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About HFSA

The Heart Failure Society of America's vision is to significantly reduce the burden of heart failure. HFSA's mission is to provide a platform to improve and expand heart failure care through collaboration, education, innovation, research, and advocacy.

2023 Board of Directors

**2023 Elected Officers**
- President: John Teerlink, MD, FHFSA
- President Elect: James C. Fang, MD, FHFSA
- Secretary: Mike Felker, MD, FHFSA
- Treasurer: Mona Fiuzat, PharmD, FHFSA
- Immediate Past President: Mark Drazner, MD, MSC, FHFSA

**Board Members**
- Michelle Kittleson, MD, PhD
- Ken Margulies, MD, FHFSA
- Colleen McIlvennan, PhD, DNP, ANP, FHFSA
- Natalie W. Pierson, MSN, RN, NC-BC, FHFSA
- Nancy Sweitzer, MD, PhD, FHFSA
- Orly Vardeny, PharmD

**2023 ASM Program Committee**

**2023 Chair:** Akshay Desai, MD, MPH, FHFSA
**2023 Co-Chair:** Windy Alonso, PhD, RN, FHFSA
**2023 Co-Chair:** Zachary Cox, PharmD, FHFSA
**2023 Co-Chair:** Prateeti Khazanie, MD, MPH, FHFSA
- David Lanfear, MD, MS
- Laura Peters, DNP, FNP
- Mitch Psotka, MD, PhD
- Nosheen Reza, MD
- Jo Ellen Rodgers, PharmD, FHFSA
Corporate Members

GOLD Level

AstraZeneca
Boehringer Ingelheim
Lilly
CVRx
Cytokinetics
Daiichi-Sankyo
Lexicon Pharmaceuticals
MERCK
NOVARTIS
Pfizer
scPharmaceuticals

SILVER Level

ABIOMED
Bayer
bridgebio
CAREDx
GETINGE
IMPULSE DYNAMICS
nuwellis
Roche

BRONZE Level

Abbott
attralus
Boston Scientific
DAXOR
Edwards
Ella
Medtronic
OM1
Otsuka
REGENERON
V-WAVE
All schedules are listed in Eastern Standard Time.

Registration Desk Hours

Located at the Concourse Level Pre-function Space of the Huntington Convention Center

- Friday, October 6 | 10:00 AM – 8:00 PM
- Saturday, October 7 | 6:30 AM – 6:00 PM
- Sunday, October 8 | 6:30 AM – 6:00 PM
- Monday, October 9 | 6:30 AM – 9:00 AM

Exhibit Hall Hours

Located in Convention Center Hall C

- Friday, October 6 | 6:15 PM – 7:45 PM
- Saturday, October 7 | 12:30 PM – 2:30 PM / 5:30 PM - 7:00 PM
- Sunday, October 8 | 12:00 PM – 2:00 PM

HFSA Membership Desk Hours

Located in Convention Center Hall C

- Friday, October 6 | 6:15 PM – 7:45 PM
- Saturday, October 7 | 12:30 PM – 2:30 PM / 5:30 PM - 7:00 PM
- Sunday, October 8 | 12:00 PM – 2:00 PM

Press Room Hours

Located in Room 2

- Saturday, October 7 | 7:00 AM – 5:00 PM
- Sunday, October 8 | 7:00 AM – 5:00 PM
- Monday, October 9 | 7:00 AM – 12:00 PM

Mobile App | Certification | Information Desk Hours

Located at the Exhibit Level Pre-function Space of the Huntington Convention Center outside Room 13

- Friday, October 6 | 12:00 PM – 8:00 PM
- Saturday, October 7 | 7:15 AM – 7:15 PM
- Sunday, October 8 | 8:00 AM – 5:00 PM
- Monday, October 9 | 8:00 AM – 1:15 PM

Professional In Training (PIT) Lounge Hours

Located in Convention Center Hall C

- Friday, October 6 | 6:15 PM – 7:45 PM
- Saturday, October 7 | 7:45 AM – 4:30 PM
- Sunday, October 8 | 7:45 AM – 4:30 PM

Research Hub Hours

Located in Convention Center Hall C

- Friday, October 6 | 6:15 PM – 7:45 PM
- Saturday, October 7 | 8:00 AM – 5:45 PM
- Sunday, October 8 | 8:00 AM – 2:00 PM

ePoster and Oral Abstract Viewing Sessions

Located in the ePoster Hub and Oral Abstract Stage in Convention Center Hall C. Open during regular meeting hours, see viewing sessions for a chance to meet abstract presenters.

**Friday, October 6**

- **Session I:** 6:30 PM - 7:30 PM

**Saturday, October 7**

- **Session II:** 8:00 AM - 9:00 AM
- **Session III:** 1:00 PM - 2:30 PM

**Sunday, October 8**

- **Session VI:** 8:00 AM - 9:00 AM

- **Session V:** 6:00 PM - 7:00 PM

- **Session VII:** 12:15 PM - 1:45 PM
Meeting Information
Things to Know

Wi-Fi Information
*Complimentary Wi-Fi is available in education sessions.*

**Network Name:** HFSA Annual Meeting
**Password:** HFSA2023

Dress Code
Meeting attire is business casual. We suggest you dress in layers as meeting room temperatures often vary.

Children
The HFSA does not allow children under the age of 16 in the Exhibit Hall at any time. Due to limited seating capacity and the technical nature of the program, children (under age 16) are not allowed into the scientific sessions.

Special Needs
The HFSA strives to hold meetings that are accessible to all. Please tell us what you require to help make your participation more enjoyable and meaningful. For questions and more information, contact Lindsey Best at lbest@etherio.com.

No Smoking Policy
HFSA and the Conference Center prohibit smoking in all meeting and hotel areas. Thank you for your cooperation.

Questions?
Visit the Information Desk with questions or email HFSA staff at info@hfsa.org. Emailed responses may be delayed due to staff being onsite at the meeting.

Food Policy
The Physician Payment Sunshine Act, part of the Affordable Care Act, requires that manufacturers of drug and devices report to CMS certain payments and items of value given to physicians. These items of value include meals at CME activities, such as this annual meeting. For this reason, the following food and refreshments provided at the HFSA Annual Scientific Meeting will be paid for out of registration fees and the HFSA operating budget: the Opening Reception, Poster Receptions, early morning refreshments, lunches, and coffee breaks.

Screen Recording and Photography Policy
HFSA staff members, HFSA photographers, HFSA videographers, preapproved videographers, and pre-approved photographers, are the only ones authorized to photograph and film events and virtual educational sessions throughout the meeting. Any photographs, screen shots, screen recordings, and videos taken by our HFSA Staff and HFSA photographers and videographers are used exclusively by HFSA for promotional purposes and continuing education offerings. They may be used in the society’s publications, website, social media accounts, programs, or other HFSA promotional materials. If you are attending a virtual session and you do not wish to be photographed or recorded, please identify yourself via email to HFSA staff at LPoko@hfsa.org.

Liability Statement
The Heart Failure Society of America (HFSA) cannot accept, and hereby specifically disclaims, any liability for death, injury, any loss, cost or expense suffered or incurred by any person if such loss is caused by, arises from or results from the act, default or omission of any person other than an employee or agent of HFSA. In particular, neither HFSA nor its agents can accept, and hereby specifically disclaims, any liability for losses arising from, caused by, or resulting from, the provision or non-provision of services provided by the hotels, companies, or transport operators. Neither HFSA nor its agents can accept, and hereby specifically disclaims, liability for losses suffered by reason of war including threat of war, riots and civil strife, terrorist activity, natural disaster, weather, fire, flood, drought, technical, mechanical or electrical breakdown within any premises visited by delegates and/or participants in connection with the meeting, industrial disputes, government action, regulations or technical problems that affect or may affect the services provided in connection with the meeting. HFSA is not able to warrant and does not warrant that a particular person will appear as a speaker. As a condition to any participation in or attendance at the Annual Scientific Meeting or any function associated or affiliated herewith, each attendee and participant accepts the foregoing Disclaimer.
Thank you to our Sponsors, Supporters and Partners!

**Satellite Symposium (CEs)**
*Hosted by Medical Education Partners*

The Heart Failure Society of America acknowledges the following for providing an unrestricted educational grant to support this year’s Satellite Symposia.

- Cleveland Clinic
- Clinical Care Options supported by AstraZeneca
- Clinical Care Options supported by Boehringer Ingelheim Pharmaceuticals, Inc./Lilly USA
- Medscape supported by American Regent
- Medscape supported by Cytokinetics
- Peerview supported by Bristol Myers Squibb
- Vindico supported by Merck & Co. Inc.
- Voxmedia supported by AstraZeneca

**Hands-on & Interactive Workshops (CEs)**

The Heart Failure Society of America acknowledges the following for providing an unrestricted educational grant and/or in-kind donations to support this year’s workshops.

