ASX ANNOUNCEMENT **26 April 2023**

CardieX receives FDA 510(k) Clearance for CONNEQT Pulse

Highlights:

- **The US FDA has granted 510(k) clearance for the CONNEQT Pulse vascular biometric monitor.**
- **The Pulse is CardieX's first medical device to incorporate CardieX subsidiary ATCOR's market-leading SphygmoCor® central blood pressure technology in a device targeted at new and significant clinical and consumer applications.**
- **Pulse incorporates a unique suite of vascular biomarkers and digital health insights not available on traditional blood pressure devices.**
- **Pulse's vascular biosensing technology is fully patented and trademarked.**
- **FDA clearance of the Pulse found it "substantially equivalent" to CardieX's XCEL SphygmoCor® device parameters.**
- **Outputs enable clinicians and consumers to gain a more comprehensive and precise insight into overall cardiovascular health and other vascular diseases.**
- **The Pulse is scheduled to be commercially available in Q3 of this year and will target new significant global markets in home health monitoring, remote patient monitoring, and decentralized clinical trials.**

CardieX Limited (ASX: CDX) (CardieX, the Company), is pleased to announce that it has been granted 510(k) clearance from the US Food and Drug Administration (FDA) for the CONNEQT Pulse (**Pulse**).

The Pulse is a world-first multi-use vascular biometric monitor that provides measurements of both brachial blood pressure (the pressure at your arm) and **central blood** pressure (the pressure at your heart/aorta) along with arterial waveform analysis and other unique vascular biomarkers.

As previously announced the Pulse is targeted at the home health, remote patient monitoring (**RPM**), and decentralized clinical trial (**DCT**) markets – markets that are not currently covered by the Company's existing suite of medical devices.

About CardieX's new FDA Cleared 'Pulse' Device

Developed by CardieX subsidiary CONNEQT Health (**CONNEQT**), the Pulse provides heart and vascular health insights previously only available in specialist doctor's offices, hospitals, and research facilities.

Unlike CardieX's existing suite of products, the Pulse is a "stand-alone" medical device in a form factor that is easy to use and operate without requiring specialist training.

Although the Pulse provides "substantially equivalent" outputs to CardieX's existing XCEL SphygmoCor device, it is targeted at significant new markets not currently served by the Company's existing product lines.

CardieX's XCEL SphygmoCor® will continue to be the flagship for the Company in its existing target markets where specialist health insights and research level data is required and where a medical clinician is able to take a reading.

The addition of the Pulse to our suite of products now provides an enhanced product offering together with our "on site" specialist monitoring solution (the "XCEL SphygmoCor"), a remote solution (the Pulse), and an ambulatory solution (the SunTech Oscar 2 "with SphygmoCor inside"). The new product portfolio will broaden the Company's exposure and relevance in a range of clinical trial opportunities and existing partnerships, and in time, will be further complemented with the launch of the CONNEQT Band wearable (once FDA cleared).

Powered by CardieX's patented SphygmoCor® technology, which has been used for over two decades by leading hospitals and research facilities all over the world, the Pulse incorporates a full suite of patented and trademarked heart and vascular biomarkers **not available in traditional blood pressure monitors**.

The Pulse measures multiple clinically relevant digital vascular biomarkers that will enable primary care clinicians, patients, and consumers alike to gain a much more comprehensive and precise picture of vascular health than a traditional brachial home blood pressure monitor.

The Pulse will be marketed under the Company's CONNEQT brand and is scheduled to be commercially available in Q3 of this year under the Company's current production plan which has been pursued in parallel to the receipt of anticipated FDA clearance.

The Importance of Central Blood Pressure

Research shows that central aortic pressures (the pressure in the aorta/heart) can be considered as having independent and higher predictive value for the consequences of hypertension such as heart disease, stroke, vascular disease and kidney failure relative to traditional brachial blood pressure.

This is because central pressures reflect the pressure directly exerted on vital organs such as the heart, brain and kidneys.

