Adherium Receives U.S. 510(k) Clearances for SmartDisk and SmartHandy

Melbourne, Australia – 15 July 2019: Adherium (ASX: ADR), an award-winning digital health platform that improves medication adherence, patient outcomes and engagement, today announced the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for over-the-counter (OTC) sales of its Hailie™ sensors for asthma and COPD inhalers using Advair® and Flovent® in the Diskus® format (known as Seretide® and Flixotide® Accuhaler® outside of the U.S.), and Spiriva® in the Handihaler®.

Adherium's Hailie™ sensors, previously known as Smartinhaler™, are devices that attach to a patient's asthma or COPD medication inhaler to monitor and promote adherence as part of a self-management plan. These clearances from the U.S. FDA add to Adherium's existing range of OTC cleared sensors in the U.S., and increase coverage to an estimated 80% of asthma and COPD medications, mostly supplied by AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline and Teva Pharmaceuticals.

Importantly, the broader coverage of asthma and COPD medications provides disease management organisations and healthcare providers with a solution that will suit the vast majority of their patient pools. Adherium is working with a number of parties in the U.S. to commercially rollout at scale. This includes an innovative Provider system with a target up to 10,000 patients in the first 12 months, two Provider population disease management companies representing access to over 100,000 patients, and a U.S. respiratory device manufacturer on a large scale joint commercial roll out. Further commercial discussions are in progress on the back of this deployment traction as we scale in the U.S. (our priority market).

In December 2018, the Adherium Board took measures to restructure the Company in order to accelerate global deployment and commercial success. The Board are pleased to announce significant progress has been made toward commercial growth while delivering on current operations and commercial obligations. In doing so, the organisation headcount has remained consistent since.

In addition to the 510(k) OTC regulatory successes noted above, Adherium has also undergone U.S. FDA and ISO 13485:2016 audits with no significant findings arising.

Our Hailie™ mobile patient app and physician platform has also been completely reconcepted, with our strategic partner Arthur D. Little (ADL) and their Digital Practice. The ADL team have led the ground-up development of our next generation Hailie™ platform using a leading and globally scalable architecture model. The architecture leverages cloud-first, horizontally scalable and serverless design and is constructed using a microservices architecture with platform-agnostic languages. The Company believes the platform fully meets health regulatory compliance needs (including ISO 13485, HIPPA, GDR). Further, integration with customer platforms extending commercial deployment opportunities has now been made easier as the reconcepted platform is interoperable and meets emerging HL7/FHIR standards (enabling integration with EHR and other healthcare platforms) and can be easily "white-labelled" for customer-branding.

The rollout of our Hailie™ technology continues to gather pace as we work on commercial deployments based on our new platform with customers around the world. We are also supporting new clinical trials

in Europe, expected to launch H2 2019. The Board is very pleased with the progress and collaboration efforts so far in 2019.

About Adherium

Adherium is a digital health platform and global leader in connected respiratory medical devices, with over 150,000 sensors sold. The Company develops, manufactures and supplies patients, pharmaceutical companies, healthcare providers and contract research organizations with the broadest range of connected medical devices for respiratory medications.

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's time to take doses, and by providing access to usage history to better understand patterns in their asthma and COPD. These tools ultimately enable people who live with asthma or COPD to more easily manage their condition alongside their physician.

You can follow Hailie on Twitter, Instagram and Facebook.

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