

ASSESSING THE COST-EFFECTIVENESS OF INTRODUCING BENRALIZUMAB IN THE TREATMENT OF SEVERE UNCONTROLLED EOSINOPHILIC ASTHMA PATIENTS IN PRINCE SULTAN MILITARY MEDICAL CITY(PSMMC) - KINGDOM OF SAUDI ARABIA (KSA)

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Background

- Asthma is a long-term inflammatory disorder of the airways characterized by signs or symptoms including; Breathlessness, chest tightness, wheezing, sputum production, airflow obstruction, hyper-responsiveness of airways and cough¹.
- Asthma affects around 235 million people globally and there were 383,000 deaths due to asthma in 2015².
- Severe uncontrolled asthma is defined as poor control despite eliminating environmental allergens and correctly optimizing standard of care³.
- Approximately 5-10% of asthma patients are unable to achieve good control of their asthma despite using high levels of anti-asthma medicines⁴.
- Benralizumab is a humanized, afucosylated, monoclonal antibody (mAb) that binds specifically to the human IL-5 receptor alpha (IL-5Rα) subunit on the target cell, Benralizumab is administered as a single fixed-dose subcutaneous injection, with a prefilled syringe. 30mg is administered every 4 weeks for the first 3 doses followed by every 8 weeks thereafter; increases adherence to medications, and hence, decreases risk of exacerbation⁵.

Objective

- To estimate the incremental costs and quality adjusted life-years (QALYs) associated with Benralizumab, compared to Omalizumab, or no additional biological treatment – all in addition to the standard of care (SOC).

Method

- A three-state excel based Markov model was adapted using 3 Phase III trials (ZONDA, SIROCCO and CALIMA) to assess the incremental cost-effectiveness ratio of Benralizumab vs. standard of care (SOC) alone and vs. Omalizumab.
- Health outcomes were estimated in terms of quality adjusted life years (QALYs) over a lifetime-horizon.
- Patients with severe uncontrolled asthma were defined as those on chronic oral corticosteroids (OCS) use or ≥3 exacerbations; baseline eosinophil count of ≥300 cells/μL in the previous year.

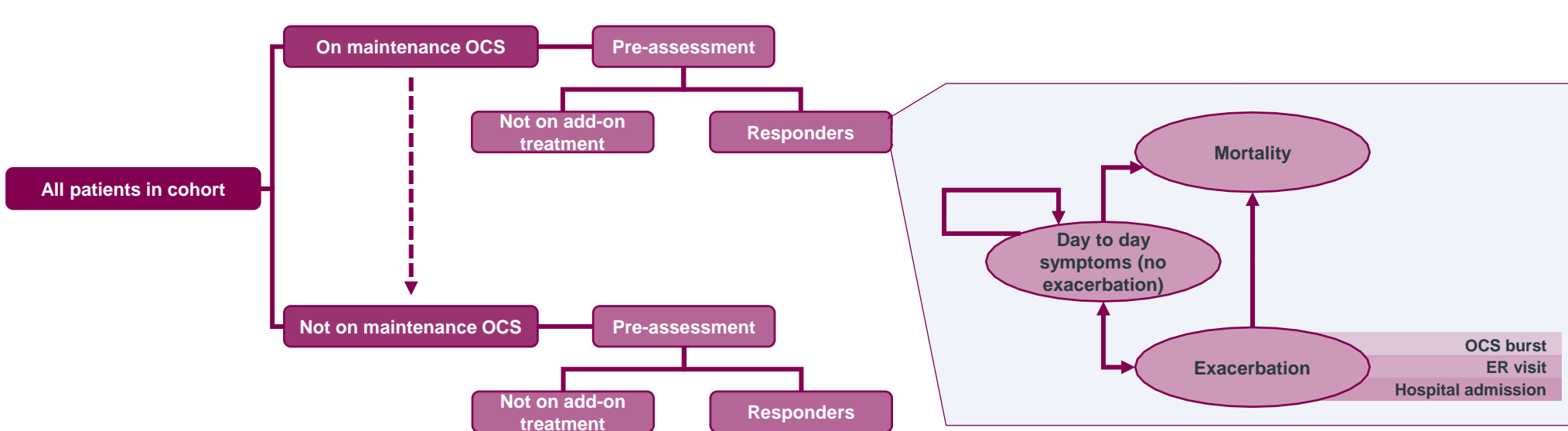


Figure 1. Model Structure

Inputs

- Key model inputs included: rates of exacerbations, treatment response rates, OCS-dose reduction, and cost-components. Further details on key model elements are summarized in **Table 1**.

