EE116

Modelling the clinical and economic impact of clesrovimab against respiratory syncytial virus among infants in Italy

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Background

- Respiratory syncytial virus (RSV) is a major cause of illness in infants, the leading cause of bronchiolitis hospitalizations among newborns in Italy.
- Clesrovimab is a long-acting human monoclonal antibody that targets the RSV fusion protein and delivers durable protection through six months following a single dose.

Objective

- To assess the health and economic impact of clesrovimab on medically attended RSV (MA-RSV) infections (i.e., hospitalizations, emergency department, and outpatient visits) among infants in Italy compared to the current standard of care.

Methods

- A decision tree model (Figure 1) [1] simulated the clinical and economic impact of clesrovimab in infants entering their first RSV season (seasonal with a catch-up implementation), compared with nirsevimab.

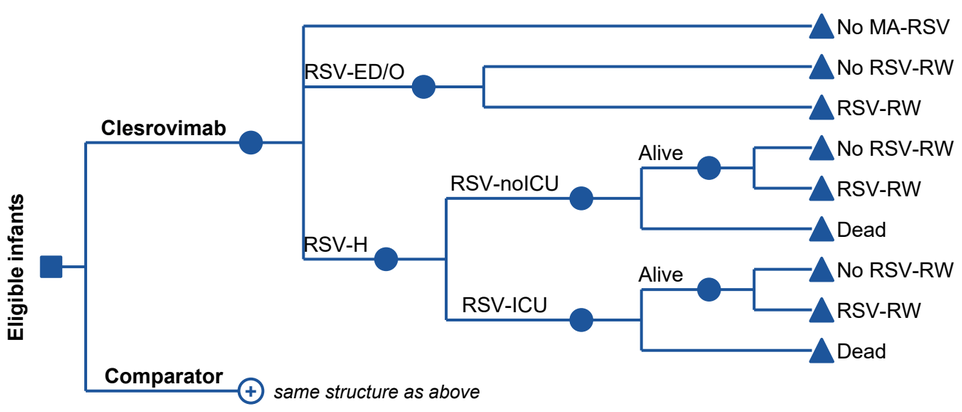


Figure 1: Decision tree model structure.
Abbreviations: ICU, intensive care unit; RSV-H-noICU, RSV hospitalization without ICU admission; RSV-H-ICU, RSV hospitalization with ICU admission; RSV-O, RSV outpatient visit; RSV-ED, RSV emergency department; RSV-RW, RSV recurrent wheezing.

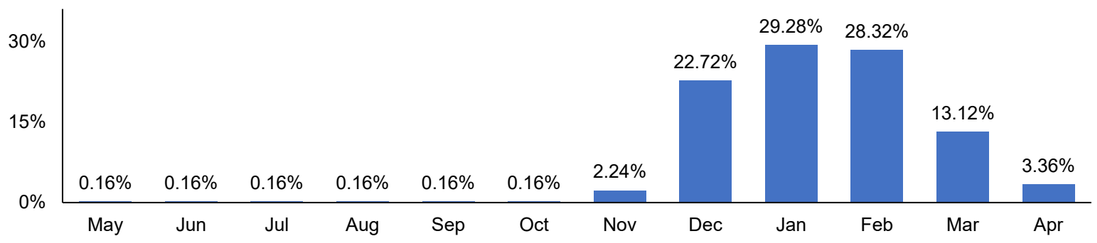


Figure 2: RSV-positive test results by month (total RSV-positive test results over one year is 100%) [2].

- Model inputs were obtained from published literature.
- RSV season: November-April (Figure 2).
- Efficacy estimates for both interventions were obtained from randomized clinical trials (RCTs) [3-5].
- In the base case, medically attended lower respiratory infection (MALRI) efficacy, using the most comparable endpoint definitions available, was applied equally to all outcomes, with duration of protection based on the maximum follow-up time reported in the respective global registrational RCTs. Two additional scenarios were evaluated:
  - equal 5-month MALRI durations of protection for both interventions (scenario 1), and
  - efficacy against hospitalization for LRTI was applied to hospitalization outcomes (scenario 2).
- An 80% coverage rate was assumed for both interventions.
- Outcomes included office visits, emergency department visits (ED), hospitalizations, and treatment costs averted (excluding intervention costs).
- Time horizon: 1-year post-dose administration.