*Supported by in-kind educational donations from:*

- Abbott
- GETINGE
- Vyaire Medical

**Industry Expert Theaters (No CEs)**

- Boehringer Ingelheim Pharmaceuticals, Inc./Lilly USA
- Bristol Myers Squibb
- CVRx
- Cytokinetics
- GETINGE
- Lexicon Pharmaceuticals, Inc.
- Pfizer

**Contemporary Forums (No CEs)**

- Alnylam Pharmaceuticals, Inc.
- Attralus
- Cytokinetics
- Daiichii Sankyo, Inc.
- Merck & Co. Inc.
- Prothena
2023 Award Recipients

2023 HFSA Lifetime Achievement Award
Randall Starling, MD, MPH, FHFSA
This award is presented by the Executive Council of the HFSA to recognize a lifetime body of work by an individual who has made a significant and sustained contribution to the field of heart failure.

2023 Distinguished HFSA Member Award
Sara Paul, DNP, FNP, FHFSA
This award is intended to celebrate a member's body of work in the field of heart failure and their work and service to the Heart Failure Society of America. Intended for non-physician members of HFSA.

2023 Outstanding Heart Failure Care Team Award
Pediatric Heart Failure Team at Texas Children's Hospital
This award celebrates the accomplishments of a Heart Failure Care Team, collectively.

2023 HFSA Pioneer Award
Jeffrey Towbin, MD, FHFS, FACC, FAAP, FAHA
This award is given to an innovator and pioneer in the field of heart failure. The award notes the HFSA member's innovative role in heart failure, which helps to set the stage for future generations of heart failure providers.

2023 HFSA Distinguished Leadership Award
Christopher O’Connor, MD, FHFSA
This award celebrates a leader in the field of heart failure in the areas of education and mentorship.

2023 HFSA Nursing Clinical Excellence Leadership Award
Laura Peters, DNP, FNP, FHFSA
This award honors and supports clinical nursing excellence by a registered nurse who works directly with heart failure patients, their families, and other nurses providing heart failure services.

2023 HFSA Nursing Research Leadership Award
Miyeon Jung, PhD, MSN, BSN, FAHA
This award honors those with extraordinary achievement and excellence in nursing science that improves outcomes of patients with heart failure.

2023 Thomas L. Force Memorial Lecture
Bonnie Ky, MD, MSCE
Selected by the ASM Program Chairs Session: Cardio-Oncology Saturday, October 7 | 2:45 PM - 4:00 PM | Ballroom A

JNC New Investigator Award – Basic and Clinical
Presentations: Sunday, October 8 | 10:45 AM - 11:45 AM | 25C
Announcement: Monday, October 9 | 12:00 PM | Ballroom A

Nurse Investigator Award – Research and Clinical
Presentations: Sunday, October 8 | 2:00 PM - 3:00 PM | 25C
Announcement: Monday, October 9 | 12:00 PM | Ballroom A
## Schedule at a Glance

### Friday, October 6, 2023

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00PM - 4:00PM</td>
<td>26 B/C</td>
<td>TEACH Workshop <em>(Pre-Registration Required)</em></td>
</tr>
<tr>
<td>4:00PM - 5:00PM</td>
<td>Ballroom C</td>
<td>1\textsuperscript{st} Annual HFSA Case Competition</td>
</tr>
<tr>
<td>5:00PM - 6:00PM</td>
<td>Ballroom A</td>
<td>“The State of the Specialty” Town Hall</td>
</tr>
<tr>
<td></td>
<td>25C</td>
<td>Engaging Cardiovascular Team Clinicians in Clinical Trial Research and Quality Improvement</td>
</tr>
<tr>
<td>6:15PM - 7:45PM</td>
<td>Exhibit Hall</td>
<td>Opening Reception</td>
</tr>
<tr>
<td>6:30PM - 7:30PM</td>
<td>Theater 1</td>
<td>Transthyretin Cardiac Amyloidosis*: The Importance of Early Diagnosis and Treatment *Also known as transthyretin amyloid cardiomypathy (ATTR-CM) *Sponsored by Pfizer</td>
</tr>
<tr>
<td></td>
<td>Theater 2</td>
<td>Barostim and The Window of Opportunity in Class II/III HFrEF Patients *Sponsored by CVRx</td>
</tr>
<tr>
<td></td>
<td>Research Hub</td>
<td>Mentorship for Translational Investigators</td>
</tr>
<tr>
<td>8:00PM - 9:30PM</td>
<td>Room 1</td>
<td>Heart in Jeopardy: Innovations in Hypertrophic Cardiomyopathy *Provided by Medscape and supported through an independent educational grant from Cytokinetics</td>
</tr>
<tr>
<td></td>
<td>Room 6</td>
<td>The First and Only Treatment for ID in Adult Patients with HF *Sponsored by Daiichi Sankyo, Inc.</td>
</tr>
</tbody>
</table>

