

Adherium submits FDA 510(k) application for next generation Hailie sensor for GSK pMDI inhalers

Melbourne, Australia – 2 August 2022: Adherium Limited (“Adherium”; 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 GlaxoSmithKline® (GSK) Ventolin®, Advair®, and Flovent® pressurized metered-dose inhaler (pMDI) users with its new, next generation Hailie® sensor with physiological measures, for monitoring Asthma and COPD medication use.

This 510(k) submission for the next-generation Hailie sensor, the third in a series of new sensors following AstraZeneca® Symbicort® pMDI inhaler and GSK’s Ellipta®, is designed to capture physiological parameters such as respiratory flow rate in litres per minute.

Tara Creaven-Capasso, Adherium’s Vice President of Quality, Regulatory and Clinical Affairs, commented, “Submitting this market application marks another development milestone towards our vision of enabling healthcare providers to enhance patient care by capturing clinical data and supporting patient management. Following the recent 510(k) market clearance of GSK’s Ellipta® inhaler, designed for use with Breo®, Anoro®, Incruse®, Trelegy® and Arnuity®, this 510(k) submission marks, once again, execution on our strategy and delivering on our product roadmap milestones.”

Adherium has 510(k) clearances for 91% of the US top 20 branded inhalers for adherence usage enabling the Remote Therapeutic Monitoring (RTM) reimbursement codes, and 32% coverage for physiological parameters enabling the Remote Physiological Monitoring (RPM) reimbursement codes. This broad market coverage makes possible a total patient view to improve their quality of life with combined assessment of both reliever (rescue) and maintenance treatments. The combined data and insights help doctors understand a patient’s degree of adherence and symptom control which a single device approach will not provide. A recently published clinical

study demonstrates digital physiological sensors measuring inhalation parameters can predict impending Asthma exacerbation within 5 days prior to the start of the event.

“Our objective with each generation of the Hailie sensor is the pursuit of our mission - to be the leading digital solution for remote patient monitoring; integrating devices and data to optimise outcomes for patients, healthcare professionals and payors. We recognise the importance of integrating technology into patient care and one of the challenges healthcare providers are faced with in caring for their Asthma and COPD patients is knowing if their patients are using their inhaled medication as they should.

With the US Centers for Medicare and Medicaid Services (CMS) focused on providing new and expanded reimbursement options for virtual care management programs, more reimbursement opportunities for doctors are available, which gives access to comprehensive patient data for more effective care delivery, better care coordination, and improved health outcomes”, added Mrs. Creaven-Capasso.

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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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