Results

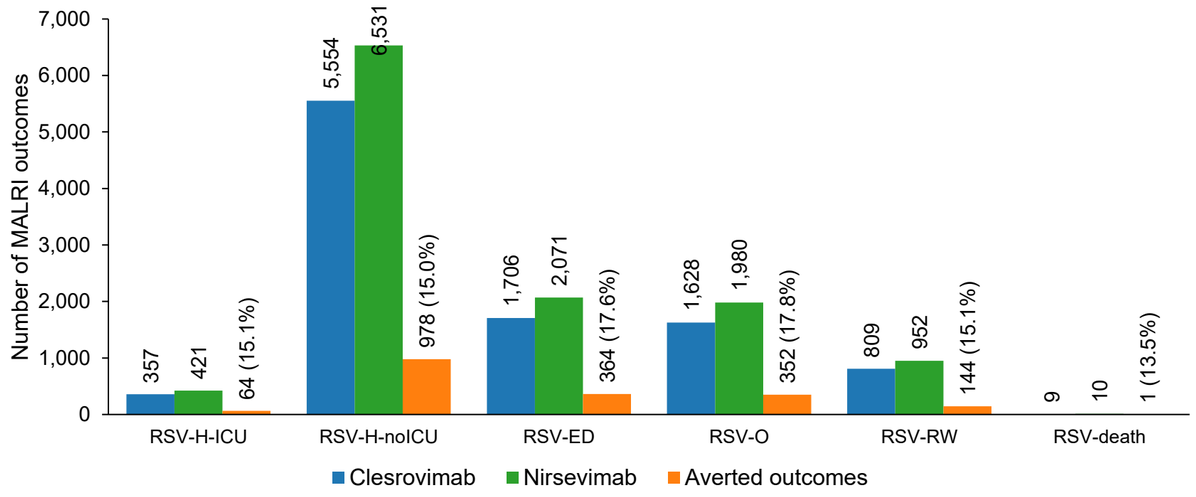


Figure 3: Base-case MALRI outcomes with clesrovimab (blue bars), nirsevimab (green bars), and averted outcomes (orange bars). Percentages show the reduction relative to nirsevimab. Case counts are rounded to the nearest integer and percentages to one decimal place. Abbreviations: ICU, intensive care unit; RSV-H-noICU, RSV hospitalization without ICU admission; RSV-H-ICU, RSV hospitalization with ICU admission; RSV-O, RSV outpatient visit; RSV-ED, RSV emergency department; RSV-RW, RSV recurrent wheezing.

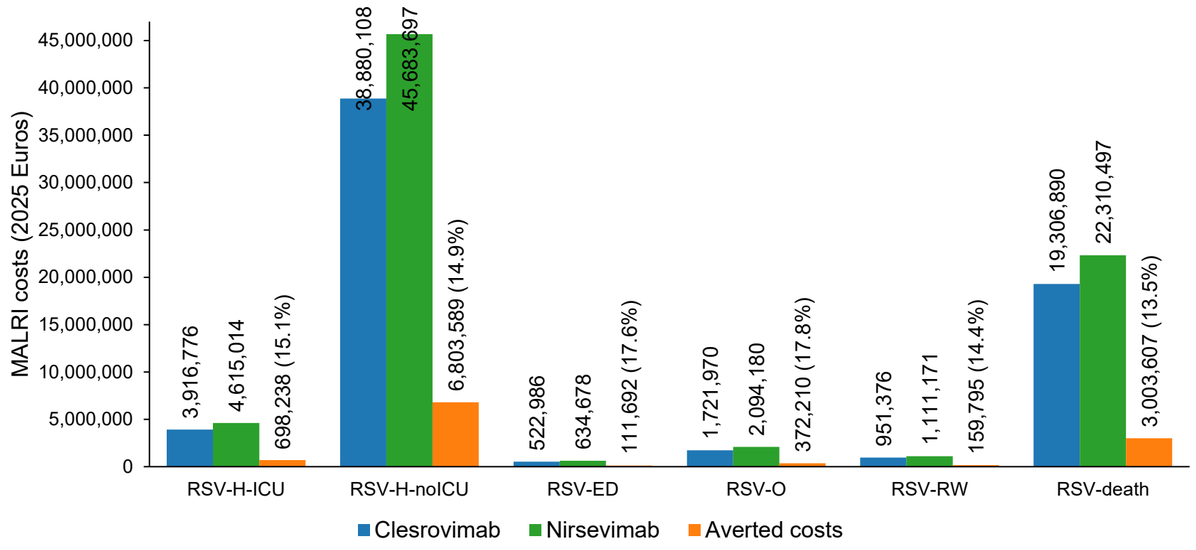


Figure 4: Base-case MALRI costs (2025 Euros) with clesrovimab (blue bars), nirsevimab (green bars), and averted costs (orange bars). Percentages show the reduction relative to nirsevimab. Cost values are rounded to the nearest integer and percentages to one decimal place. Abbreviations: ICU, intensive care unit; RSV-H-noICU, RSV hospitalization without ICU admission; RSV-H-ICU, RSV hospitalization with ICU admission; RSV-O, RSV outpatient visit; RSV-ED, RSV emergency department; RSV-RW, RSV recurrent wheezing.

- Base case: Clesrovimab was projected to reduce RSV outcomes and associated costs by 13.5–17.8% versus nirsevimab across outcome categories, excluding intervention costs. RSV-H-noICU showed the largest absolute reductions: 978 cases averted and €6.8 million saved (Figures 3–4).
- Scenarios: Clesrovimab also projected fewer RSV cases and lower costs in scenario 1. In scenario 2, projected reductions versus nirsevimab were 1,140 RSV hospitalizations (16.8%) and €7.62 million in hospitalization costs (16.7%).
- One-way deterministic sensitivity analysis: Coverage rates and efficacy were the key drivers of results.

Conclusion

The findings of this study suggest that implementing clesrovimab in Italy could improve health outcomes among infants while reducing the economic burden associated with RSV disease.

References

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