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Applicability of the GALACTIC-HF Trial and Omecamtiv Mecarbil to Patients Hospitalized for Heart Failure in the US: The GWTG-HF Registry

Announcer:
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Dr. Greene:
Hi, I'm Dr. Stephen Greene from the Duke Clinical Research Institute. And on behalf of my coauthors, I'm pleased to present applicability of the GALACTIC-HF trial in omecamtiv mecarbil to patients hospitalized for heart failure in the United States: Findings from the Get With The Guidelines Heart Failure Registry.

By way of background, in the large-scale multinational GALACTIC-HF trial, omecamtiv mecarbil, a novel myosin activator, reduce the risk of cardiovascular death, or worsening heart failure among patients with HFrEF with an ejection fraction of less than or equal to 35%. However, in GALACTIC-HF, the magnitude of treatment benefit with omecamtiv mecarbil was greater among those with particularly low ejection fraction. However, the applicability of the GALACTIC-HF trial and the proportion of U.S. patients who may be candidates for omecamtiv mecarbil has not yet been well characterized.

The objectives of the current study were to examine the proportion of patients hospitalized for HFrEF in the United States, who may meet eligibility criteria for the GALACTIC-HF trial. We also did dedicated analyses among the subset of patients with severely reduced ejection fraction, less than or equal to 30%, since this is the subset of patients who may derive the most benefit from omecamtiv mecarbil. To do this, we leveraged the American Heart Association's Get With The Guidelines Heart Failure Registry, which is a nationwide U.S. registry of patients hospitalized for heart failure. Specifically in this analysis, we included 423 sites in the Get With The Guidelines Heart Failure Registry. In the study population, were those hospitalized for worsening chronic heart failure with an ejection fraction less than or equal to 40%, who did not have severe kidney disease or a history of heart transplantation or durable mechanical circulatory support.

We then examined patients according to key GALACTIC-HF trial inclusion and exclusion criteria. And we grouped patients in Get With The Guidelines Heart Failure into two EF subgroups, those with severely reduced ejection fraction less than or equal to 30%, and those with less severely reduced ejection fraction with an ejection fraction 31 to 40%. These are the results of our analysis, and show the proportion meeting GALACTIC-HF trial eligibility criteria in the Get With The Guidelines Heart Failure Registry.

So overall, we included more than 113,000 hospitalizations for worsening chronic heart failure with an ejection fraction less than or equal to 40%. And in that cohort, we saw that 69% of hospitalizations were associated with an ejection fraction less than or equal to 30%. And among this subset with severely reduced ejection fraction, nearly 3 of 4 patients, were potentially eligible for omecamtiv mecarbil. Among the subset of hospitalizations associated with a less severely reduced ejection fraction, those with an ejection fraction 31 to

40%, we found 53% of hospitalizations were potentially eligible for omecamtiv mecarbil.

So putting it all together, looking at the overall cohort of hospitalizations for worsening chronic heart failure less than or equal to 40%, so the standard definition of HFrEF, we saw that more than half of patients had severely reduced ejection fraction less than or equal to 30%, so the subset of patients who might derive larger benefit for omecamtiv mecarbil, and were potentially eligible for omecamtiv mecarbil.

Limitations of this analysis should be noted. Participation in Get With The Guidelines Heart Failure is voluntary and may not be representative of patients with heart failure across all U.S. hospitals. And in addition, in determining potential eligibility for omecamtiv mecarbil, we did not apply a requirement that patients were already receiving quadruple medical therapy for HFrEF.

So in conclusion, among hospitalizations for worsening chronic HFrEF in the United States, more than two-thirds were potentially eligible for omecamtiv mecarbil. In addition, 69% of patients with worsening chronic HFrEF have a severely reduced ejection fraction less than or equal to 30%, so the subset that may derive most benefit from omecamtiv mecarbil. And in this large subset, approximately 3 out of 4 patients were potentially eligible to receive omecamtiv mecarbil.

Thank you very much for your attention.

Announcer:
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