Adherium receives U.S. FDA 510(k) clearance for next generation Hailie® sensor with physiological measures

Melbourne, Australia – 9 September 2021: Adherium Limited (ASX: ADR), a leader in respiratory eHealth, remote monitoring and data management solutions, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market its first, next generation Hailie® Sensor with physiological measures for monitoring Asthma and Chronic Obstructive Pulmonary Disease (COPD) medication use.

Mr Rick Legleiter, Chief Executive Officer, commented, "The FDA's first clearance of our next generation Hailie® sensors with physiological measures is a significant regulatory step for the business. The stage is now set for physiological measures to be coupled with our existing adherence sensor capability giving us the total 'one-two punch' to deliver the best value proposition of any smart inhaler digital solution in the world. As we deliver our clearly defined development roadmap including new additional physiological enabled sensors and alongside digitally enabled peak flow and spirometers, Adherium will expand its addressable respiratory medication market coverage and establish a preeminent business partnering position for providers, payors and digital health affiliates."

Adherium's Hailie® Sensors are devices that attach to a patient's Asthma or COPD medication inhaler to monitor and allow caregivers to provide the most advanced patient monitoring available. The 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 and treatment. The addition of physiological measurements to the Hailie® range of products will allow provider's access to existing U.S. reimbursement criteria to fund their remote patient monitoring including managing severe, uncontrolled and difficult to treat Asthma and COPD patients in the U.S. This patient group is estimated to represent a total addressable market of US$1.5 billion.

Mr Legleiter, continues, “This FDA decision increases the number of 510(k) cleared Adherium devices to ten in the U.S. and represents an unequalled and formidable track record of development and experience by the market leader in respiratory digital health.”

“Today marks an important milestone in Adherium’s commitment to the expansion of our digital respiratory ecosystem, with the 510(k) clearance of our new sensor for AstraZeneca’s Symbicort® pMDI”, said Geoff Feakes, Adherium’s Chief Technology Officer. “The new Symbicort® sensor is the first in our new range of digital smart inhalers that will be delivered over the next 12 months providing physiological measures including, inhalation duration, volume, and peak inhalation flow. Our commitment is expanding Adherium’s Asthma and COPD medication coverage in the U.S. from 50% to over 80% by volume supporting 18 medications. An important step in enabling Asthma and COPD sufferers in receiving increased support assisting with their medication usage and disease treatment.”

“Physiological measures were consistently identified as a key data set to improve patient management and, importantly, access reimbursement in the U.S. to enable the patient population to benefit from this state-of-the-art technology”, Feakes added.

In addition to Hailie® Sensors, Adherium’s product portfolio goes beyond medical devices to include our total digital platform comprised of the Hailie® apps, online interface portals, and data management and analytics cloud. The Company is continuing to invest in advanced development, updates and enhancements of the digital infrastructure required of the respiratory digital health leader.

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.

Learn more at www.adherium.com

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

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