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| Element | Input |
|--------------------|---|
| Perspective | Prince Sultan Military Medical City- Kingdom of Saudi Arabia (payer's perspective) |
| Patient population | <ul style="list-style-type: none"> Adults aged ≥12 years with Severe eosinophilic asthma who are inadequately controlled despite being treated with standard of care(SOC): <ul style="list-style-type: none"> OCS use or ≥3 exacerbations; Baseline eosinophil count of ≥300 cells/μL in the previous year |
| Comparators | <ul style="list-style-type: none"> Standard of care: High-dose inhaled corticosteroid (ICS) + long-acting β2-agonist (LABA)+ Leukotriene receptor antagonist (LTRA – 35%) + Tiotropium (60%) + Theophylline (2.5%) + Azithromycin (2.5%)] Omalizumab + SOC |
| Intervention | • Benralizumab |

Cost Inputs & Discounting

- Export price (*CIF) price of drugs were used in the model, referenced from Saudi Food & Drug Administration (SFDA) published price list.
- Productivity loss was estimated based on calculating the number of days patients were absent from work due to asthma-related symptoms, cost per workday lost was calculated based on the average GDP per capita n KSA⁶.
- A discount rate equals to 3.5% was applied for both costs and outcomes.

| Drug | Cost Category | Total Costs, SAR* (Year 1) | Total Costs, SAR (Year 2 onwards) |
|---------------|---------------------------|----------------------------|-----------------------------------|
| Standard Care | Treatment Costs | 2,113 | 2,113 |
| Standard Care | Administration Costs | 0 | 0 |
| Standard Care | Adverse events management | 2.29 | 2.29 |
| Standard Care | Add-on Costs* | 1,977 | 1,977 |
| Omalizumab | Treatment Costs | 115,830 | 115,830 |
| Omalizumab | Administration Costs | 200 | 200 |
| Omalizumab | Adverse events management | 14.49 | 14.49 |
| Omalizumab | Add-on Costs* | 1,537 | 1,537 |
| Benralizumab | Treatment Costs | 69,820 | 62,062 |
| Benralizumab | Administration Costs | 200 | 0 |
| Benralizumab | Adverse events management | 1.95 | 1.95 |
| Benralizumab | Add-on Costs* | 1,537 | 1,537 |

*CIF: price of goods or services delivered to importing country including the cost, insurance and the freight charges.
 *SAR: Saudi Arabia Riyal.
 *Add-on costs: include doctor visits/consultations and routine laboratory tests done during follow-up.

Results

Standard Care Vs. Benralizumab

- Over a life-time horizon , the total discounted costs associated with the SOC Vs. Benralizumab were SAR**145,972** and SAR**396,578** respectively. (**Table 3**)

- Benralizumab generated a total of **14.35** QALYs compared to **13.68** QALYs for SOC per patient. (**Table 3**)
- The model results demonstrated that Benralizumab is associated with higher QALYs and higher costs with less exacerbations compared to SOC, generating an estimated ICER of SAR**372,674** per QALY.

Benralizumab Vs. Omalizumab

- Over a life-time horizon –
- The total discounted costs associated to Benralizumab Vs. Omalizumab were SAR**421,037** and SAR**696,739** respectively. (**Table 4**)
- Benralizumab generated a total of **14.35** (QALYs) compared to **14.25** QALYs for Omalizumab per patient. (**Table 4**)
- The model results demonstrated that Benralizumab is associated with higher QALYs and lower costs which makes it a dominant option when compared to Omalizumab.

- A one-way sensitivity analysis was done to confirm on the robustness of model outcomes, the parameters that exhibited the greatest influence on incremental QALYs results were Benralizumab Day-to day utility- chronic OCS use and SoC Day-to day utility (**Figure 2**). Omalizumab Day-to day utility was the parameter of greatest influence on comparing Benralizumab to Omalizumab. The conclusion for both comparisons remained the same.

| TOTAL DISCOUNTED | | | | | INCREMENTAL (Benra Vs. SC) | | | |
|------------------|-------------|-------|-------|---------------|----------------------------|------|--------|-----------------|
| Intervention | Costs (SAR) | LY | QALY | Exacerbations | ▲ Costs (SAR) | ▲ LY | ▲ QALY | ▲ Exacerbations |
| Total | | | | | | | | |
| Benralizumab | 396,578 | 18.50 | 14.35 | 26.60 | REFERENCE | | | |
| Standard care | 145,972 | 18.29 | 13.68 | 31.33 | 250,606 | 0.20 | 0.67 | -4.74 |

