

Adherium receives U.S. FDA 510(k) clearance for Teva's ProAir® and Albuterol Sulphate inhaler users to remotely monitor physiological parameters

Melbourne, Australia – 23 March 2023: Adherium Limited (“Adherium”; ASX: ADR), a leader in respiratory eHealth, remote monitoring and data management solutions, is pleased to announce that it has received U.S. Food and Drug Administration (**FDA**) 510(k) clearance to market application, connecting Teva Pharmaceutical Industries Ltd. (**Teva**) HFA pressurised metered dose inhalers (pMDIs) including ProAir®, and Albuterol Sulphate with its new, next generation Hailie® sensor with physiological parameters.

“Reaching yet another major regulatory milestone, we can now move forward with the next steps for Hailie market release of Teva pMDI inhalers expanding our product portfolio on the path toward building a sustainable, cash flow positive business,” commented Mr. Rick Legleiter, Adherium Chief Executive Officer. “These regulatory milestones are done in parallel with multiple U.S. partner discussions where the feedback has been they are seeking a supplier with a board range of sensors to ensure patients have the complete coverage to match the wide range of doctor prescribed medications.”

“This is the fourth FDA 510(k) market clearance of the next-generation Hailie sensors capturing physiological data so we are now covering 79% U.S. top 20 branded inhalers, following AstraZeneca’s Symbicort® pMDI inhaler, and GSK’s Ellipta® DPI’s, as well as their Ventolin®, Advair®, and Flovent® pMDIs, enabling even more medication coverage for U.S. remote patient monitoring reimbursement. We continue to sequentially execute and deliver as we expand our regulatory footprint supporting our commercial strategy to be the drug agnostic, respiratory digital health provider.”

Adherium is first to market with 510(k) cleared respiratory flow rate sensors with physiological data capabilities allowing multiple data inputs. Adherium is well positioned to offer a single-source customer solution to capitalise on remote patient monitoring opportunities.

With Adherium, the doctors always own the medication decision. As shown in the two

competitive analysis graphics shown below, with Hailie for Teva's ProAir® HFA and Albuterol Sulphate pMDIs, this FDA 510(k) clearance together with the GSK 510(k) clearances received last year, Adherium progressed from covering U.S. top 20 branded inhaler medications by sales volume as follows:

- 79% coverage today up from 11% in 2021 to be the differentiated market leader with physiological parameter sensors enabling the US Centers for Medicare and Medicaid Services (CMS) Remote Physiological Monitoring reimbursement codes published in 2019,
- 91% coverage today up from 71% in 2021 for adherence usage remote patient monitoring enabling access by healthcare providers for the CMS Remote Therapeutic Monitoring reimbursement codes published in 2022.

Using Adherium's drug agnostic platform, doctors and healthcare partners own the medication decision and receive the data and insights for improving patient care without changing a patient's prescriptions.

These new generation devices provide superior data and insights into patient inhaler technique and usage giving healthcare providers immediate, real-time feedback enabling physicians to enhance patient care by capturing clinical data supporting patient management and treatment. Adherium's broad medication market coverage makes possible a total patient view with digital sensor technology applied in a combined monitoring of both maintenance and reliever (rescue) medications. A recently published clinical study demonstrates digital physiological sensors can predict impending asthma exacerbation within 5 days prior to the start of the event¹.

Tara Creaven-Capasso, Adherium's Vice President of Quality, Regulatory and Clinical Affairs, commented, "As remote patient monitoring becomes more prevalent, healthcare providers have an opportunity to provide an easy to use and affordable solution with better quality care for their patients. The addition of this latest sensor as a virtual care solution, not only creates more reimbursement opportunities for healthcare providers, but also gives access to comprehensive patient data for more

¹ Safioti G, Granovsky L, Li T, Reich M, Cohen S, Hadar Y, Pleasants R, Chrystyn H, Hill T, DePietro M. A Predictive Model for Clinical Asthma Exacerbations Using Albuterol eMDPI (ProAir Digihaler): A Twelve-Week, Open-Label Study, *iproc* 2019;5(1):e15173, doi: [10.2196/15173](https://doi.org/10.2196/15173).



effective care delivery, better care coordination, and improved health outcomes.”

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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.

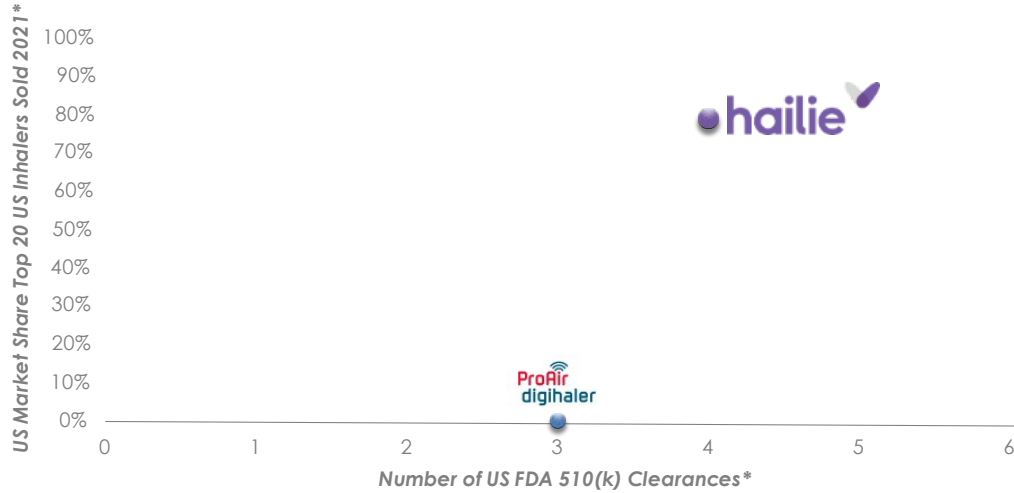
Learn more at www.adherium.com

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

Physiological Parameters (US CMS 2019 Remote Physiological Monitoring 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).

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Adherence Parameters (US CMS 2022 Remote Therapeutic Monitoring 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).

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