According to Ray Townsend, M.D., Director of Hypertension at the University of Pennsylvania:

> *"A traditional brachial cuff measures pressure in your arm, but that's not the same as the pressure in your heart,"*
>
> *To get an accurate picture of cardiovascular risk, Dr. Townsend says: "you need to measure central aortic systolic pressure and other vascular biomarkers because they can reveal underlying problems like arterial stiffness – a measure of the rigidity of blood vessel walls".*

Heart disease is the number one killer in the United States[1], with one person dying every 34 seconds according to the CDC. Under the newest guidelines, which were revised in 2018, nearly half of all American adults now meet the criteria for high blood pressure (defined as a reading over 130/80 mmHG).

The FDA's 510(k) clearance of the CONNEQT Pulse has the potential to dramatically help stem this epidemic by improving access to, and reliability of, remote patient monitoring with advanced biometric insights.

CONNEQT Pulse – Prescription Vascular Biometric Monitor with SphygmoCor® Technology:

CONNEQT Pulse

Pulse is an integral part of a new digital and device ecosystem built upon CardieX's SphygmoCor® central blood pressure technology. Previous FDA cleared devices using CardieX's SphygmoCor® technology have predominantly been used in specialist medical and research settings and in clinical trials that have "fixed" trial sites (where trial participants are required to physically visit the trial clinic to be monitored).

---

1 https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20disease%20is%20the%20leading,groups%20in%20the%20United%20States.&text=One%20person%20dies%20every%2034,United%20States%20from%20cardiovascular%20disease.&text=About%20697%2C000%20people%20in%20the,1%20in%20every%205%20deaths.

The Pulse is targeted at new, high growth market opportunities and expands the Company's SphygmoCor technology into the home, primary care physician office, and the decentralized clinical trial market (where trial participants can now participate in a trial wherever they are physically located).

Joseph Raffaele, M.D. the founder of PhysioAge commented:

> *"When doctors use a traditional brachial cuff alone, all they see is the top of the curve [systole] and the bottom [diastole]. All the other information about the pulse wave—how fast the blood is moving, how much of the pulse is reflected—is lost. The shape of the arterial wave provides health care providers with much more insight into the health of the arterial tree."*

In addition to central blood pressure and brachial blood pressure the Pulse also measures multiple other clinically relevant digital vascular biomarkers including: subendocardial viability ratio, medical grade heart rate (similar to readings obtained in an ICU/clinical setting), central pulse pressure, augmentation pressure, and augmentation index.

These advanced biomarkers can also be monitored remotely by physicians and clinical researchers without requiring patients to leave the comfort of their homes.

Pulse in Home and Remote Settings

Pulse is CardieX's first integration of the Company's SphygmoCor® central aortic waveform technology into an arterial health monitor specifically targeted at the home health, remote patient monitoring, and decentralized clinical trial markets.

Available for prescription to patients who need to monitor their heart health and other vascular diseases, the device offers a user-friendly interface that makes it easy for individuals to track their blood pressures and other vascular biomarkers regularly, empowering them to take more control of their cardiovascular health.

After a patient takes a reading, the data is wirelessly transmitted to the CONNEQT Patient Management Portal (CPMP), a cloud-based, HIPAA-compliant database that allows physicians to view patients' arterial health metrics and better manage their health via remote patient monitoring (RPM).

In the United States, when a physician qualifies a patient for RPM, the physician is then able to bill for these remote management procedures under specific RPM codes (depending on individual State and payer-based reimbursement policies). The global RPM market opportunity is expected to reach $USD175B by 2027 (*Markets and Markets* report).

The CONNEQT app provides the same benefit for patients, giving them easy access to sophisticated insights into their health, as well as a platform for coaching, health programs, lifestyle tips, and notifications.

Use of Pulse in the Management of Decentralized Clinical Trials

In addition, CardieX's existing clinical trial partners will also be able to use the Pulse and CPMP to remotely manage Decentralized Clinical Trials (DCT's), which the Company sees as a significant opportunity with the global DCT market forecast to reach $US14.2B by 2026 (*Medi-Tech Insights*[2]).

CONNEQT app

The Pulse will integrate with the CONNEQT app to provide medical-grade insights into a suite of arterial diagnostics – enabling patients to make better informed decisions about their health.

CardieX reported the FDA classification of the "CONNEQT app" as a 'Medical Device Data System' ("MDDS") on 18 May 2022.

