Prior IV Iron Studies (Heart Failure)

Trial	Patients	Time	Primary endpoint
FAIR-HF	459	24	Self-reported patient global assessment and NYHA functional class
CONFIRM-HF	304	52	6-MWD
AFFIRM-AHF	1,132	52	Composite of recurrent events of HF hospitalization and cardiovascular death

Improvements in:

- Patient-reported outcomes
- Functional status (6-MWD, NYHA class)
- Reduction in HF hospitalizations

6-MWD, 6-minute walk distance; HF, heart failure; NYHA, New York Heart Association.

Lewis GD, et al. *Circ Heart Fail*. 2016;9(5):e000345. Anker SD, et al. *N Engl J Med*. 2009;361(25):2436-2448. Ponikowski P, et al. *Eur Heart J*. 2015;36(11):657-668. Ponikowski P, et al. *Lancet*. 2020;396(10266):1895-1904.

Comparison of IV Iron Studies (Heart Failure)[1]

Study Name	AFFIRM-AHF	HEART-FID
# of Patients	1,132	3,014
Diagnosis	Acute HF EF < 50%	Chronic HF EF ≤ 40%
Recruitment	Hospital	Outpatient
Study Arm	Ferric carboxymaltose	Ferric carboxymaltose
Duration	52 weeks	Event driven + 12 mos last patient
Primary Endpoint	HF hospitalizations + CV death	All-cause mortality + total HF hospitalizations through 12 mos and 6-month 6-MWD
Anticipated Completion Date	**Completed**	**June 2023**

6-MWD, 6-minute walk distance; CV, cardiovascular; EF, ejection fraction; HF, heart failure

1. von Haehling S, et al. *JACC Heart Fail.* 2019;7(1):36-46; 2. Mentz RJ, et al. *Circ Heart Fail*. 2021;14(5):e008100.

Comparison of IV Iron Studies (Heart Failure)[1]

Study Name	AFFIRM-AHF	HEART-FID
# of Patients	1,132	3,014
Diagnosis	Acute HF EF < 50%	Chronic HF
Recruitment	Hospital	
Study Arm	Ferric carboxymaltose	
Duration	52 weeks	
Primary Endpoint	HF hospitalizations + CV death	hospitalizations through 12 mos and 6-month 6-MWD
Anticipated Completion Date	**Completed**	**June 2023**

Additional HEART-FID Key Inclusion Criteria[2]:

- Either documented hospitalization for heart failure within 12 months of enrollment, or
- Elevated N-terminal pro-brain natriuretic peptide (NT-proBNP) within 90 days of randomization

6-MWD, 6-minute walk distance; CV, cardiovascular; EF, ejection fraction; HF, heart failure

1. von Haehling S, et al. *JACC Heart Fail.* 2019;7(1):36-46; 2. Mentz RJ, et al. *Circ Heart Fail*. 2021;14(5):e008100.