

# Review of: "Sotorasib Treatment Could Worsen the Prognosis of Advanced KRASG12C-Mutated Non-Small Cell Lung Cancer"

Piush Srivastava<sup>1</sup>

<sup>1</sup> Surgery, University of Illinois at Chicago, United States

Potential competing interests: No potential competing interests to declare.

## Suggestions:

### 1. Clarify Statistical Terminology:

- The distinction between HR and absolute risk should be clearly explained for clinicians without a formal statistics background.
- Including an appendix or explainer on statistical methods (e.g., Kaplan-Meier analysis, informative censoring) could help readers interpret results accurately.

### 2. Highlight Clinical Implications:

- Discuss how HR and absolute risk discrepancies might impact treatment decisions.
- Address the implications of using PFS as a surrogate endpoint in clinical trials, especially for regulatory decisions.

### 3. Address FDA Decision Context:

- Provide a detailed discussion of the FDA's rationale for rejecting sotorasib's regular approval and its implications for other accelerated approval drugs.
- Explore how confirmatory trials could resolve current uncertainties.

### 4. Incorporate Visuals and Sensitivity Analyses:

- Include graphical representations of absolute risks alongside Kaplan-Meier curves to communicate discrepancies better.
- Present outcomes under various censoring scenarios to reinforce how informative censoring can bias results.

### 5. Encourage Rigorous Peer Review:

- Stress the importance of independent, expert statistical reviewers for high-impact journals.
- Suggest reforms in trial reporting guidelines (e.g., CONSORT) to mandate absolute risk disclosures.

By refining statistical communication, encouraging robust peer-review processes, and emphasizing absolute risk, this

analysis could serve as a valuable resource for clinicians and researchers interpreting survival analyses in oncology.