CONNEQT Pulse with mobile App

Fully customizable, the CONNEQT app allows both clinicians and patients to choose which parameters patients see on the Pulse, enabling them to personalize their screens based on their specific health conditions.

The Pulse is the first at home blood pressure device to offer this level of "over the air" (**OTA**) customizable cardiovascular insight allowing complete control over the Pulse via the CONNEQT app.

---

[2] According to Global News Wire/Absolute Reports April 29, 2022

CONNEQT Patient Management Portal

When connected to the CONNEQT Patient Management Portal (CPMP), a tablet-based patient management platform, the Pulse will enable physicians to remotely manage and monitor a patient's health, providing the ability to significantly enhance practice revenues and patient health outcomes.

These features will make the Pulse unique in the remote patient monitoring (RPM) market in multiple ways, including:

- Providing a full suite of unique and proprietary arterial health parameters in an easy-to-use device for more advanced insights into a patient's vascular health, beyond traditional blood pressure measurements;

- Enabling physicians to monitor multiple risk factors for hypertension and cardiovascular disease and other health disorders such as Alzheimer's, kidney disease, preeclampsia, and stroke risk;

- Empowering physicians with new diagnostic insights into a patient's overall vascular health including arterial stiffness, central blood pressures, and central pulse pressures, to name a few;

- Allowing physicians to bill for remote patient monitoring reimbursement at a level not available with traditional blood pressure monitors due to the unique, additional, CPT reimbursement code payable on the use of Pulse for central arterial waveform analysis; and

- Being fully customizable – allowing physicians and patients to remotely set up specific personalized arterial health parameters specific to the patients' needs. For example, a patient at risk for Alzheimer's' may wish to prioritize the display of central pulse pressure and augmentation index – key indicators that can influence brain health.

Craig Cooper, CEO & Managing Director commented:

> *"CONNEQT Pulse's 510(k) clearance by the FDA marks a major milestone in the field of cardiovascular health management. The Pulse is targeted at new, high growth market opportunities and expands the Company's SphygmoCor technology into the home, primary care physician office, and the decentralized clinical trial market, allowing trial participants to now participate in a trial wherever they are physically located.*
>
> *For individuals with hypertension and other vascular disease we now have an innovative new way to monitor their arterial health at home, with the same tools the country's top cardiologists use in their research facilities and clinics.*
>
> *At the time of launch, there is no other vital signs monitor that provides the level of features, personalization, or vascular health insights that will be available on the Pulse. This technology has the potential to truly revolutionize the way hypertension and vascular disease is diagnosed and managed in the future".*

For more information and to stay *conneqted,* visit conneqthealth.com and sign up to receive updates.

Approved by the Board of Directors and Released by Jarrod White, Director.

For more information, please contact:

Investor Relations
Rod Hinchcliffe
rod.hinchcliffe@mcpartners.com.au

Media Relations
Melissa Hamilton
melissa.hamilton@mcpartners.com.au

Investor Relations – USA
Matt Selinger
Managing Director, Integrous Communications
mselinger@integcom.com

About CardieX
CardieX is a health technology company focused on devices & solutions for the world's largest population health disorders. Its ATCOR subsidiary is a world leader in the monitoring of vascular biomarkers for clinical trials and health care research based on the Company's "gold standard" SphygmoCor® central blood pressure technology. CardieX's CONNEQT subsidiary develops and markets medical devices, digital solutions, and wearables for home health, remote patient monitoring, and decentralized clinical trials.

About SphygmoCor®
SphygmoCor® vascular biosensing technology has been documented as the "gold standard" of central blood pressure and arterial waveform measurement. SphygmoCor® has been in use for over 20 years and is deployed in more than 4,500 installations worldwide at major medical & research institutions, specialist clinician practices, and in over 46 clinical trials to date by major pharmaceutical companies. SphygmoCor® non-invasively measures what is known as "central aortic waveforms" and enables deep insights into a range of clinically relevant vascular biomarkers including a patient's arterial stiffness, central blood pressure, arterial pulse pressures, and other key indicators of the vascular health of major organs (heart, brain, kidneys etc.).