ASX ANNOUNCEMENT **28 June 2022**

CardieX Announces FDA 510(k) submission for CONNEQT Pulse Dual Blood Pressure and Arterial Health Monitor

Highlights:

- **Submission of a US FDA 510(k) clearance application for the Company's "Pulse" dual blood pressure monitor, together with its manufacturing partner, Andon – incorporating CardieX subsidiary ATCOR's market-leading SphygmoCor® central aortic blood pressure technology.**

- **Subject to final FDA clearance, the Pulse will be CardieX's first device targeted at both clinicians and consumers, to monitor and incorporate a suite of unique arterial health parameters beyond traditional blood pressure.**

- **Pulse's health parameters have been fully patented and trademarked, with their output enabling clinicians and consumers to gain advanced insights into cardiovascular health.**

- **Following FDA clearance, Pulse will be marketed under the Company's CONNEQT brand, and will target new significant global markets in home health monitoring, remote patient management, and decentralized clinical trials.**

CardieX Limited (ASX: CDX) (**CardieX,** the **Company**), is pleased to announce (together with its manufacturing partner, Andon) the filing of a 510(k) submission with the US Food and Drug Administration ("**FDA**") for the CONNEQT Pulse ("**Pulse**") – a dual blood pressure and arterial health monitor targeted at the home health, remote patient monitoring ("**RPM**"), and decentralized clinical trial ("**DCT**") markets.

Subject to final FDA clearance, Pulse will also be the CardieX's first arterial health monitor, to incorporate a full suite of patented and trademarked heart and vascular health parameters beyond traditional blood pressure, that is marketed to both clinicians and consumers.

The Pulse will enable clinicians, patients, and consumers alike to gain more advanced insights into cardiovascular health. To the Company's knowledge, Pulse will also be the first blood pressure monitor to incorporate "over the air" ("**OTA**") customizable display screens, based on specific health parameters and disease conditions.

CONNEQT Pulse - Dual Blood Pressure Monitor with SphygmoCor® Technology

CONNEQT Pulse device

Pulse is an integral part of a new digital and device ecosystem for both consumers and clinicians built upon CardieX's existing FDA-cleared SphygmoCor® central blood pressure technology, developed by CardieX's subsidiary ATCOR, that is considered to be the "gold standard[1]" of central blood pressure measurement.

About SphygmoCor®

SphygmoCor® technology has been in use for over 20 years by researchers, specialist clinicians, and pharmaceutical companies, looking to obtain advanced arterial health insights beyond traditional blood pressure.

SphygmoCor® non-invasively measures what is known as "central aortic waveforms" and enables insight into a range of clinically relevant arterial health indicators including a patients arterial stiffness, central blood pressure, arterial pulse pressures, and key indicators of the vascular health of major organs (heart, brain, kidneys etc.).

Measuring central blood pressure at the heart is a clinically superior measurement to standard measurements of blood pressure at the arm, mainly due to the proximity of the heart to the major organs.

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[1] Covic. PWV Ratio – the new Gold Standard editorial. Hypertens 2015

Through the Company's ATCOR devices embedded with SphygmoCor® technology, SphygmoCor® is currently used in over 4000 clinical sites globally, over 250 current research projects by major medical research institutions, and 49 clinical trials to-date with the likes of Bayer, AstraZeneca, Andwin, GlaxoSmithKline (GSK), Novartis, and others.

The same SphygmoCor® technology (as embedded in the Company's ATCOR XCEL device) is also currently deployed in a major global research setting, which to the Company's knowledge is the world's largest study on the impact of COVID-19 on cardiovascular health, as well as being deployed in other existing clinical trials with Yale University, Andwin Scientific, and Philip Morris.

Pulse – Central Aortic Waveform Technology in Home and Remote Settings

"Pulse" is CardieX's first integration of ATCOR's SphygmoCor® central aortic waveform technology into a blood pressure monitor targeted at the home health, remote patient monitoring, and decentralized clinical trial markets.

The Pulse will be marketed under the Company's CONNEQT brand and FDA lodgement is a significant step forward in the Company's product development journey to commercial launch.

Commenting on the significance of the Pulse device for global health outcomes, Alberto Avolio Professor Emeritus – Macquarie Medical School, Macquarie University stated:

> *"ATCOR's market leading central aortic pressure technology (SphygmoCor®) has been the 'gold standard' for over a decade with researchers, specialist clinicians, and pharmaceutical companies in their clinical trials.*
>
> *Following receipt of FDA approval in the application to the 'Pulse' device, the Pulse will launch that same technology into significant new healthcare markets, giving physicians and patients alike deeper insights into cardiovascular health"*

Pulse Digital Ecosystem to Provide Advanced Insights to Consumers and Clinicians

CONNEQT App

On receipt of FDA clearance, Pulse will integrate with the CONNEQT App to provide medical-grade insights into a suite of arterial diagnostics – enabling consumers and patients to make better informed decisions about their health. The Company reported the FDA classification of the "CONNEQT App" as a 'Medical Device Data System' ("MDDS") on 18 May 2022.

CONNEQT Pulse with mobile App

CONNEQT Physician Portal

When connected to the CONNEQT Portal (the "**Portal**"), a tablet-based patient management platform, the Pulse will enable physicians to remotely manage and monitor patients via a cloud-based, HIPAA-compliant, patient management portal – providing physicians with the ability to significantly enhance practice revenues and patient health outcomes.

