H&T Presspart and Cohero Health Launch First Market-Ready, Fully-Connected Metered Dose Inhaler to Optimize care of Asthma and COPD

*eMDI enables improved adherence, engagement in self-care and real-time monitoring by caregivers*

Poor adherence is a key driver of asthma attacks and COPD exacerbations that result in 3.25 million deaths and huge healthcare costs globally

Drug Delivery to the Lungs (DDL) 2016, Edinburgh, 8 December 2016 - H&T Presspart and Cohero Health have today launched the first market-ready, intuitive, fully-embedded and connected metered dose inhaler (eMDI) aimed at improving adherence and enabling continually optimized care of patients with asthma and COPD. It is the only eMDI integrated seamlessly with BreatheSmart from Cohero Health, a comprehensive respiratory disease management platform that uniquely enables tracking of both controller and rescue medications, along with clinically accurate lung function measurement, in real-time.

Adherence to preventer (controller) inhalers is vital to improve quality of life, control symptoms and prevent attacks, which are responsible for 3.25 million deaths globally every year1,2 and represent a significant burden for healthcare systems.3,4 Yet fewer than 50% of patients take their preventer medication as prescribed5, leading to poor symptom management, hospitalizations, avoidable deaths and spiraling healthcare costs.6,7

The H&T Presspart eMDI is the result of a multi-year development between H&T Presspart, the world’s leading manufacturer of MDI devices, and Cohero Health, a digital health company that has established leading connected health tools and technologies to empower respiratory patients and improve care through smart mobile devices. It is an evolution of existing inhaler technology, and closely mirrors the design and compact size of existing MDI devices, making it as easy as possible for patients to adopt, and minimizing scale-up costs and time to market for pharmaceutical manufacturers.

“We already have effective medicines for asthma and COPD. But we can only improve and save lives in the face of rising healthcare costs if we find new ways to ensure that patients get the right dose at the right time every time,” said Dr Caralee Caplan-Shaw, Assistant Professor, Co-Director of a New York City Pulmonary Clinic.

By tracking, recording and sharing data on the use of both preventer (controller) and reliever (rescue) medications, the eMDI will engage and empower patients in their self-care, leading to improved adherence, whilst enabling real-time monitoring of medication use and symptom flare-ups by caregivers and the healthcare community. Medication utilization data from the eMDI can be merged in real-time with lung function data from Cohero Health’s mSpirometer - a clinical grade handheld wireless spirometer that precisely measures critical lung function metrics. This allows, for the first time, for the effects of preventer and rescue medication use on lung function to be tracked and analyzed.
“In designing the eMDI, our mission was to help pharmaceutical companies bring the best possible care to patients in an intuitive device in the fastest time and most cost-efficient way,” said Peter Schmelzer, CEO of H&T Presspart. “We have thus combined the design of the world’s most widely used and established inhaler technology with the only respiratory platform that gives a complete and objective picture of how a patient is responding to treatment between reviews,” said Mellissa Manice, Co-Founder and CEO of Cohero Health.

**eMDI functionality**
Sensors embedded within the inhaler track the date and time of medication use as well as the quality of delivery, which is both recorded in onboard memory and shared wirelessly Bluetooth, syncing seamlessly with the BreatheSmart app, which can provide customized reminders, real-time alerts and updates on medication usage, as well as weekly and monthly summary reports.

Patients can opt to share their data with family, caregivers and/or healthcare providers, with access via a web app on a secure, dedicated, HIPPA-compliant server. The technology supports EMR integration, allowing patient data to be transferred automatically and securely directly into a patient’s medical record.

The H&T Presspart eMDI incorporates an FDA approved mechanical dose counter allowing pharmaceutical companies to transition current products to connected devices more easily and in a step-wise manner. Additional sensors and electronic displays can be incorporated for additional data monitoring and messaging.

Unique features include:

- Fully embedded device to promote adoption and repeated use to generate unadulterated data
- Seamless integration into the BreatheSmart connected respiratory care platform from Cohero Health
- Embedded sensors to detect medication use and quality of medication administration (detection of proper inhaler actuation)
- Embedded mechanical or electronic dose counting and display
- Intuitive and discrete design, operation consistent with standard pMDI operation
- No disruption to medication delivery pathway, reducing regulatory hurdles and expediting time to market
- Compatibility with any valve or canister
- Battery life consistent with product shelf life – no replacement parts, no recharging or battery changes
- Modular design enabling sensing and communication capabilities to be applied to a range of MDI, DPI and other drug delivery devices

H&T Presspart and Cohero Health are currently collaborating with pharmaceutical manufacturers who are leveraging the technology for pipeline development and value-added product differentiation.
About H&T Presspart
H&T Presspart offers pharmaceutical customers high-precision injection moulded plastic components and deep drawn metal cans for respiratory drug delivery systems, with more than 40 years' experience and a worldwide reputation for competence, quality and innovation in pharmaceutical and industrial sectors. H&T Presspart Inhalation Product Technology Centre (IPTC) supports new product developments and strategic initiatives with its customers. Founded in 1970 and acquired by the Heitkamp and Thumann group in 2002, H&T Presspart has 3 European manufacturing sites in Germany, Spain and the UK, with Sales offices in China, India, South America and the USA.

