Transcript Details

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The STELLAR Trial: Key Data on Sotatercept for PAH

Announcer:
You're listening to *Heart Matters* on ReachMD. On this episode, we'll hear from Dr. Marius M. Hoeper, who is the Deputy Director of the Department of Respiratory Medicine at Hannover Medical School in Hannover, Germany. Dr. Hoeper will be taking a look at the STELLAR trial and its impacts on patients with pulmonary arterial hypertension, or PAH for short. Let's hear from him now.

Dr. Hoeper:
The STELLAR study was a phase 3 trial with sotatercept and pulmonary arterial hypertension following the phase 2 PULSAR study, which had already shown that sotatercept in these patients improved hemodynamics, in that case, pulmonary vascular resistance; and exercise capacity, in that case, six-minute walk distance. So STELLAR was now the pivotal phase 3 study aiming at reproducing these results, extending these results, and also giving a bit more of long-term data and safety tolerability data.

STELLAR met its primary endpoint, which was change in six-minute walk distance from baseline at week 24, and the improvement was about 40 meters compared to placebo. In addition, STELLAR had nine secondary endpoints, which were tested hierarchically, eight of which were positive including, so-called modicum component improvement endpoint, which is a composite of prespecified improvements at functional class six-minute walk distance and anti-proBNP. Functional class anti-proBNP improved significantly as well. There was a significant improvement in pulmonary vascular resistance in the French noninvasive low-risk score and in two out of three domains of PAH-SYMPACT, which is a disease-specific quality of life tool, and there was a quite remarkable improvement also in time to death or first clinical worsening event with an 84 percent risk reduction compared to placebo. So the hazard ratio of having such an event with sotatercept was 0.16.

So, STELLAR demonstrated that sotatercept is efficacious for effective medication for patients with pulmonary arterial hypertension who are on background therapy. That's for sure. The study also showed that sotatercept does have some side effects, including bleeding, mostly mild epistaxis and gum bleeds, and the development of telangiectasia, which was seen in 14 percent of the patients up to the day when the data cutoff was made. Nevertheless, the risk-benefit profile was clearly in favor of sotatercept. Very few patients discontinued study medications due to side effects. And overall, we believe that the data is sufficiently strong to obtain approval in all parts of the world for this new medication, and I believe and I think the entire community believes that this will become one of the new mainstays of the treatment of pulmonary arterial hypertension.

Announcer:
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