These features will make 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 to set up specific personalized arterial health parameters to monitor for each patient.

Remote Management of Clinical Trials

In addition, CardieX's existing clinical trial partners will also be able to use the Pulse and Portal to remotely manage Decentralized Clinical Trials ("**DCT's**"), which the Company sees as a significant opportunity with the global DCT market forecast to reach $US16B by 2027[2].

Commenting on the use of the Pulse in clinical practice, John R. Cockcroft, Visiting Professor, Dept Advanced Cardiology, Columbia University Medical Center, New York stated:

> *" Following it's FDA approval, the Pulse will enable healthcare practitioners to obtain unique cardiovascular health insights in order to inform better decision making around treatment.*
>
> *Importantly, the Pulse will also be the first device available to both clinician's and consumers to target widespread adoption of arterial stiffness and central blood pressure as key indicators of cardiovascular health."*

Pulse to Include Arterial Health Parameters

Following receipt of FDA clearance, the Pulse device will enable patients, clinicians and consumers to be empowered with advanced, medical grade insights into vascular health.

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

Traditionally only available to specialist clinician markets, a sampling of the Pulse parameters available to clinicians and consumers will include:

- **Brachial Systolic Blood Pressure.**
- **Brachial Diastolic Blood Pressure.**
- **Central Systolic Blood Pressure**: Based on central arterial waveform analysis – a measurement of blood pressure at the heart (the ascending aorta).
- **Arterial Age (ArtyAge®)**: A measurement of both Augmentation Pressure (AP) + Heart Rate.
- **Exercise Capacity® (eCAP®)**: based on the SEVR Index (Subendocardial Viability Index) – an index of myocardial oxygen supply and demand, and other proprietary algorithms.
- **Heart Stress (HSX™):** an index based on proprietary algorithms that measure stress on the heart.
- **TruHR®:** Clinical grade beat-to-beat heart rate - similar to that obtained in a hospital setting.
- **Arterial Stiffness Factor (ASF®)**: Based on Augmentation Pressure (AP) – a clinical standard for measuring arterial stiffness, and other proprietary algorithms.
- **ARTY® Score**: A comprehensive heart-health score based on a patient's combined ArtyAge®, eCAP®, HSX™, TruHR®, and ASF®.
- **VitalsRisk®**: a measurement of central pulse pressure and other proprietary algorithms that measure the vascular health of major organs (the heart, brain, kidneys etc.).
- **7-Day Brachial Blood Pressure Average.**
- **30-Day Brachial Blood Pressure Average.**
- **7-Day Central Blood Pressure Average.**
- **7-Day Arty Score Trend,** ArtyAge®, eCAP®, HSX™, TruHR®, ASF®.
- **Blood Pressure Variability (BPV+®).**

Each Pulse parameter provides a unique and valuable insight into a patient's cardiovascular health validated by decades of studies, research, and specialist clinical use.

Clinicians and patients will be able to customize and prioritize the parameters they see on the Pulse via the CONNEQT App, thereby enabling personalized insights into specific health conditions. So, for example, a patient at risk for Alzheimer's' may wish to prioritize the display of central pulse pressure and arterial stiffness, whereas a patient looking to manage hypertension may wish to prioritize both central and brachial blood pressures.

Recognizing the significance of the Pulse for global health markets, Hunter Champion, MD, PhD, and Cardiologist at Southeastern Cardiology Associates commented:

> *"Once launched, ATCOR's Pulse device has the potential to significantly improve treatment decisions by physicians and the health outcomes of patients through the use of advanced blood pressure and vascular health technologies."*

In addition, Mark C. Houston MD MS MSC FACP – Director at the Hypertension Institute and Vascular Biology – Saint Thomas Medical Group commented:

> *"ATCOR's "gold standard" blood pressure technology is now being made available to all healthcare providers and clinicians with the company's forthcoming Pulse device.*
>
> *The cardiovascular insights and accuracy obtained through ATCOR's SphygmoCor technology are revolutionary, impactful and based on current scientific clinical studies regarding blood pressure and cardiovascular outcomes."*

CardieX Group CEO, Craig Cooper, also provided the following comments on the significance of the Pulse for global healthcare:

> *"The submission of our application for FDA clearance on the Pulse represents the most significant event for CardieX in over 20 years when we were initially granted FDA clearance on our SphygmoCor® technology, the current 'gold standard' in central arterial waveform measurement.*
>
> *Pulse extends that legacy into new, significant markets and importantly, is set to redefine the diagnostic paradigm for the identification and treatment of vascular and arterial disease.*
>
> *Traditionally, the level of technology incorporated in the Pulse was only available to specialist clinicians, research institutions, and pharmaceutical companies for clinical trials. Pulse is the 'tip of our spear' in now driving widespread adoption of arterial stiffness and central blood pressure as key indicators of cardiovascular health - at a price point targeted at consumers, mass-clinician markets, and other significant healthcare channels."*

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

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About CardieX

CardieX is a global health technology company. Its ATCOR subsidiary is a world leader in medical devices for hypertension, cardiovascular disease, and other vascular health disorders 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, primary clinician, and other healthcare channels. CardieX is listed on the Australian Stock Exchange (ASX:CDX).