### Saturday, October 7, 2023

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30AM - 8:45AM</td>
<td>Room 3</td>
<td>Improving Outcomes with SGLT2 Inhibitors in Patients with Heart Failure: From Evidence to Clinical Practice *Provided by Voxmedia and HFSA and supported through an independent educational grant from AstraZeneca</td>
</tr>
<tr>
<td></td>
<td>Room 5</td>
<td>Demystifying Diagnosis and Treatment of Iron Deficiency in Heart Failure *Provided by Medscape and supported through an independent educational grant from American Regent</td>
</tr>
<tr>
<td>7:30AM - 9:00AM</td>
<td>26A</td>
<td>From Policy to Patient: Closing the Gaps in Disparities in Care in HF and HCM *Sponsored by Cytokinetics</td>
</tr>
<tr>
<td></td>
<td>25C</td>
<td>Harnessing the Power of an RNAi Therapeutic to Silence TTR Expression *Sponsored by Alnylam Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>8:00AM - 8:30AM</td>
<td>PIT Lounge</td>
<td>Round Table Session: Networking - How to Find Your Tribe</td>
</tr>
<tr>
<td>8:00AM - 9:00AM</td>
<td>Research Hub</td>
<td>HFSA HFRN Update: Obstacle and Opportunities</td>
</tr>
<tr>
<td></td>
<td>Exhibit Hall</td>
<td>ePoster Viewing and Oral Abstract Sessions II</td>
</tr>
<tr>
<td>8:30AM - 9:00AM</td>
<td>PIT Lounge</td>
<td>Round Table Session: Career Options for AHF Specialists</td>
</tr>
<tr>
<td>9:00AM - 11:00AM</td>
<td>Ballroom B</td>
<td>Presidential Plenary Session - Opening Remarks: President’s Address and Award Announcements - Opening Keynote Address: The Promise of Gene-Targeted Therapies in Heart Failure *Presented by Elizabeth McNally, MD, PhD (Northwestern University)</td>
</tr>
<tr>
<td>Time</td>
<td>Location</td>
<td>Event Description</td>
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<tr>
<td>11:15AM - 12:15PM</td>
<td>Ballroom A</td>
<td>Heart Failure Editor's Forum: Journal Visions, Multi-Disciplinary Efforts, Top Science and Role in Increasing HF Clinicians</td>
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<tr>
<td></td>
<td>Ballroom C</td>
<td>Approach to Suspected HFpEF Evaluation in 2023</td>
</tr>
<tr>
<td></td>
<td>26A</td>
<td>Contemporary Management of Cardiac Sarcoidosis</td>
</tr>
<tr>
<td></td>
<td>26 B/C</td>
<td>Remote Care in Heart Failure Post Pandemic</td>
</tr>
<tr>
<td></td>
<td>25C</td>
<td>The Heart Allocation System in the United States</td>
</tr>
<tr>
<td>12:30PM - 1:30PM</td>
<td>PIT Lounge</td>
<td>Leadership Session: Top 5 Skills for Becoming an Executive Leader</td>
</tr>
<tr>
<td>12:30PM - 2:30PM</td>
<td>Exhibit Hall</td>
<td>Lunch in Exhibit Hall</td>
</tr>
<tr>
<td>1:00PM - 2:00PM</td>
<td>HFS Lounge</td>
<td>Nurse Networking Lunch: Celebrating Nurses!</td>
</tr>
<tr>
<td></td>
<td>Exhibit Hall</td>
<td>Al and Heart Failure Research</td>
</tr>
<tr>
<td>1:00PM - 2:30PM</td>
<td>Exhibit Hall</td>
<td>ePoster Viewing and Oral Abstract Sessions III</td>
</tr>
<tr>
<td>1:15PM - 2:15PM</td>
<td>Theater 1</td>
<td>Guideline-Directed Medical Therapy and the Role of SGLT2is <strong>Sponsored by Boehringer Ingelheim Pharmaceuticals, Inc./Lilly USA</strong></td>
</tr>
<tr>
<td></td>
<td>Theater 2</td>
<td>Elevating the Impact of Obstructive Hypertrophic Cardiomyopathy: A Conversation Between Providers and Patients <strong>Sponsored by Cytokinetics</strong></td>
</tr>
<tr>
<td>1:30PM - 2:00PM</td>
<td>JCF Central</td>
<td>JCF Lecture Series: Heart Failure Epidemiology and Outcomes Statistics</td>
</tr>
<tr>
<td>2:45PM - 4:00PM</td>
<td>Ballroom A</td>
<td>Advances in Cardio-Oncology <strong>Thomas L. Force Memorial Lecture presented by Bonnie Ky, MD</strong></td>
</tr>
<tr>
<td></td>
<td>Ballroom C</td>
<td>FDA Special Session: Subgroups and Subpopulations in HF Clinical Trials</td>
</tr>
<tr>
<td></td>
<td>26A</td>
<td>Challenges in Diagnosis and Management of Cardiac Amyloidosis</td>
</tr>
<tr>
<td></td>
<td>25C</td>
<td>Late Breaking Clinical Trial: Rapid Fire Oral Abstracts</td>
</tr>
<tr>
<td>2:45PM - 4:15PM</td>
<td>25 A/B</td>
<td>Hands-On Workshop: Cardiogenic Shock <strong>Limited Capacity</strong></td>
</tr>
<tr>
<td>4:30PM - 5:30PM</td>
<td>Hilton Superior A/B</td>
<td>Speed Mentoring <strong>Pre-Registration Required</strong></td>
</tr>
<tr>
<td>4:45PM - 5:45PM</td>
<td>Exhibit Hall</td>
<td>ePoster Viewing and Oral Abstract Sessions IV</td>
</tr>
<tr>
<td>5:00PM - 6:00PM</td>
<td>Research Hub</td>
<td>Updates on Incorporating Patient-Reported Outcomes in HF Research</td>
</tr>
<tr>
<td>5:30PM - 7:00PM</td>
<td>Exhibit Hall</td>
<td>Poster Reception</td>
</tr>
<tr>
<td>6:00PM - 7:00PM</td>
<td>Theater 1</td>
<td>A Review of Long-Term Outcomes for Cardiac Myosin Inhibition in Adults with NYHA Class II-III Obstructive HCM <strong>Sponsored by Bristol Myers Squibb</strong></td>
</tr>
<tr>
<td></td>
<td>Theater 2</td>
<td>Reviving Hearts, Renewing Lives: The Evolution of Counterpulsation in Heart Failure <strong>Sponsored by GETINGE</strong></td>
</tr>
<tr>
<td></td>
<td>Exhibit Hall</td>
<td>ePoster Viewing and Oral Abstract Sessions V</td>
</tr>
<tr>
<td></td>
<td>HFS Lounge</td>
<td>Women in Heart Failure Reception <strong>Hosted by the Women in Heart Failure Committee in partnership with Women in Heart Transplantation and MCS</strong></td>
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<tr>
<td>Time</td>
<td>Room/Location</td>
<td>Event Description</td>
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<tr>
<td>6:45AM - 8:00AM</td>
<td>Room 3</td>
<td>Following the Evolution of Cardiac Myosin Inhibition: Remodeling Clinical Workflows to Realize the Greatest Benefit in oHCM and Beyond Provided by Peerview and supported through an independent educational grant from Bristol Myers Squibb</td>
</tr>
<tr>
<td>7:00AM - 8:00AM</td>
<td>Room 6</td>
<td>Addressing Risk of HF Rehospitalization with an Additional Guideline-Recommended Medication Sponsored by Merck &amp; Co., Inc.</td>
</tr>
<tr>
<td>7:00AM - 8:15AM</td>
<td>Room 5</td>
<td>The New Standard of Care: Leveraging the Benefits of SGLT2 Inhibitors Across the Heart Failure Spectrum Provided by Clinical Care Options and HFSA and supported through an independent educational grant from Boehringer Ingelheim Pharmaceuticals, Inc./Lilly USA</td>
</tr>
<tr>
<td>8:00AM - 9:00AM</td>
<td>Exhibit Hall</td>
<td>ePoster Viewing and Oral Abstract Sessions VI</td>
</tr>
<tr>
<td>8:15AM - 8:45AM</td>
<td>PIT Lounge</td>
<td>FHFSA Information Session</td>
</tr>
<tr>
<td>8:15AM - 8:45AM</td>
<td>26A</td>
<td>What You Need to Know in 30 Minutes: Sleep Apnea in Heart Failure</td>
</tr>
<tr>
<td>8:15AM - 8:45AM</td>
<td>26 B/C</td>
<td>What You Need to Know in 30 Minutes: Urine Sodium to Manage Acute Heart Failure</td>
</tr>
<tr>
<td>8:15AM - 8:45AM</td>
<td>25C</td>
<td>What You Need to Know in 30 Minutes: Frailty Assessment and Cardiac Rehabilitation in Patients with HF</td>
</tr>
<tr>
<td>9:00AM - 10:30AM</td>
<td>Ballroom B</td>
<td>Sunday Plenary Session: HFSA Spotlight on Late Breaking Clinical Trials -HFSA Membership Update and Award Announcements -Late Breaking Clinical Trial Abstract Presentations</td>
</tr>
<tr>
<td>10:45AM - 11:45AM</td>
<td>Ballroom A</td>
<td>The Future of Machines</td>
</tr>
<tr>
<td>10:45AM - 11:45AM</td>
<td>Ballroom C</td>
<td>New Paradigms of Care in Hypertrophic Cardiomyopathy</td>
</tr>
<tr>
<td>10:45AM - 11:45AM</td>
<td>26A</td>
<td>The Importance of Implementation</td>
</tr>
<tr>
<td>10:45AM - 11:45AM</td>
<td>26 B/C</td>
<td>Hot Topics in HF: Management of Anemia and Iron Deficiency</td>
</tr>
<tr>
<td>10:45AM - 11:45AM</td>
<td>25C</td>
<td>Jay N. Cohn (JNC) New Investigator Award Presentations</td>
</tr>
<tr>
<td></td>
<td>25 A/B</td>
<td>Hands-On Workshop: Genetics in Heart Failure (Limited Capacity)</td>
</tr>
<tr>
<td>12:00PM - 1:00PM</td>
<td>PIT Lounge</td>
<td>Leadership Session: Fundamentals of Negotiation, Consensus Building, and Managing Change Featuring Liz Peschges, MBA, Vice President of Culture &amp; Strategy of the Rock &amp; Roll Hall of Fame</td>
</tr>
<tr>
<td></td>
<td>Research Hub</td>
<td>Clinical Research in VAD Patients: Evidence for Best Practice</td>
</tr>
<tr>
<td>12:00PM - 2:00PM</td>
<td>Exhibit Hall</td>
<td>Heart Failure Team Lunch - Where Heart Failure Teams Gather!</td>
</tr>
<tr>
<td>12:15PM - 1:45PM</td>
<td>JCF Central</td>
<td>JCF Lecture Series: Pregnancy and Heart Failure</td>
</tr>
<tr>
<td>12:15PM - 1:45PM</td>
<td>Exhibit Hall</td>
<td>ePoster Viewing and Oral Abstract Sessions VII</td>
</tr>
<tr>
<td>Time</td>
<td>Location</td>
<td>Session Description</td>
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<tr>
<td>12:30PM - 1:30PM</td>
<td>Theater 1</td>
<td>Guidance for Implementing Cardiac Myosin Inhibition Treatment in Clinical Practice:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A Case-Based Presentation in Patients with Obstructive HCM **Sponsored by Bristol</td>
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<td></td>
<td>Myers Squibb**</td>
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<tr>
<td></td>
<td>Theater 2</td>
<td>Harnessing SGLT Inhibition in Heart Failure **Sponsored by Lexicon Pharmaceuticals,</td>
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<td>Inc.</td>
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<tr>
<td>1:00PM - 1:30PM</td>
<td>PIT Lounge</td>
<td>Round Table Session: Meet the Editors of Heart Failure Journals **Includes: JCF, JACC</td>
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<tr>
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<td>HF, Journal of HLT</td>
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<tr>
<td>1:00PM - 2:00PM</td>
<td>Research Hub</td>
<td>Designing Pragmatic Clinical Trials for Heart Failure</td>
</tr>
<tr>
<td>1:30PM - 2:15PM</td>
<td>PIT Lounge</td>
<td>Round Table Session: Women in Heart Failure - Opportunities and Challenges</td>
</tr>
<tr>
<td>2:00PM - 3:00PM</td>
<td>Ballroom A</td>
<td>Practical Implementation of Guideline-Directed Medical Therapy in Heart Failure</td>
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<td>Ballroom C</td>
<td>Managing Congestion: Targeting Pressure vs Volume</td>
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<td>26A</td>
<td>Electrophysiology Considerations in Heart Failure</td>
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<td>26 B/C</td>
<td>Structural Interventions for Heart Failure: Challenges and Controversies</td>
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<td>25C</td>
<td>Nursing New Investigator Award Presentations</td>
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<td>3:15PM - 4:45PM</td>
<td>Ballroom A</td>
<td>Targeting Obesity to Treat Heart Failure</td>
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<td>Ballroom C</td>
<td>Artificial Intelligence &amp; Machine Learning: The Future is Now or Later?</td>
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<td>26A</td>
<td>Different Tools-Same Goals: Heart Failure on the Global Stage **Mihai Gheorghiade</td>
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<td>Lecture presented by Carolyn Lam, MD</td>
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<td>26 B/C</td>
<td>Current Electrophysiology Perspectives in LVAD Patients</td>
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<td>25 A/B</td>
<td>Hands-On Workshop: CPET Basics <strong>Limited Capacity</strong></td>
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<td>5:00PM - 6:00PM</td>
<td>Room 1</td>
<td>Transthyretin Amyloid Cardiomyopathy (ATTR-CM): Best Practices for Successful Outcomes in Patients with Heart Failure <strong>Provided by Voxmedia and HFSA and supported through an independent educational grant from AstraZeneca</strong></td>
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<td></td>
<td>Room 5</td>
<td>Striking a Balance: Managing Hyperkalemia in Heart Failure Patients with Chronic Kidney Disease <strong>Provided by Clinical Care Options and supported through an independent educational grant from AstraZeneca</strong></td>
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<td>5:30PM - 6:30PM</td>
<td>Hilton Superior D</td>
<td>JCF Reception</td>
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<td>7:00PM - 9:30PM</td>
<td>Rock &amp; Roll Hall of Fame</td>
<td>The Heart of Rock &amp; Roll Reception at the Rock &amp; Roll Hall of Fame <strong>(Secure Your Ticket at Registration)</strong></td>
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**Monday, October 9, 2023**

