Adherium submits FDA 510(k) application for next generation Hailie sensor for Teva MDI inhalers

Melbourne, Australia – 25 August 2022: Adherium Limited ("Adherium" or "the Company"; ASX: ADR), a leader in respiratory eHealth, remote monitoring and data management solutions, today announced submission to the US Food and Drug Administration (FDA) of its 510(k) clearance to market application, which connects Teva ProAir® and Teva Albuterol Sulphate HFA metered dose inhalers with its new, next-generation Hailie® sensor with physiological parameters such as respiratory flow rate in litres per minute for remote monitoring of patients with Asthma and COPD.

Following sensor applications for AstraZeneca's Symbicort®, GSK's Ellipta® and, most recently, GSK's pressurized metered dose inhalers (pMDI), this 510(k) submission for the next-generation Hailie sensor is the fourth in a series of new sensors. Delivering on the Company's commercial strategy and achieving product roadmap milestones, this new sensor series provides a superior perspective into inhaler usage and technique giving patients and doctors real-time feedback for improving patient care and treatment and reducing the cost burden on healthcare systems.

"Hailie is a clinically proven chronic respiratory management solution and is the only 510(k) cleared digital sensor available today to offer physiological data insights for inhaler technique. Submitting another 510(k) application to the US FDA represents a key milestone for the Company as we continue to execute on our market expansion strategy to extend our digital product portfolio", commented Tara Creaven-Capasso, Adherium's Vice President of Quality, Regulatory and Clinical Affairs.

The ongoing support from the United States Centers for Medicare & Medicaid Services (CMS) in advocating for smart medicine by providing two reimbursement code options for remote patient monitoring advances Adherium's path toward value-based care. Currently, for the top 20 US branded inhaler medications, Adherium's 510(k) clearances cover 91% of the market for inhaler usage enabling doctors access for the CMS Remote Therapeutic Monitoring reimbursement codes (up from 71% last year)

and 32% of the market for enabling Remote Physiological Monitoring reimbursement codes (up from 11% last year). Adherium's drug agnostic platform is uniquely positioned allowing doctors to keep patients on existing medications while receiving valuable data and insights, tracking medication usage and thereby guiding clinical care.

Mrs Creaven-Capasso continued, "The 510(k) submission is the first step in the review process with the FDA, and we look forward to working with the Agency to obtain market clearance. The addition of Teva ProAir® and Teva Albuterol Sulphate HFA to the Hailie range of products will broaden the pathway for Adherium's customers in the US to access reimbursement for remote monitoring of patients prescribed Asthma and COPD medications."

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About Adherium (ASX: ADR)

Adherium is a provider of integrated digital health solutions and a worldwide leader in connected respiratory medical devices, with more than 180,000 sold globally. Adherium's Hailie® platform solution provides clinicians, healthcare providers and patients access to remotely monitor medication usage parameters and adherence, supporting reimbursement for qualifying patient management.

The Hailie® solution includes a suite of integration tools to enable the capture and sharing of health data via mobile and desktop apps, Software Development Kit (SDK) and Application Programming Interface (API) integration tools, and Adherium's own broad range of sensors connected to respiratory medications. Adherium's Hailie® solution is designed to provide visibility to healthcare providers of medication use history to better understand patterns in patient respiratory disease.

Learn more at www.adherium.com

This ASX announcement was approved and authorised for release by the Board of Adherium.

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