Table 3. ICER standard Care VS. Benralizumab

| TOTAL DISCOUNTED | | | | | INCREMENTAL (Benralizumab VS) | | | |
|------------------|-------------|-------|-------|---------------|-------------------------------|------|--------|-----------------|
| Intervention | Costs (SAR) | LY | QALY | Exacerbations | ▲ Costs (SAR) | ▲ LY | ▲ QALY | ▲ Exacerbations |
| Total | | | | | | | | |
| Benralizumab | 421,037 | 19.15 | 14.35 | 16.49 | REFERENCE | | | |
| Omalizumab | 696,739 | 19.12 | 14.25 | 17.13 | -268,551 | 0.03 | 0.10 | -0.64 |

Table 4. ICER Benralizumab Vs. Omalizumab

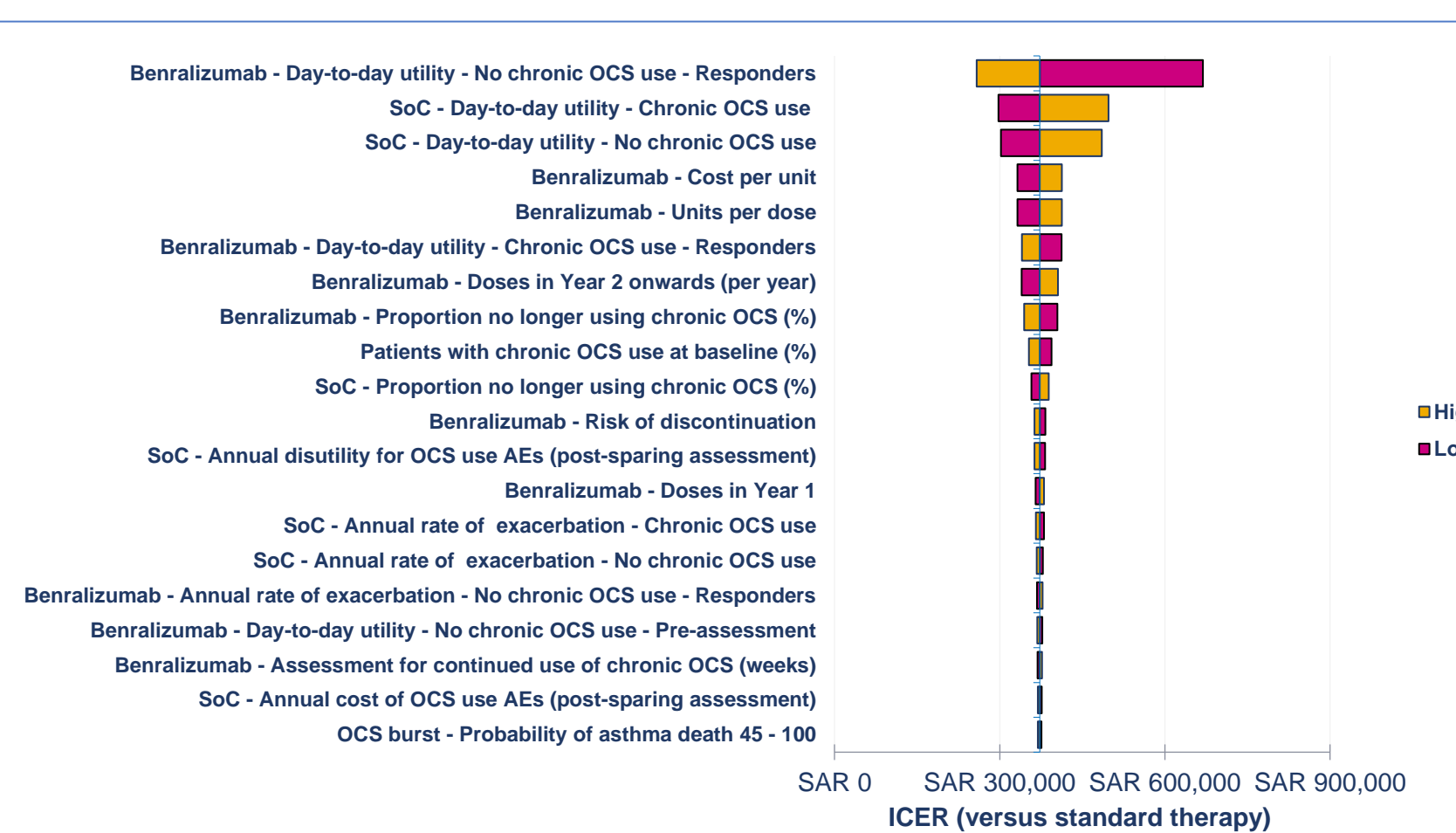


Figure 2. Tornado Diagram(Standard Care Vs. Benralizumab)

