

DSMB RECOMMENDATION FORM

Study: CHANGE AFib
Study Intervention: Dronedarone

Meeting Date: 6/29/2023
Database cut-off date: 4/26/2023

After review of all available data, the DSMB makes the following recommendation:

- >>> Continuation of study under the current study protocol
- Modify the study (e.g., eligibility criteria or protocol procedures such as additional safety monitoring or data collection)
 - Halt study enrollment; or temporary/permanent discontinuation of the study.

Comments:

Thanks to Dr. Piccini and the CHANGE AFib Study Team for the excellent presentation and discussion during the open and closed sessions of the DSMB meeting. It is the unanimous recommendation of the Committee that the study continue forward under the current protocol. We commend the study team for the efforts to activate clinical sites and accelerate patient enrollment. This is an important study, and we encourage continued vigorous efforts be focused on increasing enrollment.

The closed session review was based on only 64 patients. Thus the amount of data at this early stage of the trial is quite limited. The DSMB did note and express concern about the amount of missing information among the patient demographics (e.g., sex, race, and ethnicity) and other baseline characteristics. This information should be relatively straightforward to capture and will be important in characterizing the patients enrolled in the study. The committee urges the study team to emphasize data quality and focus on data completeness. This will require working closely with IQVIA in their data management role with the study.

We look forward to receiving the quarterly enrollment update, and the next meeting of the DSMB in approximately six months.



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Representing the CHANGE Afib DSMB