

## **Adherium receives U.S. FDA 510(k) clearance for GSK pMDI inhaler users to remotely monitor physiological parameters**

**Melbourne, Australia – 28 November 2022:** Adherium Limited (“Adherium”; 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) Ventolin®, Advair®, and Flovent® pressurised metered dose inhaler (pMDI) users with its new, next generation Hailie® sensor with physiological parameters.

“This is the third 510(k) market clearance of the next-generation Hailie sensors capturing physiological data, following the Hailie sensors for AstraZeneca’s Symbicort® pMDI inhaler and GSK’s Ellipta® dry powder inhalers enabling even more medication coverage for US remote patient monitoring reimbursement. Achieving these significant milestones for the Company, we continue to broaden our regulatory footprint to be the drug agnostic, global digital partner of choice on our path toward building a sustainable, cash flow positive business,” commented Mr Rick Legleiter, Adherium Chief Executive Officer.

With these 510(k) market clearances and an integrated and highly scalable digital platform allowing multiple data inputs, Adherium is well positioned to offer a single-source customer solution to capitalise on remote patient monitoring opportunities.

As shown in the attached competitive analysis graphic, with this Hailie for GSK pMDI 510(k) clearance together with the Ellipta 510(k) clearance received earlier this year, Adherium progressed from covering U.S. top 20 branded inhaler medications by sales volume as follows:

- 91% today up from 71% in 2021 for adherence usage remote patient monitoring enabling access by healthcare providers for the US Centers for Medicare and Medicaid Services (CMS) Remote Therapeutic Monitoring reimbursement codes,
- 51% today up from 11% in 2021 to be the clear market leader with physiological parameter sensors enabling the CMS Remote Physiological Monitoring 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 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 event<sup>1</sup>.

Tara Creaven-Capasso, Adherium's Vice President of Quality, Regulatory and Clinical Affairs, commented, "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. With 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."

**-ENDS-**

### **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

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<sup>1</sup> 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).



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.

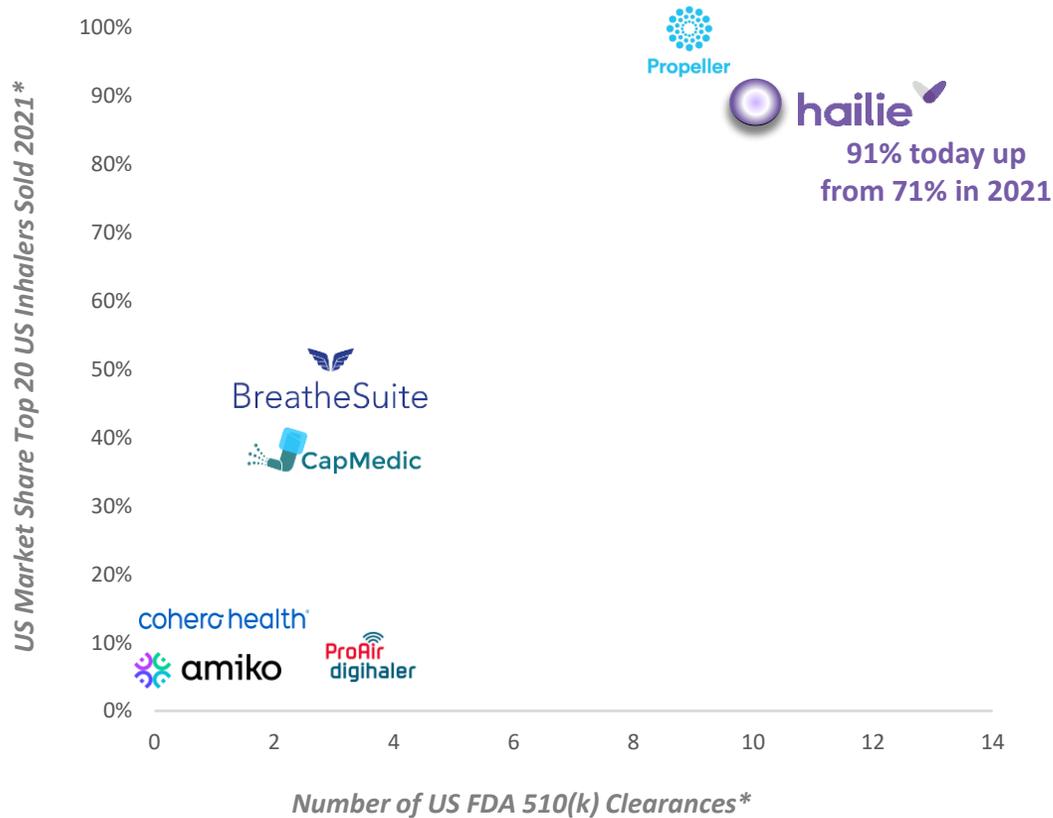
Learn more at [www.adherium.com](http://www.adherium.com)