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<tr>
<th>Time</th>
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<tr>
<td>7:30AM - 8:45AM</td>
<td>Room 6</td>
<td>Unfolding Advanced Light Chain (AL) Amyloidosis with Cardiac Dysfunction: From Diagnostic Challenges to Emerging Therapies <strong>Sponsored by Prothena</strong></td>
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<tr>
<td>9:00AM - 10:30AM</td>
<td>Ballroom B</td>
<td>Monday Plenary Session: HFSA Spotlight on Featured Clinical Science - Incoming Presidential Address and Award Announcements - Clinical Trial Update Abstract Presentations</td>
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Schedule at a Glance

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<td>Ballroom C</td>
<td>HFpEF Mechanisms of Disease: New Insights and Therapeutic Implications</td>
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<td>26A</td>
<td>Value Based Payment &amp; the Business of Heart Failure</td>
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<td>Cardiogenic Shock Management</td>
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<td>25 A/B</td>
<td>Hands-on Workshop: LVAD Troubleshooting/Devices (Limited Capacity)</td>
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<td>12:00PM - 1:00PM</td>
<td>Ballroom A</td>
<td>Great Debates in Heart Failure</td>
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<td>Ballroom C</td>
<td>Novel Implementation Strategies and How-to</td>
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<td>26A</td>
<td>Caring for the Pregnant Patient with Heart Failure</td>
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<td>26 B/C</td>
<td>Pulmonary Hypertension and RV Failure in Advanced Heart Failure</td>
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Looking for detailed CE information? View the CE Book here!

The official mobile app for the HFSA Annual Scientific Meeting 2023

Easily access all session details and abstracts, along with speakers and exhibitors. Personalize your schedule, bookmark sessions, and more!

DOWNLOAD THE APP NOW!
Satellite symposia provide opportunities to learn about new and emerging clinical options that complement the education offered in the official scientific program. While not part of the official scientific program, these industry-supported symposia are an important part of the ASM as they are planned to meet the same standards of evidence, scientific rigor, and fair balance as scientific sessions.

**Friday, October 6**

**Heart in Jeopardy: Innovations in Hypertrophic Cardiomyopathy**
8:00 PM - 9:30 PM | Room 1
Sara Saberi, MD, MS / Ahmad Masri, MD, MS / Florian Rader, MD, MSc
*Provided by Medscape and supported through an independent educational grant from Cytokinetics*

**Saturday, October 7**

**Improving Outcomes with SGLT2 Inhibitors in Patients with Heart Failure: From Evidence to Clinical Practice**
7:30 AM - 8:45 AM | Room 3
Muthiah Vaduganathan, MD, MPH / Stephen Greene, MD / Mikhail Kosiborod, MD / Alanna Morris, MD, MSc
*Provided by Voxmedia and HFSA and supported through an independent educational grant from AstraZeneca*

**Demystifying Diagnosis and Treatment of Iron Deficiency in Heart Failure**
7:30 AM – 8:45 AM | Room 5
Andrew P. Ambrosy, MD / Gregory D. Lewis, MD / Nosheen Reza, MD
*Provided by Medscape and supported through an independent educational grant from American Regent*

**Evolving Concepts for Heart Failure Treatment and Recovery at Cleveland Clinic**
7:15 PM – 8:45 PM | Room 1
Maria Mountis, DO / Randall C. Starling, MD, MPH / Edward Soltesz, MD, MPH
Nancy Albert, CNS, PhD / Pavan Bhat, MD / Eileen Hsich, MD / Samir Kapadia, MD / M. Trejeeve (Tre) Martyn, MD / W.H. Wilson Tang, MD / Michael Tong, MD, MBA / Sara Ward, PharmD
Amit Goyal, MD
*Provided by the Cleveland Clinic*

**Key Insights to Optimize the Management of HFrEF and Role of sGC Modulators**
7:15 PM – 8:45 PM | Room 4
James L. Januzzi, MD, FACC, FESC / Biykem Bozkurt, MD, PhD, FACC, FAHA, FHFSA / Javed Butler, MD, MPH, MBA
*Provided by Vindico and supported through an independent educational grant from Merck & Co., Inc.*
**Sunday, October 8**

**Following the Evolution of Cardiac Myosin Inhibition: Remodeling Our Clinical Workflows to Realize the Greatest Benefit in oHCM and Beyond**
7:00 AM - 8:00 AM | Room 3
Milind Desai, MD, MBA / Anjali Tiku Owens, MD

*Provided by Peerview and supported through an independent educational grant from Bristol Myers Squibb*

**The New Standard of Care: Leveraging the Benefits of SGLT2 Inhibitors Across the Heart Failure Spectrum**
7:00 AM – 8:15 AM | Room 5
Javed Butler, MD, MPH, MBA / Lee Goldberg, MD, MPH

*Provided by Clinical Care Options and HFSA and supported through an independent educational grant from Boehringer Ingelheim Pharmaceuticals, Inc. / Lilly USA*

**Transthyretin Amyloid Cardiomyopathy (ATTR-CM): Best Practices for Successful Outcomes in Patients with Heart Failure**
5:00 PM – 6:00 PM | Room 1
Matthew Maurer, MD / Ahmad Masri, MD, MS / Brett Sperry, MD

*Provided by Voxmedia and HFSA and supported through an independent educational grant from AstraZeneca*

**Striking a Balance: Managing Hyperkalemia in Heart Failure Patients with Chronic Kidney Disease**
5:00 PM – 6:00 PM | Room 5
Ileana L. Pina, MD, MPH, FAHA, FACC, FHFSAn / Biykem Bozkurt, MD, PhD, FACC, FAHA, FHFSAn

*Provided by Clinical Care Options and supported through an independent educational grant from AstraZeneca*
Industry Expert Theaters are non-CEU educational activities that allow industry experts to provide clinical updates and educate attendees on current therapies, disease states, products, and pipeline activities. Sessions are formatted for learning and are a great way to receive higher level interaction and engagement with company representatives.

Educational activities held in the exhibit hall do not provide continuing education credit.

**Friday, October 6**

**Transthyretin Cardiac Amyloidosis*: The Importance of Early Diagnosis and Treatment**

*Also known as transthyretin amyloid cardiomyopathy (ATTR-CM)*

6:30 PM – 7:30 PM | Industry Expert Theater 1, Exhibit Hall

**Description:** ATTR cardiac amyloidosis is a serious, underrecognized and underdiagnosed cause of heart failure. Early recognition of clinical clues and accurate diagnosis are crucial to starting patients on the appropriate continuum of care. Join us to raise awareness of the signs and symptoms of ATTR cardiac amyloidosis, and the role cardiac specialists can play in potentially shortening the length of time to diagnosis and intervention. The program will end with an overview of a treatment option for patients with ATTR cardiac amyloidosis.

*Sponsored by Pfizer*

**Barostim and The Window of Opportunity in Class II/III HFrEF Patients**

6:30 PM – 7:30 PM | Industry Expert Theater 2, Exhibit Hall

**Faculty:** Dmitry Yaranov, MD / Rachel Garcia, MD / Gurusher Panjrat, MD / William Abraham, MD

**Description:** This Industry Expert theater will discuss the unmet needs with guideline-directed medical therapy, and review the latest in clinical data, mechanism of action, patient selection, and real world outcomes for the use of Barostim in patients with HFrEF.

