

Adherium submits US FDA 510(k) application for next generation Hailie® sensor with physiological measures

Melbourne, Australia – 1 June 2021: Adherium Limited (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 a 510(k) clearance to market application for its first next generation Hailie® sensor with physiological measures for monitoring Asthma and COPD medication use.

Adherium’s latest Hailie® sensor, designed for use with AstraZeneca’s Symbicort® aerosol inhaler, is the first in a series of devices specifically designed to enable physicians and providers to enhance patient care and clinical workflow by capturing clinical data and supporting patient management. This addition to the Hailie® range of products will allow access to reimbursement in the US for the remote monitoring of patients. “This is an important step in the extension of our digital respiratory management ecosystem. This latest development signals the start of Adherium’s next generation of sensors that capture physiological measures” said Geoff Feakes, Adherium’s Chief Technology Officer. “Clinicians globally have told us of the importance of building on our core adherence capability to extend the range of clinical data we capture and expand our market coverage of inhaled medications for Asthma and COPD. Physiological measures were consistently identified as a key data set to improve patient management and importantly, access reimbursement to enable the widest possible patient population to benefit from the technology. As part of Adherium’s market expansion we intend to release a further four new sensors with physiological measures over the next 18 months, taking our anticipated Asthma and COPD medication coverage in the US to over 80% by volume and supporting 18 medications.”

Roy A. Pleasants, PharmD, a clinical researcher at the University of North Carolina with extensive experience in pharmacology and aerosol drug delivery studies, shared his thoughts on this digital inhaler technology. “Gaps in medication adherence and proper inhaler technique persist today and continue to have a substantial impact on the lives of patients with chronic lung diseases. Studies in Asthma and COPD (Chronic Obstructive Pulmonary Disease) with digital inhalers show better outcomes by documenting adherence, especially if feedback is given to patients. While inhalers that electronically record each dose are valuable based on published research, the addition of inspiratory-capable sensors substantially improves the functionality of these devices by providing information on inhaler technique and measuring inhalational flows that could guide clinical care. Both clinical experience and

additional research will provide further insights into the use of inspiratory-capable digital inhalers. I think this is one of the biggest steps forward in inhalational drug therapies in many years.”

Interest in telehealth and remote patient monitoring remains high, driven by a positive reimbursement environment in many regions and from the necessity to protect patients and healthcare systems during the COVID-19 pandemic. A number of healthcare systems, hospitals, commercial insurers and other ecosystem partners in the US, Canada, Australia, New Zealand and the UK have made unsolicited approaches to Adherium looking to evaluate the Hailie® solution as part of their coverage of patients with respiratory disease (Asthma and COPD).

About Adherium (ASX: ADR)

Adherium is a provider of digital health solutions and a global leader in connected respiratory medical devices, with more than 170,000 sold globally. The Company develops, manufactures and supplies a broad range of connected medical devices for respiratory medications for patients, pharmaceutical companies, healthcare providers and contract research organisations. Adherium’s Hailie® solution is designed to help patients achieve better adherence and provide visibility to parents and caregivers. It does this by tracking medication use and reminding the user with helpful nudges when it is time to take doses, and by providing access to usage history to better understand patterns in their asthma and COPD.

Adherium has a series of new asthma and COPD sensors in development which, with their existing capabilities, will also enable the capture of physiological measures enabling access to CPT reimbursement for remote patient monitoring in the US.

These tools ultimately enable patients, with their physicians, to more effectively manage their Asthma and COPD and at the same time potentially deliver significant healthcare cost savings to payors and providers.

Learn more at adherium.com

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

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