

# **AMENDMENT NO. 2 TO CLINICAL TRIAL AGREEMENT**

**Between**

**CardioPharm International, Inc.** ("Sponsor")

**and**

**Memorial Medical Center** ("Institution")

**Original Agreement Date:** January 15, 2022

**Amendment No. 2 Effective Date:** February 3, 2023

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## **RECITALS**

WHEREAS, Sponsor and Institution entered into a Clinical Trial Agreement dated January 15, 2022, as amended by Amendment No. 1 dated June 22, 2022 (collectively, the "Agreement"), for the conduct of Study Protocol No. CP-2847-301 (HEARTBEAT-3);

WHEREAS, Dr. Sarah Chen, the original Principal Investigator named in the Agreement, has relocated and is no longer available to serve as Principal Investigator;

WHEREAS, Dr. James Martinez, MD, FACC, has been identified and qualified to assume the role of Principal Investigator for the Study;

WHEREAS, the parties desire to formally amend the Agreement to reflect the change in Principal Investigator;

NOW, THEREFORE, in consideration of the mutual covenants herein, the parties agree as follows:

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## **AMENDMENTS**

## **1. Principal Investigator Designation**

All references in the Agreement to "**Dr. Sarah Chen**" as Principal Investigator are hereby deleted and replaced with "**Dr. James Martinez, MD, FACC**".

Specifically, without limitation:

- Article 1.4 (Definition of Principal Investigator)
- Article 3 (Principal Investigator Qualifications and Obligations)
- All Exhibits referencing the Principal Investigator

## **2. Updated PI Documentation**

The following documents for Dr. James Martinez are attached hereto and incorporated by reference:

- **Attachment 1:** Updated FDA Form 1572 (Statement of Investigator) signed by Dr. James Martinez
- **Attachment 2:** Curriculum Vitae of Dr. James Martinez
- **Attachment 3:** Medical License (State of Ohio) for Dr. James Martinez
- **Attachment 4:** Board Certification in Cardiology for Dr. James Martinez
- **Attachment 5:** Updated Delegation of Authority Log

These documents replace the corresponding documents for Dr. Sarah Chen previously filed as Exhibits D and E to the original Agreement.

## **3. PI Qualifications Reaffirmation**

Dr. James Martinez represents and warrants that he meets all qualifications set forth in Article 3.1 of the Agreement, including:

- (a) Qualification by training, education, and experience to conduct the Study;
- (b) Current, valid, and unrestricted medical license in the State of Ohio;

(c) Board Certification in Cardiology by the American Board of Internal Medicine;

(d) No debarment, disqualification, or sanctions under 21 U.S.C. § 335a;

(e) No exclusion from federal health care programs; and

(f) Commitment to comply with all Study obligations under the Agreement.

#### **4. Study Continuity**

The change in Principal Investigator does not affect any other terms of the Agreement. Dr. Martinez assumes full responsibility for ongoing Study conduct, including:

- Oversight of currently enrolled Study Subjects (12 patients enrolled as of February 1, 2023)
- Completion of remaining enrollment (8 patients to target of 20)
- Compliance with Protocol Version 2.0 (as amended)
- All PI obligations under Articles 3, 4, and 5 of the Agreement

#### **5. IRB Notification**

Institution confirms that the IRB has been notified of the Principal Investigator change and has approved Dr. Martinez as the new PI via IRB amendment dated January 20, 2023.

#### **6. No Budget Impact**

This Amendment does not modify Exhibit B-1 (Budget and Payment Schedule). All payment terms remain unchanged.

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### **GENERAL PROVISIONS**

#### **7. Ratification**

Except as specifically modified by this Amendment No. 2, all terms, conditions, and provisions of the Agreement, as previously amended by Amendment No. 1, shall remain in full force and effect and are hereby ratified and confirmed.

## **8. Effective Date**

This Amendment is effective as of February 3, 2023, upon execution by both parties.

## **9. Counterparts**

This Amendment may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

## **10. Governing Law**

This Amendment shall be governed by the laws of the State of Ohio, consistent with the Agreement.

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## **SIGNATURES**

### **CARDIOPHAM INTERNATIONAL, INC.**

By: \_\_\_\_\_

Name: Jennifer Kim

Title: Senior Director, Clinical Operations

Date: February 3, 2023

### **MEMORIAL MEDICAL CENTER**

By: \_\_\_\_\_

Name: Dr. Robert Johnson

Title: Director, Clinical Research Office

Date: February 3, 2023