**Learning Objectives:**

- Discuss challenges, and opportunities for guideline-directed medical therapy in HFrEF
- Describe the mechanism of action of baroreflex activation therapy (BAT)
- Review the latest clinical data on the use of BAT in patients with heart failure
- Understand how BAT can be incorporated into an Advanced Heart Failure Program
- Discuss real world outcomes and patient identification strategies in Class II/III heart failure

*Sponsored by CVRx*

**Saturday, October 7**

**Guideline-Directed Medical Therapy and the Role of SGLT2is**

1:15 PM – 2:15 PM | Industry Expert Theater 1, Exhibit Hall

**Faculty:** Javed Butler, MD, MPH, MBA / Kris Vijay, MD, MS, FACP, FACC, FNLA, FHfSA / Robert J. Chilton, DO, FACC, FAHA, FSCAI, MACOI / Lisa D. Rathman, MSN, CRNP, CHFN

**Description:** This expert panel will review the most recent guideline-directed medical therapies (GDMT) and the role of SGLT2 inhibitors. The panel will also review Jardiance® (empagliflozin) tablets clinical data, in addition to information on initiation and dosing. Attendees will have the opportunity to ask faculty questions about implementing GDMT and the data presented.

*Sponsored by Boehringer Ingelheim Pharmaceuticals, Inc./Lilly USA*
Elevating the Impact of Obstructive Hypertrophic Cardiomyopathy: A Conversation Between Providers and Patients
1:15 PM – 2:15 PM | Industry Expert Theater 2, Exhibit Hall
Faculty: Sara Saberi, MD, MS

Learning Objectives:
- Better understand symptomatic, obstructive hypertrophic cardiomyopathy (oHCM) and how it impacts patients and their families
- Drive awareness of the impact of the disease itself and identify how health care practitioners can help patients with quality of life considerations
- Discuss the psychological impact of oHCM and strategies to help improve the dialogue between patients and providers

Sponsored by Cytokinetics

A Review of Long-Term Outcomes for Cardiac Myosin Inhibition in Adults with NYHA Class II–III Obstructive HCM
6:00 PM – 7:00 PM | Industry Expert Theater 1, Exhibit Hall
Faculty: Richard Wright, MD, FACC

Description: Join this session to learn about cardiac myosin inhibition—its mechanism of action, pivotal study data, and long-term outcomes in adult patients with New York Heart Association (NYHA) Class II–III obstructive hypertrophic cardiomyopathy (HCM).

Learning Objectives:
- Review the mechanism of action of cardiac myosin inhibition and results from the pivotal Phase 3 studies in adult patients with symptomatic NYHA Class II–III obstructive HCM
- Present the long-term outcomes for cardiac myosin inhibition using extension data in adult patients with symptomatic obstructive HCM

Sponsored by Bristol Myers Squibb

Reviving Hearts, Renewing Lives: The Evolution of Counterpulsation in Heart Failure
6:00 PM – 7:00 PM | Industry Expert Theater 2, Exhibit Hall
Faculty: David A. Baran, MD, FACC, FSCAI, FHFSA / Ran Lee, MD / Shashank Sinha, MD, MSc, FACC, FAHA / Claudia Gidea, MD, FACC

Description: The program explores the impact of IABP on HF patients with restrictive myopathies, valvular/structural disease, as well as the benefits of optimizing patients before transplantation and VAD placement. Discover the potential of counterpulsation in HF management.

Sponsored by GETINGE
Sunday, October 8
Guidance for Implementing Cardiac Myosin Inhibition Treatment in Clinical Practice: A Case-Based Presentation in Patients with Obstructive HCM
12:30 PM – 1:30 PM | Industry Expert Theater 1, Exhibit Hall
Faculty: Mariko Harper, MD

Description: Join this session to overview the dosing and administration through cardiac myosin inhibition through illustrative patient cases outlining a real-world use situation with practical scenarios in patients with obstructive HCM. Additionally, review dosing and monitoring protocols with operational insights.

Learning Objectives:
• Review the Dosing and Administration guidance for cardiac myosin inhibition
• Present the dosing and monitoring protocol for implementing cardiac myosin inhibition in clinical practice
• Describe the appropriate real-world use of cardiac myosin inhibition product and potential clinical scenarios through illustrative patient cases

Sponsored by Bristol Myers Squibb

Harnessing SGLT Inhibition in Heart Failure
12:30 PM – 1:30 PM | Industry Expert Theater 2, Exhibit Hall
Faculty: Javed Butler, MD, MPH, MBA / Muthu Vaduganathan, MD, MPH, FACP / Deepak Bhatt, MD, MPH, FACC, FAHA, FESC, MSCAI / Anuradha Lala-Trindade (Anu Lala), MD, FACC, FHFS

Description: Revisit the continuing burden of HF and review the evolution of heart failure guidelines. Underscore the importance of initiating SGLTis upon stabilization and prior to hospital discharge in patients with heart failure transitioning to outpatient care. Explore the clinical features and benefits of newly approved INPEFA™, an inhibitor of SGLT2 and SGLT1, through an overview of its pivotal studies, SOLOIST-WHF and SCORED.

Learning Objectives:
• Understand the continuing burden of and unmet needs in heart failure
• Understand the impact and importance of early, inpatient initiation of GDMT, with SGLTis being a cornerstone therapy, in patients with heart failure
• Understand the outcomes of the INPEFA™ pivotal studies: SOLOIST-WHF and SCORED
• Understand the clinical opportunities for newly approved, INPEFA™ in hospitalized patients transitioning to outpatient care

Sponsored by Lexicon Pharmaceuticals, Inc.
Contemporary Forums are industry-supported sessions offering attendees clinical updates and education on current therapies, disease states, products and pipeline activities.

**Friday, October 6**

**The First and Only Treatment for ID in Adult Patients with HF**

8:00 PM – 9:30 PM | Room 6

**Description:** Attendees will walk away with an understanding of the prevalence and pathophysiology of ID/IDA in patients with heart failure, what signs and symptoms to be aware of in order to differentially diagnose, and the treatment goals and considerations. Injectafer® (ferric carboxymaltose injection) as an option to treat will be described as well as the clinical data and rationale supporting it’s indication.

**Learning Objectives:**
- The essential role of iron and iron repletion in patients with HF
- How to differentially diagnose ID and IDA and how it affects your treatment paradigm
- Current treatment guidelines and therapeutic goals for optimal management of patients
- Evidence for using Injectafer® (ferric carboxymaltose injection) and details on how to implement into clinical practice

*Sponsored by Daiichi Sankyo, Inc.*

**Saturday, October 7**

**From Policy to Patient: Closing the Gaps in Disparities in Care in HF and HCM**

7:30 AM – 9:00 AM | Room 26A

**Faculty:** Ahmad Masri, MD, MS / Nihar Desai, MD, MPH / Jagpreet Chhatwal, PhD / Karen Van Nuys, PhD

**Learning Objectives:**
- Better understand how public health policy has addressed disparities of care in Heart Failure
- Drive awareness of how the progressive landscape in HF can inform emergent models of care in Hypertrophic Cardiomyopathy (HCM)
- Examine health economic and predictive modeling as a conduit for new insights to understanding acute cardiovascular conditions

*Sponsored by Cyokinetics*

**Harnessing the Power of an RNAi Therapeutic to Silence TTR Expression**

7:30 AM – 9:00 AM | Room 25C

**Faculty:** Marcus Anthony Urey, MD

**Description:** Join us Saturday, October 7, at 7:30 AM in room 25C for an engaging presentation to learn about an RNAi therapeutic that reduces production of a disease-causing protein. Our faculty, Marcus Anthony Urey, MD, (University of California, San Diego) will discuss the disease and clinical profile of a treatment option. The presentation is sponsored by Alnylam.

**Learning Objectives:**
- Learn about an RNAi therapeutic and how it silences TTR expression
- Understand the clinical profile
- Patient support services through Alnylam Assist®

*Sponsored by Alnylam Pharmaceuticals, Inc.*
Anti-Amyloid Therapy: A Novel Approach in the Evolving Landscape of Cardiac Amyloidosis
7:15 PM – 8:45 PM | Room 6
Faculty: Matthew Maurer, MD / Dan Judge, MD / Lorena Saelices Gomez, PhD
Moderator: Ahmad Masri, MD, MS

Description: The symposium will review the evolving landscape of treatments for amyloidosis with a focus on the investigational therapeutic approach of directly targeting amyloid removal.

Learning Objectives:
- Educate on the pathobiology of cardiac amyloidosis and the preclinical rationale for directly targeting amyloid fibrils
- Identify unmet needs in cardiac amyloidosis
- Describe the current and developing treatment landscape
- Educate on endpoints utilized in cardiac amyloidosis trials
- Describe the currently available data on anti-amyloid therapy

Sponsored by Attralus

Sunday, October 8
Addressing Risk of HF Rehospitalization With an Additional Guideline-Recommended Medication
7:00 AM – 8:00 AM | Room 6
Faculty: Payal Kohli, MD

Learning Objectives:
- Discuss the increased risk of rehospitalization for HF with additional HFH
- Review an outcome study in high-risk patients with HFrEF

Sponsored by Merck & Co., Inc.

