurement scores of AS. Paired t-test was done to evaluate significance of mean change at baseline and week 24.
- Safety was assessed by adverse events (AE) records.

# Result

Mean score at baseline & 24 weeks			
Parameter	Baseline	WK24	P Value
BASFI	8.52	2.74	P<0.0001
BASFI	7.77	2.33	P<0.0001
ESR	53.07	13.58	P<0.0001
CRP	23.77	6.99	P =0.0008
VAS	8.7	2.53	P<0.0001
HAQ (Pain)	83.73	17.32	P<0.0001
HAQ (Health)	72	22.86	P<0.0001

# Result

- Out of 30 patients (mean age 37) assessed, 60% were male. Overall mean change in standard outcome measurements at baseline and week 24 is mentioned in Table 1.
- At week 24, significant reduction in BASDAI and BASFAI were achieved in 96.67% of patients. Mean VAS, HAQ (Pain and Health) scores were also reduced significantly ( $p < 0.0001$ ), from baseline. There was no gender difference.
- No pain at injection site was reported. No AE or relapse during 24 weeks of treatment were observed.

# Conclusion



- Adalimumab biosimilar (Exemptia™) is effective in treatment of AS and well tolerated.

# Abridged Prescribing Information

**COMPOSITION:** Exemptia™ (Adalimumab) 40 mg /0.8 mL single use pre filled syringe and 20mg /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- $\alpha$ ). 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- $\alpha$  and blocks its interaction with the p55 and p75 cell surface TNF- $\alpha$  receptors. Adalimumab also lyses surface TNF expressing cells in vitro in the presence of complement. Elevated levels of TNF- $\alpha$  is found in the synovial fluid of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis patients and play an important role in both the pathologic inflammation and the joint destruction that are hallmarks of these diseases. **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 EXEMPTIA™. 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. For 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg s.c. every other week and for  $\geq$  30 kg (66 lbs): 40 mg s.c. every other week. Plaque Psoriasis or Non-Infectious Uveitis: Initial dose of 80 mg, followed by 40 mg every other week starting from week one after initial dose. Hidradenitis Suppurativa: 160 mg (Day 1) (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every week. Adult Crohn's Disease and Ulcerative Colitis: Initial dose (Day 1): 160 mg s.c. (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days). Second dose two weeks later (Day 15): 80 mg. Two weeks later (Day 29): Begin a maintenance dose of 40 mg s.c. every other week. For patients with Ulcerative Colitis only: Only continue EXEMPTIA™ in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy. Pediatric Crohn's Disease: For weight 17 kg (37 lbs) to < 40 kg (88 lbs): Initial dose (Day 1): 80 mg s.c. (two 40 mg injections in one day). Second dose two weeks later (Day 15): 40 mg s.c.. Two weeks later (Day 29): Begin a maintenance dose of 20 mg s.c. every other week. For  $\geq$  40 kg (88 lbs): Initial dose (Day 1): 160 mg s.c. (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days). Second dose two weeks later (Day 15): 80 mg s.c. (two 40 mg injections in one day). Two weeks later (Day 29): Begin a maintenance dose of 40 mg s.c. every other week. **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. **SPECIAL WARNINGS AND PRECAUTIONS:** Serious and fungal infections: Do not start EXEMPTIA™ 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. If reactivation occurs, stop EXEMPTIA™ and begin antiviral therapy • Demyelinating disease: Exacerbation or new onset, may occur • Heart failure: Worsening or new onset, may occur • Lupus-like syndrome: Stop EXEMPTIA™ if syndrome develops **USE IN PREGNANCY AND LACTATION:** Pregnancy Category B: Adequate and well controlled studies with EXEMPTIATM have not been conducted in pregnant women. Adalimumab is an IgG1 monoclonal antibody and IgG1 is actively transferred across the placenta during the third trimester of pregnancy. Lactation: No data is available on the absorption of adalimumab from breast milk in newborn or preterm infants. Caution should be exercised when EXEMPTIATM is administered to a nursing woman. **DRUG INTERACTION** Biological Products- Concomitant administration of EXEMPTIA™ with other biologic DMARDs (e.g., Anakinra and Abatacept) or other TNF blockers is not recommended • Live Vaccines- Avoid the use of live vaccines with EXEMPTIA™. • Cytochrome P450 Substrates- The formation of CYP450 enzymes may be suppressed by increased levels of cytokines (e.g., TNF $\alpha$ , IL-6) during chronic inflammation. Upon initiation or discontinuation of EXEMPTIA™ in patients being treated with CYP450 substrates with a narrow therapeutic index, monitoring of the effect (e.g., Warfarin) or drug concentration (e.g., Cyclosporine or Theophylline) is recommended and the individual dose of the drug product may be adjusted as needed. **UNDESIRE EFFECTS:** The most serious adverse reactions include the following • Serious Infections- Tuberculosis and Opportunistic Infections • Malignancies. The Clinical experience has reported Upper Respiratory Tract Infection (URTI), Increased creatine phosphokinase, Headache, Rash, Sinusitis, Nausea, Urinary Tract Infection (UTI), Abdominal pain, Flulike syndrome, Hyperlipidemia, Back pain, Hypercholesterolemia, Hematuria, Hypertension, Increased alkaline phosphatase as common side effects. **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.

Zydu Biovation – Copyright ©

Please refer to the full Prescribing Information before starting EXEMPTIA™.

**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

Thank you

