Adherium receives U.S. FDA 510(k) clearance for Ellipta inhaler users to connect to Hailie platform with physiological parameters

Melbourne, Australia – 25 July 2022: 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 application connecting GlaxoSmithKline's (**GSK**) Ellipta® inhaler users with Adherium's new, next generation Hailie® sensor with physiological parameters for monitoring Asthma and COPD medication use.

Mr Rick Legleiter, Adherium Chief Executive Officer, commented, "Executing our strategy and once again delivering on our product roadmap milestones, we continue to demonstrate Adherium is the global partner of choice for remote patient monitoring."

"The FDA's clearance to connect Ellipta inhaler users with our new, next generation Hallie platform represents another major step forward in our drug agnostic strategy. In addition, this further broadens the pathway for doctors and hospital groups in the US to access reimbursement for remote monitoring of patients prescribed Asthma and COPD medications on our path toward building a sustainable, cash flow positive business."

Following market clearance of the Hailie sensor with physiological parameters for AstraZeneca's Symbicort® pMDI inhaler, Adherium's latest Hailie sensor is designed for use with the Breo®, Anoro®, Incruse®, Trelegy® and Arnuity® Ellipta dry powder inhalers (**DPIs**), and captures physiological parameters, including inhalation duration, volume, and peak inhalation flow. This new series of devices provide a superior perspective into inhaler usage and technique giving patients and doctors immediate, real-time feedback thereby allowing patients to improve their quality of life and enabling physicians to enhance patient care by capturing clinical data supporting patient management and treatment.

Adherium continues its global expansion strategy to extend its digital technological innovations to enable reimbursement on 18 of the top 20 US branded inhaler medications in CY23. As shown in the attached competitive analysis graphic, with this Hailie for Ellipta 510(k) clearance, Adherium progressed from covering 71% to 91% of the top 20 branded inhaler medications for adherence usage parameters enabling access by healthcare providers for the Remote Therapeutic Monitoring (RTM) reimbursement codes and progressed from 11% to 32% coverage for physiological parameters enabling the Remote Physiological Monitoring (RPM) reimbursement codes. Using Adherium's drug agnostic platform, doctors and healthcare partners always own the medication decision and receive the data and insights for improving patient care without changing prescriptions.

"We enhance healthcare outcomes by improving quality of life for patients around the world and reduce emergency department visits and hospital admissions and the economic burden of chronic respiratory diseases. With another FDA clearance, we continue to demonstrate our leadership position providing digital solutions for the management of the 8.5 million severe and difficult-to-treat Asthma and COPD patients in the US", said Tara Creaven-Capasso, Adherium's Vice President Quality, Regulatory and Clinical Affairs.

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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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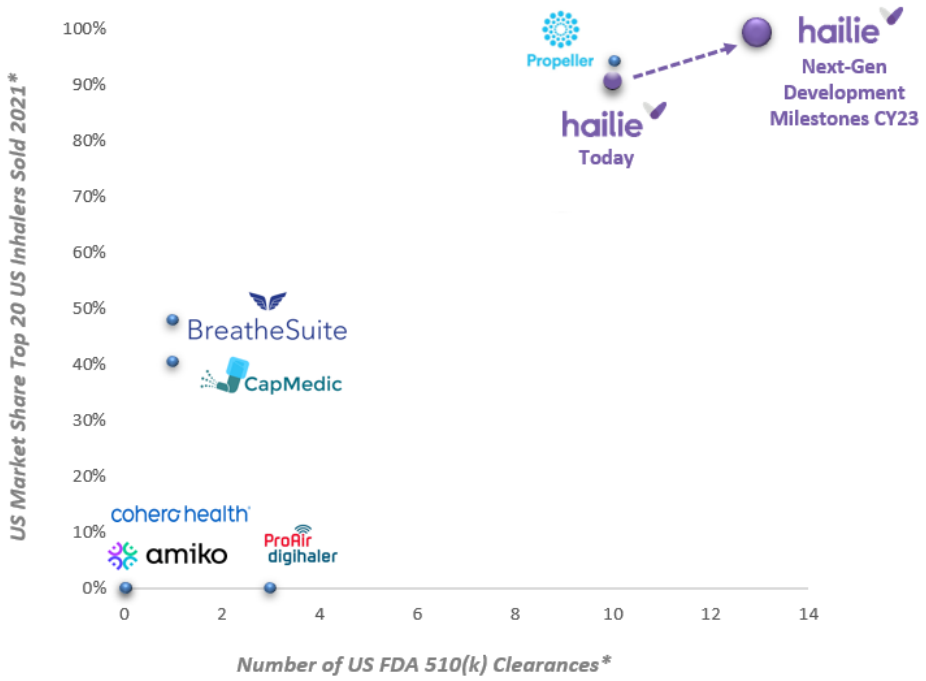
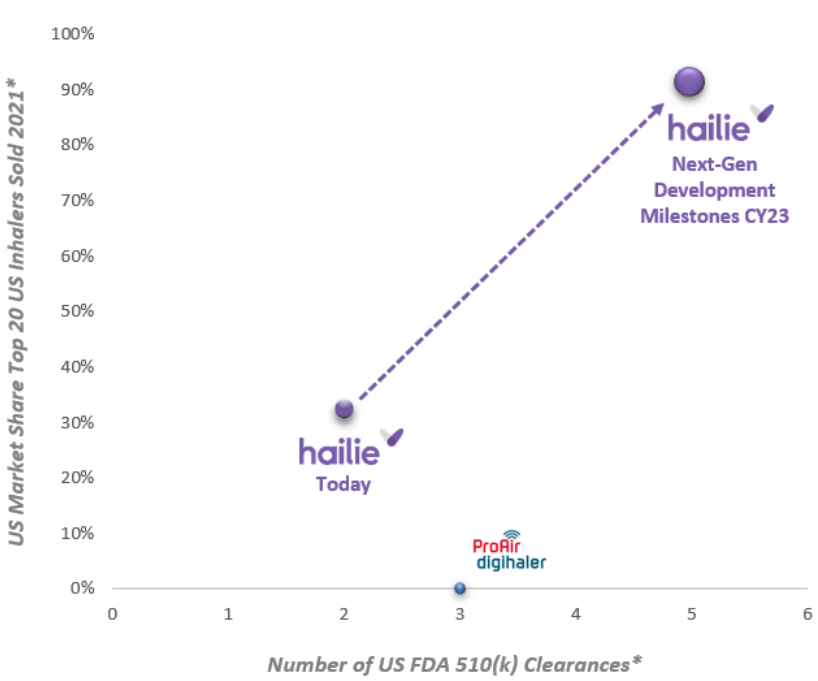
Competitor Analysis – FDA 510(k) clearances vs Top 20 US branded inhalers

Adherence Parameters (US CMS RTM codes)



Physiological Parameters (US CMS RPM codes)



*US Market Share from IQVIA 2022 dataset based on the Top 20 US inhaler unit volume sold in the US market in 2021. US Centers for Medicare and Medicaid Services (CMS) Remote Therapeutic Monitoring (RTM) and Remote Physiological Monitoring (RPM) codes. RPM coverage only considers digital inhalers that incorporate physiological parameters in the core digital sensor without additional attachments. ProAir® Digihaler® based upon FDA supplemental new drug application (sNDA).