Monday, October 9
Unfolding Advanced Light Chain (AL) Amyloidosis with Cardiac Dysfunction: From Diagnostic Challenges to Emerging Therapies
7:30 AM – 8:30 AM | Room 6
Faculty: Ahmad Masri, MD, MS / Kevin Alexander, MD, FACC, FHFSA / Anita D’Souza, MD, MS

Description: Join our expert faculty for this Prothena-sponsored session as they discuss how patients with advanced light chain (AL) amyloidosis and cardiac dysfunction may present to cardiologists and provide strategies to avoid diagnostic pitfalls and delays. Faculty will also describe the high risk of early mortality in advanced AL amyloidosis with cardiac dysfunction and ongoing clinical trials of anti-amyloid therapies.

Learning Objectives:
- Describe how patients with advanced AL amyloidosis may present to cardiologists and strategies to avoid diagnostic pitfalls and delays
- Educate on the urgent unmet needs of patients with AL amyloidosis and advanced cardiac involvement
- Raise awareness of ongoing clinical trials of anti-amyloid therapies for the treatment of advanced AL amyloidosis

Sponsored by Prothena
**CTC-001**

**Study To Evaluate The Efficacy And Safety Of Birtamimab In Mayo Stage IV Patients With AL Amyloidosis (AFFIRM-AL)**

**Acronym:** AFFIRM-AL  
**Sponsor:** Prothena  
**Supporter:** Prothena  

**Description:** Phase 3 AFFIRM-AL Clinical Trial to Confirm Survival Benefit With Birtamimab in Mayo Stage IV AL Amyloidosis Observed in the Phase 3 VITAL Clinical Trial

**Background:** Light chain (AL) amyloidosis is a rare, progressive, and typically fatal hematologic disorder caused by plasma cells that produce misfolded light chains (LCs), resulting in amyloid deposits in tissues and organs that cause organ dysfunction and failure. Birtamimab is an investigational humanized monoclonal antibody that directly binds a conserved epitope on kappa and lambda LCs and is designed to neutralize circulating soluble LC aggregates and deplete deposited insoluble amyloid by promoting phagocytic clearance. VITAL was a Phase 3 randomized, double-blind, placebo (PBO)-controlled clinical trial (NCT02312206) in newly diagnosed, treatment-naive patients with AL amyloidosis. The trial was terminated early after an interim futility analysis. There was no significant difference in the primary composite endpoint (time to all-cause mortality [ACM] or time to cardiac hospitalization ≥ 91 days after first study drug infusion, although the hazard ratio [HR] numerically favored birtamimab + standard of care (SoC) over PBO + SoC (0.826, 95% confidence interval [CI]: 0.574, 1.189; P=0.303). A post hoc analysis of ACM over 9 months revealed a significant survival benefit (HR=0.413, 95% CI: 0.191, 0.895; P=0.021) in patients at high risk for early death (Mayo Stage IV). Post hoc analyses of secondary endpoints in Mayo Stage IV patients also supported clinical and functional benefits of birtamimab + SoC, with clinically meaningful improvements observed in health-related quality of life (assessed with the Short Form-36, version 2 Physical Component Summary score [SF-36v2 PCS]) and 6-minute walk test (6MWT) distance (both P<0.05) at 9 months. Overall, birtamimab was generally well tolerated, and rates of any-grade treatment-emergent adverse events (TEAEs), Grade ≥ 3 and serious TEAEs were generally similar between treatment arms. These results led to the confirmatory Phase 3 AFFIRM-AL trial of birtamimab + SoC in Mayo Stage IV patients (NCT04973137).

**Aims:** The AFFIRM-AL clinical trial is prospectively evaluating the efficacy and safety of birtamimab + SoC vs placebo + SoC in patients with Mayo Stage IV AL amyloidosis.

**Methods:** The Phase 3, global, double-blind, placebo-controlled AFFIRM-AL clinical trial will enroll up to 150 patients with newly diagnosed, treatment-naive Mayo Stage IV AL amyloidosis. Patients will receive either 24 mg/kg intravenous birtamimab or placebo every 28 days (both arms will also receive SoC, defined as concomitant chemotherapy with a first-line bortezomib-containing regimen). Patients will be randomly assigned 2:1 to birtamimab or placebo. The primary endpoint of AFFIRM-AL is time to ACM, which will be analyzed using a log-rank test. Secondary endpoints are change in 6MWT distance and SF-36v2 PCS score. Safety endpoints include adverse events, clinical laboratory observations, and immunogenicity analyses. The Phase 3 AFFIRM-AL study was designed under a Special Protocol Assessment agreement with the US FDA, at a significance level of 0.10.

**Conclusion/Summary:** Effective treatments to improve survival in AL amyloidosis are needed, particularly for patients with advanced cardiac involvement, as median overall survival for those with Mayo Stage IV disease is >6 months. Birtamimab is the only investigational therapeutic in which a survival benefit has been observed in a post hoc analysis of patients with Mayo Stage IV AL amyloidosis in VITAL. AFFIRM-AL is currently enrolling. These data were previously presented at the 64th American Society of Hematology Annual Meeting and Exposition held December 10-13, 2022, in New Orleans, LA, USA.

**CTC-002**

**GenePHIT, A Phase 2 Trial Of AB-1002 (formerly NAN-101), A Novel Gene Therapy For Congestive Heart Failure**

**Acronym:** GenePHIT  
**Sponsor:** Asklepios BioPharmaceutical, Inc., a Bayer Cell & Gene Therapy Platform Company  
**Supporter:** Asklepios BioPharmaceutical, Inc., a Bayer Cell & Gene Therapy Platform Company  

**Description:** Gene Phosphatase Inhibition Therapy (GenePHIT; NCT04179643) is a phase 2, adaptive, double-blind, placebo-controlled, randomized, multicenter trial evaluating the efficacy, safety, and tolerability of a single...
Clinical Trial Central

intracoronary infusion of AB-1002 for subjects with congestive heart failure. AB-1002 is an investigational adeno-associated virus (AAV) gene therapy composed of a novel cardiotoxic vector (AAV2i8) and a gene promoting increased expression of constitutively active inhibitor 1 (I-1c) in cardiac myocytes, resulting in inhibition of protein phosphatase-1, subsequent enhancement of SERCA2a activity, restoration of Ca2+ cycling, and increased cardiac contractility in the failing heart. An ongoing phase 1 trial (NCT04179643) of AB-1002 has demonstrated clinically meaningful improvements in New York Heart Association functional class (NYHA FC), left ventricular ejection fraction (LVEF), and 6-minute walk test distance (6MWT) results in subjects with NYHA Class III Heart Failure (HF). GenePHIT will include adults with nonischemic cardiomyopathy, LVEF 15%-35%, 6MWT >50 meters, and NYHA Class III HF who have been medically stable for ≥4 weeks while on guideline-directed medical therapy. Following screening, patients will be randomized to low- or high-dose AB-1002 or placebo, with outcomes assessed at 52 weeks. The primary efficacy endpoint will use a modified win ratio defined by a hierarchical evaluation of the following: CV-related death, NYHA FC, and change from baseline in LVEF, peak exercise VO2, and 6MWT. Key secondary efficacy endpoints include hospitalizations, ECG assessments, NT-proBNP levels, and safety. Participants will be monitored for an additional 4 years following the 52-week observation period.