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

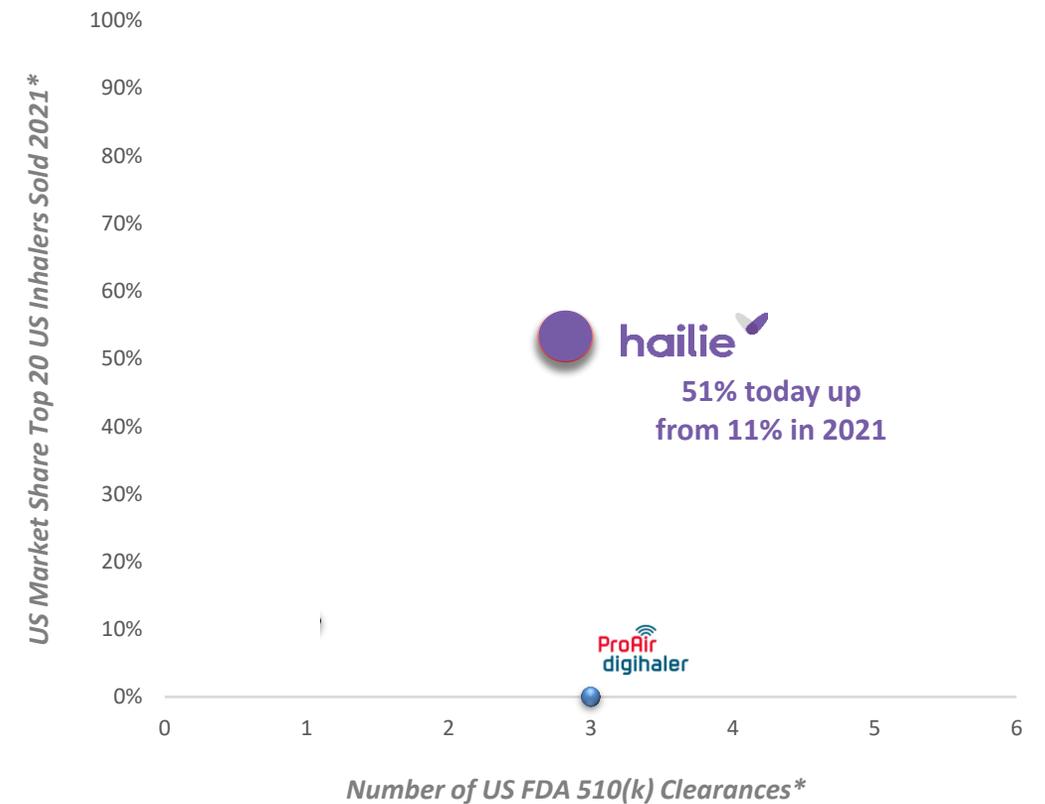
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# Competitor Analysis – FDA 510(k) clearances vs Top 20 US branded inhalers by inhaler sales volume

## Adherence Parameters (RTM codes)



## Physiological Parameters (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).