



ASX ANNOUNCEMENT

25 August 2021

## **CardieX Announces New Clinical Trial Expansion with Bayer AG**

### **Highlights**

- Bayer AG executes amendments to expand its agreement with CardieX for its CONCORD clinical trial that uses ATCOR technology;
- Expansion comes from an additional 15 sites and 2 additional countries being added to the trial;
- CONCORD trial now has ATCOR technology being used at 84 sites across 13 countries for this contract alone;
- Financially beneficial to CardieX through increases in contracted revenue of US\$495k (AU\$682k) to existing agreement;
- Total contracted revenues over the life of the contract since initiation are now in excess of US\$2m (AU\$2.76m).

CardieX Limited (ASX: CDX) (CardieX, the Company) is pleased to announce that global pharmaceutical company Bayer AG (BAYN.DE) and CardieX subsidiary ATCOR have this week entered into a new Amended Agreement for both the lease of ATCOR devices and the provision of expanded data management services for Bayer's "CONCORD" clinical trial.

### ***CONCORD Clinical Trial Agreement***

CardieX is pleased to report the second material expansion of the current CONCORD trial which commenced in 2017.

Bayer originally contracted ATCOR in December 2017 to provide clinical trial lab and data management services and devices for the trial with an initial contract value of \$US756K. The original agreement for the CONCORD trial was amended and expanded in March 2020, to a contract value of \$US1.53M (refer ASX 26 March 2020).

This week the CONCORD trial has again been amended and expanded under a new agreement with the total contract value now in excess of \$US2M (AU\$2.76m).

The US\$495K (AU\$682k) increase in contract value relates to additional incremental patient visits over a further 15 sites in two (2) extra countries.

CONCORD remains on schedule to conclude by January 2022, which was the anticipated completion date as amended in March 2020, prior to this more recent amendment.



***Summary and Impact of Key Terms of Amended Contract with Bayer AG for CONCORD Clinical Trial:***

- Study being conducted in chronic kidney disease with diabetes and/or hypertension population;
- **Increased clinical trial sites to 84 across 13 countries** (from 69 sites and 11 countries);
- Data management services for incremental XCEL and OSCAR 2 patient visits for a combined total of 2,700 patient visits (up from a combined total of 2,400 visits);
- **Increase in contract value - of \$US495K** (AU\$682k);
- **Total contract value now in excess of \$US2M** (AU\$2.76m) – up from US\$1.53m;
- ATCOR XCEL and Oscar 2 Devices Systems leased through to January 2022;
- **No change to expected conclusion of January 2022.**

***Wider Bayer AG Contracted Revenue***

The increase in contract value with Bayer is consistent with CardieX's expectations around further positive amendments in respect of additional existing contracted clinical trials – as well as new trial contracts in the immediate future – which together would and will continue to add significant new incremental revenue to the Company for FY21 and FY22.

The CONCORD trial is one of two (2) significant ongoing trials that ATCOR currently has under contract with Bayer – the other being the NEON trial.

A third clinical trial with Bayer, the AVANTI trial, has recently concluded on schedule.

***About the ATCOR Device and It's Use in CONCORD***

ATCOR's XCEL device is the only FDA cleared device for measuring the central aortic waveform and reporting on associated clinical data in all adult subjects. XCEL is used by clinicians, research institutions, and pharmaceutical companies in monitoring critical hemodynamic data during patient treatment and drug trials in multiple clinical settings and for multiple disease states.

Craig Cooper, CEO & Managing Director commented:

*"This further contract amendment and expansion with Bayer continues to validate the unique capabilities of our FDA-cleared SphygmoCor® technology. Importantly, it is this technology - that is trusted by the leading global pharmaceutical companies - that forms the basis of our competitive differentiation as we expand into wearables, smart home health devices and other new markets".*

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



For more information, please contact:

**Investor Relations**

Rod Hinchcliffe

[rod.hinchcliffe@mcpartners.com.au](mailto:rod.hinchcliffe@mcpartners.com.au)

**Media Relations**

Melissa Hamilton

[melissa.hamilton@mcpartners.com](mailto:melissa.hamilton@mcpartners.com)

**About CardieX**

CardieX is a global health technology company. Its ACTOR subsidiary is a world leader in medical devices and digital solutions for hypertension, cardiovascular disease, and other vascular health disorders. Its CONNEQT subsidiary develops and markets consumer home health devices and wearables. CardieX is listed on the Australian Stock Exchange (ASX:CDX).