CTC-003

Study Design And Rationale Of HEROIC-PKP2, A PHAse 1/2 Study Of The Safety And Efficacy Of Lx2020 Gene Therapy In Patients With Arrhythmogenic Cardiomyopathy Due To APLaKOPHilin-2 Pathogenic Variant

Acronym: HEROIC-PKP2
Sponsor: Lexeo Therapeutics
Supporter: Lexeo Therapeutics

Description: Arrhythmogenic cardiomyopathy (ACM) is a rare and life-threatening inherited cardiac disorder characterized by progressive myocardial fibrofatty replacement, increased risk of ventricular arrhythmias, and sudden cardiac death (SCD). Plakophilin-2(PKP2) gene mutations have been identified as a major cause of ACM. In the absence of any approved or effective therapy specifically indicated for ACM due to a PKP2 pathogenic variant (PKP2-ACM), affected patients receive standard of care (SOC) therapy, which can include antiarrhythmics, implantable cardioverter-defibrillators (ICDs), and ablation procedures. These therapies address the risk of SCD and can decrease arrhythmia burden but do not address the underlying cause of myocardial dysfunction and ACM. Hypothesis: LEXEO Therapeutics is developing LX2020(AAVrh.10hPKP2) as an AAV-based gene therapy designed to intravenously deliver a fully functional PKP2 gene to cardiac muscle for the treatment of PKP2-ACM. By increasing PKP2 protein levels in the heart, gene therapy could represent a transformative treatment for patients with PKP2-ACM. HEROIC-PKP2, a LEXEO-sponsored clinical trial testing the investigational gene therapy LX2020, is recruiting subjects across the US. Methods: HEROIC-PKP2 is a Phase 1/2, first in human, open-label, dose-escalating, multicenter trial to determine the safety and tolerability of LX2020 in adult subjects with PKP2-ACM. Assessments of cardiac function, structure, biomarkers, and other preliminary efficacy measures are also included to determine a dose of LX2020 that is most likely to have the best balance of benefit and risk. Eligible subjects include adults with a clinical diagnosis of PKP2-ACM (2010 revised Task Force Criteria), pathogenic or likely pathogenic variant in PKP2, frequent premature ventricular complexes, and ICDs. Up to 10 subjects may participate in this 52-week study starting with treatment and inpatient monitoring, followed by an outpatient monitoring period. A data safety monitoring board will review safety data. All subjects who receive LX2020 in this study will continue in a separate 4-year long term follow-up study. Discussion & Conclusion: HEROIC-PKP2 will evaluate the safety and preliminary efficacy of gene therapy for PKP2-ACM. Successful outcomes from this trial may pave the way for the development of gene therapies targeting other genetic causes of ACM and open new avenues for precision medicine in the management of cardiovascular diseases.

CTC-004

Danish Pragmatic Randomized Trial To Evaluate The Effect Of Heartlogic-guided Management On Heart Failure Outcomes (DANLOGIC-HF)

Acronym: DANLOGIC-HF
Sponsor: Center for Translational Cardiology and Pragmatic Randomized Trials, Department of Cardiology Copenhagen University Hospital - Herlev and Gentofte, Denmark
**Clinical Trial Central**

**Supporter:** Boston Scientific

**Description:** The DANLOGIC-HF trial is a pragmatic, registry-based, randomized controlled trial that is designed to evaluate the effects of HeartLogic-guided management on clinical outcomes in patients who are already implanted with HeartLogic-capable cardiac resynchronization therapy defibrillator (CRT-D) and implantable cardioverter-defibrillator (ICD) devices. All eligible patients in Denmark will be randomized 1:1 to either HeartLogic-guided management or to the control group. During the trial, the control group will receive usual care in the Danish health system without the involvement of the study group and will only be followed through the National registries. Consented patients in the HeartLogic arm will be contacted by a designated team at the central trial site in case of any HeartLogic alerts for evaluation and treatment decisions. These alerts will be managed according to a prespecified management guide. Any actions triggered by the alerts will be documented in an electronic case report form (eCRF). All other trial data will be retrieved from the Danish nationwide health registries for data collection including baseline information and endpoint data. There will be no mandatory follow-up visits scheduled in the trial. The primary objective will be to evaluate whether HeartLogic-guided management reduces the risk of a composite endpoint of hospitalization for heart failure or all-cause death (first event).

**CTC-005**

**A Phase 3, Multicenter, Randomized, Double-blind Trial To Evaluate The Efficacy And Safety Of Aficamten Compared To Placebo In Adults With Symptomatic Non-obstructive Hypertrophic Cardiomyopathy**

**Acronym:** N/A

**Sponsor:** Cytokinetics

**Supporter:** Cytokinetics

**Description:** Aficamten is a next-in-class cardiac myosin inhibitor undergoing evaluation for treatment of hypertrophic cardiomyopathy (HCM). ACACIA-HCM (CY6033) builds on results from REDWOOD-HCM Cohort 4, and is the first Phase 3 trial of aficamten in non-obstructive HCM (nHCM). This Phase 3, multicenter, randomized, double-blind trial will evaluate the effect of aficamten compared with placebo in approximately 420 participants with symptomatic nHCM. The study will consist of two parts: Day 1 to Week 36, for evaluation of the primary and secondary endpoints; and Week 36 to Week 72, for evaluation of cardiovascular outcomes. All participants will complete Part 1 and will then continue in a blinded fashion until the last participant has completed Week 36. The primary endpoint is change in Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) from baseline to Week 36. Secondary endpoints include changes from baseline in exercise performance by cardiopulmonary exercise testing (CPET), New York Heart Association (NYHA) Functional Class, N-terminal pro-B-type natriuretic peptide (NT-proBNP) levels, left atrial volume index (LAVI), and the incidence of clinical endpoints up to 72 weeks. Safety endpoints include the incidence of adverse events, incidence of left ventricular ejection fraction (LVEF) <50% plus signs and symptoms of worsening heart failure and/or an increase in NT-proBNP by 30% from last available value, and incidence of LVEF <40%. These results will add to data from ongoing Phase 3 trials in obstructive HCM (SEQUOIA-HCM and MAPLE-HCM) providing insights into the safety and efficacy of aficamten across the HCM spectrum.

**CTC-006**

**A Phase 3 Randomized Controlled Trial Comparing Aficamten Vs Metoprolol In Patients With Symptomatic Hypertrophic Cardiomyopathy And Left Ventricular Outflow Tract Obstruction**

**Acronym:** MAPLE-HCM

**Sponsor:** Cytokinetics

**Supporter:** Cytokinetics

**Description:** Metoprolol vs Aficamten in Patients with LVOT Obstruction on Exercise Capacity in HCM (MAPLE-HCM; NCT05767346) is a Phase 3, multicenter, randomized, double-blind, active-comparator trial evaluating the efficacy and safety of aficamten compared with metoprolol in adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). Approximately 170 eligible patients will be randomized 1:1 to aficamten or metoprolol. This study will evaluate the effect of treatment with aficamten compared with metoprolol on exercise capacity, measured by change in peak oxygen uptake (pVO2) on cardiopulmonary exercise testing (CPET), from baseline to Week 24. Secondary endpoints will evaluate the treatment effect of aficamten compared with metoprolol from baseline to Week 24 on New York Heart Association (NYHA) functional class, Kansas City Cardiomyopathy Questionnaire (KCCQ), post-Valsalva...
left ventricular outflow tract gradient (LVOT-G), cardiac biomarkers, and structural remodeling based on echocardiographic evaluation of left atrial volume index (LAVI) and left ventricular mass index (LVMI). Safety and tolerability will also be examined.

**CTC-007**

**Study Design And Rationale Of SUNRISE-FA, A Phase 1/2 Study Of The Safety And Efficacy Of LX2006 Gene Therapy In Participants With Cardiomyopathy Associated With Friedreich's Ataxia**

**Acronym:** SUNRISE-FA  
**Sponsor:** Lexeo Therapeutics  
**Supporter:** Lexeo Therapeutics

**Description:** Friedreich's ataxia (FA) is a rare autosomal recessive disease caused by a mutation in the frataxin (FXN) gene. It is a progressive, degenerative, and multi-system disorder and approximately 70% of these patients will develop FA cardiomyopathy. Hypertrophic cardiomyopathy, fibrosis, heart failure and arrhythmias are the cause of death in approximately two-thirds of Friedreich's ataxia patients. Despite this great burden of illness, there are currently no approved treatments for cardiac manifestations of FA.

**Hypothesis:** LEXEO Therapeutics is developing LX2006 (AAVrh.10hFXN), an AAV-based gene therapy delivered intravenously for the treatment of FA cardiomyopathy. LX2006 is designed to transfer the FXN gene to myocardial cells and increase frataxin levels in the mitochondria. In preclinical studies, LX2006 has demonstrated the ability to significantly reverse the cardiac phenotype. By increasing frataxin levels in the heart, gene therapy has the potential to reduce or stop the progression of heart disease in people living with FA. SUNRISE-FA, a LEXEO-sponsored clinical trial testing the investigational gene therapy, LX2006, is actively recruiting participants across the United States.

**Methods:** SUNRISE-FA is a Phase 1/2, first in human, dose-escalating, multicenter trial to determine the safety and tolerability of LX2006. Assessments of cardiac function, structure, biomarkers, and other preliminary efficacy measures are also included to determine a dose of LX2006 that is most likely to have the best balance of benefit and risk. Eligible subjects include adults (18 to 40 years) with a definitive diagnosis of FA (based on clinical phenotype and genotype) with evidence of cardiomyopathy. Approximately nine subjects may participate in the 52-week initial treatment and monitoring period followed by a 4-year long-term follow-up (LTFU) portion of the study for all participants who receive LX2006. A data safety monitoring board will review safety data.

**Discussion & Conclusion:** SUNRISE-FA will evaluate the safety and preliminary efficacy of gene therapy for cardiomyopathy associated with FA. Successful outcomes from this trial may provide a life-saving therapy for patients with FA and have the potential to serve as a milestone in gene therapy development for other elements of clinical illness and burden for patients with FA.

