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Executive Overview

Electrocardiographic effects of HBI-3000, a new drug for termination of atrial fibrillation, Product News.

Editorial

In this issue, we want to share an important recent publication in Hearth Rhythm O^2 by Dr. Jay W. Mason, in collaboration with HUYABIO International, and with the co-authorship of our Chief Scientist Fabio Badilini and Martino Vaglio from AMPS: *Electrocardiographic effects of HBI-3000 (sulcardine sulfate), a new drug for termination of atrial fibrillation*.

This paper outlines the electrocardiographic effects of a novel multi-channel blocker compound, where the analysis has been conducted using AMPS technologies. Specifically, the morphological features of the T wave and all of its segments are assessed using AMPS automated measurements, such as the J-to-T-peak and T-peak-to-T-end sub intervals. As with other recent similar efforts, this collaboration is a further, sound example of the value of AMPS technology to support specialized analyses required by complex compounds. The abstract follows:

BACKGROUND HBI-3000 (sulcardine sulfate) inhibits multiple cardiac ion channels in vitro including peak sodium current, late sodium current, L-type calcium current, and the rapid component of the delayed rectifier potassium channel current.

OBJECTIVE This study aimed to determine electrocardiographic effects, pharmacokinetics, safety, and tolerability of escalating doses of intravenously administered sulcardine in healthy volunteers.

METHODS In this first-in-human, randomized, double-blind, placebo-controlled, serial-cohort, dose-escalation study, 47 subjects were randomized to 6 cohorts of 8, each receiving 1 of 5 single ascending 30-minute intravenous infusions (20–600 mg) of HBI-3000 (sulcardine sulfate) or placebo in a 6:2 ratio.

RESULTS Clinically and statistically significant electrocardiographic effects were seen at the higher dose levels (180 mg, 360 mg, and 600 mg). At the probable therapeutic dose (360 mg), concentration-effect modeling predicted the following changes at the time of maximum plasma concentration (30 minutes): Fridericia-corrected QT interval, 13.50 ms; heart rate (HR), 7.70 beats per minute; PR, 17.53 ms; QRS, 7.81 ms; P-wave duration, 9.93 ms; HR corrected J to T peak interval (JTpc), 29.65 ms; and T peak to T end interval, 5.07 ms.

Peak plasma concentrations fell rapidly to negligible levels at 2 hours, associated with rapid redistribution from the central compartment. No significant adverse effects were observed, and no serious adverse events were reported.

CONCLUSION Sulcardine increased the QTc and PR intervals, QRS and P-wave durations, and HR dose dependently. The T-wave segment JTpc was significantly decreased, whereas the T peak to T end interval was significantly increased. These findings predict an anti–atrial fibrillation effect via inhibition of 1 or more cardiac ion channels. The strong block of the rapid component of the delayed rectifier potassium channel current was partially mitigated by JTp shortening, probably owing to late sodium current and L-type calcium current inhibition, reducing the

risk of proar-rhythmia by decreasing repolarization time.

KEYWORDS Antiarrhythmic drug; Atrial fibrillation; Cardioversion; Electrocardiogram; Ion channel

The full article, as well as other recent journal publications authored or co-authored by our staff can be found on the AMPS website

Products News

- ACG: continuous development of new features and bug fixes, release of ACG 2.2.0
- CER-S: release of version 4.8.2 (bug fixing) and start developing version 4.9.0
- ECG master: finalization of the first version for internal study
- ECGSolve: release of version 2.7.0
- The AMPS-GI telemetry product is currently under FDA review. The initial assessment has been received with only minor comments, and the response is currently being prepared.
  We do not anticipate any major issues, and the system is expected to be available in Q3 2026.