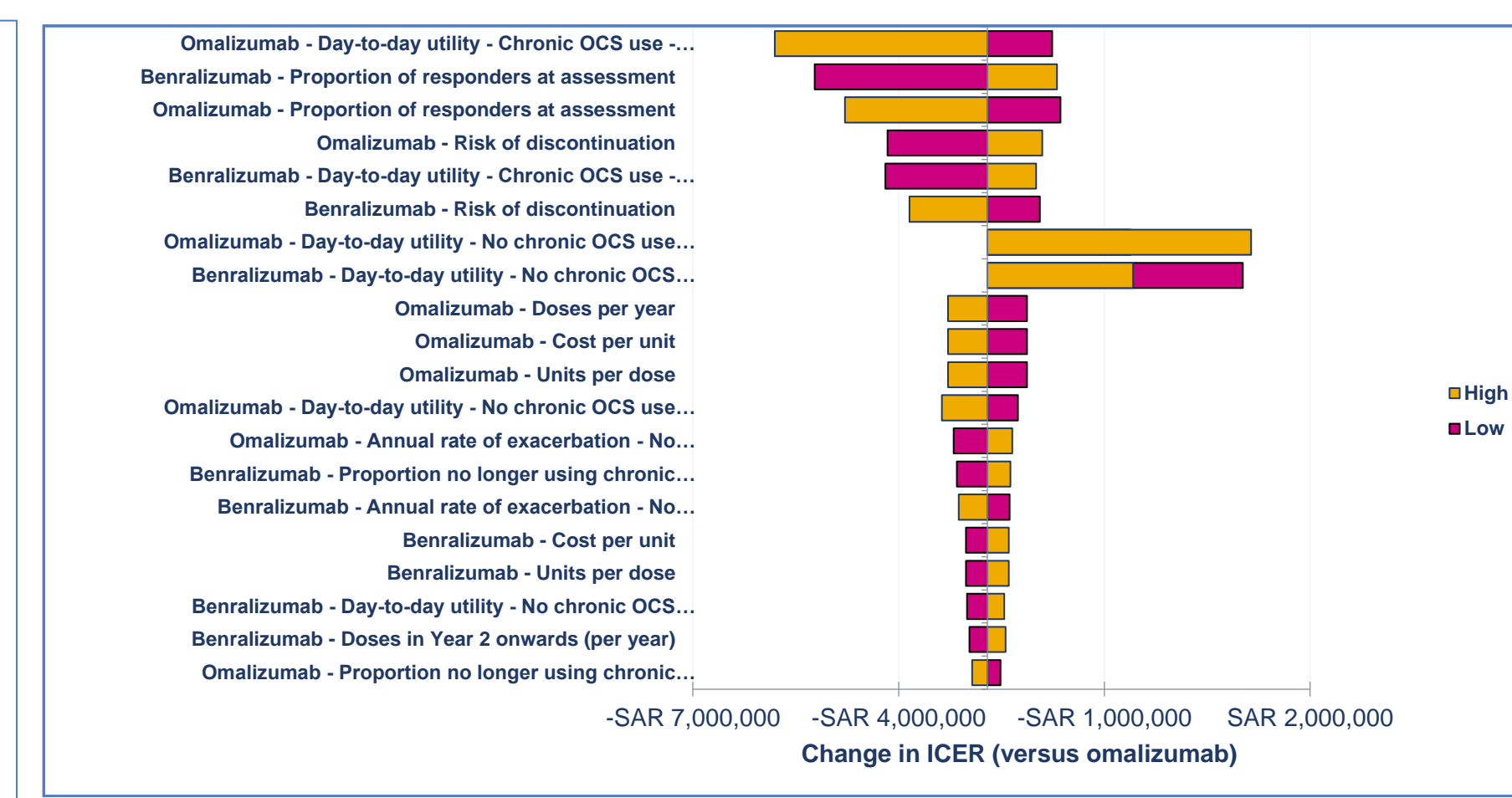


Figure 3. Tornado Diagram(Benralizumab Vs. Omalizumab)

Conclusion

- Benralizumab demonstrated higher QALYs gained per patient, as well as higher annual costs when compared to standard care alone.
- Costs increase were mainly driven by drug acquisition costs.
- When comparing Benralizumab to Omalizumab, Benralizumab has shown to be a dominant option, which means it generated more QALYs per patient at lower costs per year.

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