**CTC-008**

**DORAYA HF: Renal Vein Unloading With DORAYA Catheter**

**Acronym:** DORAYA HF  
**Sponsor:** Revamp Medical  
**Supporter:** Revamp Medical

**Description:** Acute heart failure can be complicated by diuretic resistance. A potential mechanism is renal venous hypertension and increased renal afterload. The Doraya catheter tests the hypothesis that by inhibiting venous return via the inferior vena cava, renal venous pressures are reduced, enhancing filtration and diuresis. The DORAYA HF trial is an early feasibility study to test the safety and tolerability of this treatment, and to obtain efficacy signals. The catheter is inserted into the femoral vein and left for 6-12 hours. The balloon is located immediately inferior to the renal vein, and its opening titrated to create a pressure gradient from the iliac vein to inferior vena cava of 5-10 mmHg. A pulmonary artery catheter is inserted to monitor hemodynamics. Foley catheter should be placed to accurately measure urine output. Other collected data include weights, patient symptoms, laboratory values.

**Inclusion Criteria:** Subject is hospitalized with primary diagnosis of ADHF. N-terminal-pro-brain natriuretic peptide (NT-proBNP) ≥1,000 pg/m or BNP≥250 pg/mL. Evidence of fluid overload. Subject insufficiently responds to IV diuretic therapy.

**Exclusion Criteria:** Systolic blood pressure < 90 mmHg at the time of screening. Acute myocardial infarction or acute coronary syndrome or cardiogenic shock or thoracentesis within past 14 days or cardiovascular
intervention within past 14 days. Complex congenital heart disease (e.g., Tetralogy of Fallot subjects, single ventricle physiology). Known active myocarditis, hypertrophic obstructive cardiomyopathy, infiltrative cardiomyopathy (e.g., amyloidosis), constrictive pericarditis or cardiac tamponade. Severe Aortic valvular disorder (i.e., hemodynamically relevant valvular diseases such as severe stenosis / severe regurgitation) or Severe mitral disease with planned intervention. Evidence of active systemic infection documented by either one of the following: fever >38°C/100°F, or ongoing uncontrolled infection (i.e., inflammatory parameters not decreasing despite > 48 hours of antibiotic treatment). Moribund subject or subject with severe or deteriorating damage in more than 3 critical body systems, based on investigator’s clinical judgement.

**Participating Centers:**
1. The Christ Hospital, Cincinnati, OH (contact Wendy Parker RN, PI Eugene S. Chung, MD)
2. Cleveland Clinic, Cleveland, OH (contact Teresa Fonk, PI Andrew Higgins, MD)
3. Montefiore Medical Center - Moses Campus, NY, NY (contact Julio Ramos MD, PI Daniel Sims, MD)
4. Columbia University, NY, NY (contact Lauren Privitera, PI Gabriel Sayer, MD)
5. Christian Hospital, St. Louis, MO (contact Paige Brown, PI Gil Vardi, MD)
6. Henry Ford Hospital, Detroit, MI (contact Kelsey Neaton, Gillian Grafton, MD)

**Study Contact:** Sahar Boostenay, 922544621243, sahar@revampmedical.com

**CTC-009**

A Prospective, Multi-center, Open Label, Randomized Control Clinical Trial Evaluating The Safety And Efficacy Of The CordellaTM; Pulmonary Artery Sensor System In New York Heart Association (NYHA) Class II - III Heart Failure Patients (PROACTIVE-HF-2 Trial)

**Acronym:** PROACTIVE-HF-2

**Sponsor:** Endotronix  
**Supporter:** Endotronix

**Description:** The relationship between ambulatory pulmonary artery pressures (PAP) and heart failure hospitalizations (HFH) in NYHA Class III HF has been consistently confirmed over the past 15 years. Randomized controlled trials CHAMPION, GUIDE-HF, and MONITOR-HF along with post-approval studies in US and Europe have demonstrated decreased HFH with PAP-guided management across all EF. A recent meta-analysis showed improved survival for HFrEF. Questions remain whether PAP-guided management improves upon standard blood pressure, weight, and symptom telemonitoring in NYHA II. PROACTIVE-HF-2 will address whether integration of PAP with telemonitoring will improve outcomes (Fig1). Unlike telemonitoring trials, pivotal PAP trials have blinded patients to PAP - restricting patient engagement, sense of control, and behavioral remodeling.

The Cordella system includes a hand-held reader to measure seated PAP and the Cordella HF System (CHFS) showing BP, weight, and symptoms (Fig2). To date, 614 NYHA III patients have been implanted (500 in PROACTIVE-HF, results pending).

PROACTIVE-HF-2 will enroll two patient cohorts (all EF) at risk for congestion, divided into NYHA II or III. In the NYHA II randomized cohort, half receive CHFS as active control, half receive CHFS with PAP added for patients and clinicians. The primary endpoint is HFH/cardiovascular mortality at 24 months, with key secondary endpoints including PAP change, patient sense of control over their HF, and changing RV function in relation to PAP.

Value from monitoring requires translation into actions. Patient access to approved PAP monitoring has previously been restricted by concern for potential adverse responses. The NYHA III cohort will be single-arm with open access to PAP. The primary endpoint is comparison to a 12-month performance goal of HFH or mortality. A main focus for this Class III cohort is refinement of personalized algorithms for PAP-guided therapies and patient self-management after stabilization of PAP within the target range. Clintrials.gov (NCT05934487)

**CTC-010**

A Phase 1, Randomized, Double-blind, Placebo-controlled, Single And Multiple Ascending Dose Study Of The Safety, Tolerability, Pharmacokinetics, And Pharmacodynamics Of Edg-7500 In Healthy Adults

**Acronym:** EDG-7500-101

**Sponsor:** Edgewise Therapeutics  
**Supporter:** Edgewise Therapeutics

**Description:** Hypertrophic cardiomyopathy (HCM) is a chronic, progressive disease of the sarcomere. A significant portion of affected individuals have at
least one identifiable mutation in a gene that encodes sarcomere proteins. Regardless of the genetic variant present, excess myosin-actin crossbridge formation in systole and diastole leads to hyperdynamic contraction and impaired relaxation. Over time these abnormalities lead to tissue remodeling characterized histologically by myocyte hypertrophy, myofilament disarray, microvascular remodeling, and fibrosis. Clinically, patients experience fatigue, exertional dyspnea, and an increased risk of sudden cardiac death. EDG-7500 is a novel, orally bioavailable, small molecule that slows the velocity of myocardial force generation though a direct sarcomere interaction. This molecule is initially being developed for the treatment of HCM (both obstructive and nonobstructive). Preclinical models demonstrate improved left ventricular compliance and distensibility and ameliorate hyperdynamic systolic function and LV outflow tract obstruction. Study EDG-7500-101 is a first-in-human randomized, double-blind, placebo-controlled study that will evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD). Initially, a dose range of EDG-7500 will be explored in single ascending dose escalation cohorts followed by planned once-daily (x 14 days) multiple ascending dose cohorts. Echocardiography at rest, and in some MAD cohorts after exercise, will be used to assess the effects of EDG-7500 on myocardial systolic and diastolic function. Dose and exposure response relationships with the resulting echocardiography parameters along with safety and tolerability will be used to select doses in subsequent HCM patient studies.

CTC-011

Node 301 Part 1 and Part 2 (Prespecified Pool Analysis Results)

Acronym: N/A
Sponsor: Milestone Pharmaceuticals
Supporter: Milestone Pharmaceuticals

Description: Paroxysmal supraventricular tachycardia (PSVT) is a heart rhythm disorder characterized by the sudden onset and termination of episodes of abnormally high heart rates. Clinical symptoms include heart palpitations, shortness of breath, dizziness, chest pain, and anxiety. PSVT incurs a substantial economic burden, in part due to its impact on healthcare costs including a frequent need for medical interventions and emergency department (ED) visits. Current treatments, including intravenous (IV) calcium channel blockers and IV adenosine, are effective for terminating PSVT episodes but are not feasible for self-administration in an outpatient setting due to the requirement for IV access. A rapidly acting therapy that patients could self-administer would give patients the ability to terminate acute PSVT without the need for direct medical supervision. Etripamil is a fast-acting, non-dihydropyridine L-type intranasal calcium channel blocker with a mechanism of action similar to other non-dihydropyridine calcium channel blockers. Etripamil slows atrioventricular (AV) nodal conduction and prolongs AV nodal refractoriness by inhibiting calcium ion influx through L-type calcium channels. The drug is designed to be rapidly inactivated by esterases that are ubiquitous in human blood. Etripamil nasal spray (NS) is intended for patients with AV-nodal dependent PSVT episodes when a vagal maneuver (VM), a technique sometimes used to treat rapid heartbeat conditions, is ineffective (as is often the case). The NODE-301 studies evaluated the efficacy and safety of the novel, fast-acting, investigational intranasal calcium channel blocker etripamil for conversion of PSVT in an at-home setting. This pre-specified, pooled analysis assessed the impact of etripamil on the need for additional medical intervention.