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Exploratory trial shows no incremental benefit of aliskiren add-on therapy in improving changes to cardiac shape in heart attack patients

- *Trial assessed addition of aliskiren to help limit changes to the heart's shape and function in patients after heart attack (post-myocardial infarction)¹*
- *A small numerical reduction in cardiac volume from adding aliskiren to standard therapy seen in echocardiogram results, but not statistically significant¹*
- *ASPIRE, an exploratory study, is one of 14 trials in the ASPIRE HIGHER clinical trial program evaluating aliskiren potential benefit beyond blood pressure reduction*

Basel, March 16, 2010 — The addition of the cardiovascular medicine aliskiren to standard therapy for patients recovering from a heart attack showed some positive effects in helping limit changes in the heart's shape and function, but did not demonstrate a statistically significant benefit, according to new clinical trial results¹.

Data from the ASPIRE study (Aliskiren Study in Post-MI patients to Reduce rEmodelling) were presented at the American College of Cardiology (ACC) Congress in Atlanta. Results from the study showed that the addition of aliskiren did not provide the anticipated effect of limiting adverse changes to the heart's left ventricle, which is the organ's main pumping chamber that can often reduce its ability to pump blood efficiently¹.

The 36-week study involving 820 patients, all of whom had evidence of impaired left ventricular function, assessed changes in left ventricular end systolic volume (LVESV) through echocardiograms from baseline to the study end. A small numerical reduction in cardiac volume (LVESV, -0.99 mL) was seen in patients receiving aliskiren and standard therapy compared to those given standard therapy only; however, this was not statistically significant¹.

The combined rates of cardiovascular death, hospitalization for heart failure, recurrent heart attack, stroke and resuscitated sudden death were similar in the aliskiren group and the group given standard therapy. In patients receiving aliskiren in addition to standard therapy there was a higher rate of hyperkalemia, hypotension and kidney dysfunction when compared to the group receiving standard therapy alone¹.

Based on the results of this trial, Novartis does not plan to pursue an outcome trial for post-MI patients. ASPIRE is one of 14 trials in the 35,000 patient ASPIRE HIGHER clinical trial program that is designed to evaluate potential benefit of aliskiren beyond blood pressure reduction.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “can,” “plan,” “potential,” or similar expressions, or by express or implied discussions regarding the outcome of the ASPIRE HIGHER clinical trial program, regarding potential new indications or labeling for aliskiren or regarding potential future revenues from aliskiren as a result. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with aliskiren to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees regarding the potential outcome of the ASPIRE HIGHER clinical trial program. Nor can there be any guarantee that aliskiren will be submitted or approved for any additional indications or labeling in any market. Neither can there be any guarantee that any such additional indications or labeling will result in aliskiren achieving any particular levels of revenue in the future. In particular, management’s expectations regarding aliskiren could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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References

1. Solomon S, et al. Effect of the Direct Renin Inhibitor Aliskiren on Left Ventricular Remodelling Following Myocardial Infarction with Left Ventricular Dysfunction: ASPIRE. Late Breaker presentation at American College of Cardiology 59th Annual Scientific Sessions 2010

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