Reviewer’s report

Title: Efficacy and safety of inhaled formoterol 4.5 and 9 microg twice daily in Japanese and European COPD patients: Phase III study results

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Reviewer: Amir Sharafkhaneh

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Efficacy and safety of inhaled formoterol 4.5 and 9 µg twice daily in Japanese and European COPD patients: Phase III study results by Miron A Bogdan,

The study by Dr. Bogdan and colleagues evaluated the efficacy and safety of two various doses of formoterol (4.5 and 9 micrograms bid) to placebo. The primary endpoint in this study is the FEV1 60 min post dose comparing active to placebo arms. The study showed that the improvement in the post dose FEV1 is similar and significantly more in active arms compared to placebo. Other efficacy endpoints improved similarly in both active arms compared to placebo. The higher dose of formoterol offered more improvement in SGRQ and reduction in rescue medication use.

The important shortcomings of the study

1) Please clearly state if the protocol was approved by Institutional Review Board/Ethic Committee in all the participating sites.
2) Please provide information on type of respiratory medications that the patients were on at the time of enrollment and during the study.
3) One major difference that may emerge between the two different doses is the trough FEV1 at the end of the study compared to baseline prebronchodilator FEV1. Please provide the data.
4) One major difference may arise with any degree of desensitization comparing improvement of FEV1 from predose to 1-hour post dose at day one and the end of the study. Please provide the data.
5) Table 2: the title mentions the difference in outcome variables between the two active treatment arms and names it as “ratio.” While, in reality, other than FEV1 and FVC, the rest are absolute differences. This needs to be corrected.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

No competing interest.