presspart.com | eMDI@presspart.com | @presspart

About Cohero Health, Inc.
Cohero Health is a digital health company developing innovative tools and technologies to improve respiratory care, reduce avoidable costs, and optimize medication utilization. The company’s connected devices and mobile applications actively engage and empower respiratory patients by measuring lung function and tracking adherence. Based in New York City, the company is a member of StartUp Health, Springboard Enterprises, and Grand Central Tech. The company’s platform has been used by pulmonary patients in over 25 commercial deployments reaching over 1 million covered lives.

coherohealth.com | info@coherohealth.com | @coherohealth

4 Anzueto A. Impact of exacerbations on COPD. European Respiratory Review 2010; 19: 113-118
7 Makela. Adherence to inhaled therapies, health outcomes and costs in patients with asthma and COPD. Respiratory Medicine (2013) 107, 1481 - 1290

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About the eMDI
For patients with asthma and COPD

H&T Presspart and Cohero Health are currently collaborating with pharmaceutical manufacturers who are leveraging the technology for pipeline development and value-added product differentiation. As a fully-functioning, market-ready device, it will enable pharmaceutical manufacturers to bring the best possible care to patients with asthma and COPD in the fastest time, and in the most cost-efficient way.

Key Differentiators

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<thead>
<tr>
<th>Connected</th>
<th>Fully-embedded</th>
<th>Intuitive</th>
<th>Market-ready</th>
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<tbody>
<tr>
<td>The only eMDI integrated seamlessly with BreatheSmart from Cohero Health</td>
<td>Unlike other “clip-on” connected respiratory devices already on the market, the hardware and software is incorporated within the eMDI, with no disruption to the medication delivery pathway</td>
<td>Developed to closely mirror the design and compact size of existing MDI devices, patients will find it easy to adopt and use the eMDI</td>
<td>Unlike other integrated devices in development, the eMDI is an evolution of the world’s most widely used and established inhaler technology. It is thus designed and developed for:</td>
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<td>• Efficient, large-scale commercial supply globally, with easy integration into existing MDI process manufacturing, filling and packaging</td>
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<td>• Wirelessly shares data with a smart phone app or directly into a patient’s medical records</td>
<td>• Data capture and analytical and predictive capabilities enable real-time alerts and inform clinical decision-making</td>
<td>• Evolution of existing inhaler technology to make it as easy as possible for patients to adopt and use, and to minimize global scale-up costs, regulatory pathway and time to market</td>
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The only eMDI integrated seamlessly with BreatheSmart from Cohero Health
Unique Features

- **Fully embedded device** to promote adoption and repeated use to generate unadulterated data
- **Seamless integration into the BreatheSmart connected respiratory care platform from Cohero Health**
- **Embedded sensors to detect medication use** and quality of medication administration (detection of proper inhaler actuation)
- **Embedded mechanical or electronic dose** counting and display
- **Intuitive and discrete design**, operation consistent with standard pMDI operation
- **No disruption to medication delivery pathway**, reducing regulatory hurdles and expediting time to market
- **Compatibility** with any valve or canister
- **Battery life consistent with product shelf life** – no replacement parts, no recharging or battery changes
- **Modular design enabling sensing and communication capabilities** to be applied to a range of MDI, DPI and other drug delivery devices

Benefits

**Improves adherence and engages and empowers patients in their self-care**

- Sensors embedded within the inhaler track the date and time of medication use as well as the quality of delivery, which is both recorded in onboard memory and shared wirelessly via Bluetooth to a smartphone app.
- App provides customized reminders and updates on medication use as well as real-time alerts. For example, it can alert patients of missed doses or issues with their medication use that indicate either poor adherence or a worsening of their condition, such as increased rescue inhaler use. Such real-time reminders and alerts enable the patient and caregivers to take action to reduce risk of an attack.

**The only platform that allows tracking and analysis of the effects of medication use on lung function**

- Medication use data from the eMDI can be merged in real-time with lung function data from Cohero Health’s mSpirometer - a clinical grade handheld wireless spirometer that precisely measures critical lung function metrics.

**Enables personally-optimized treatment plans and real-time monitoring of medication use and symptom flare-ups by caregivers and the healthcare community**

- Patients can opt to share their data with caregivers and/or healthcare providers, with access via a web app on a secure, dedicated, HIPPA-compliant server.
- The technology supports EMR integration, allowing patient data to be transferred automatically and securely directly into a patient’s medical record.
- Real-time monitoring connects patients to their caregivers and healthcare professional between reviews enabling them to be alerted when a patient’s condition significantly worsens and requires prompt intervention.
- Retrospective data analytics and predictive algorithms will inform clinical decision making and enable healthcare professionals to identify higher-risk patients and deliver more precise and personally-optimized asthma and COPD care.
- Treatment plans will be based on a complete and objective picture of how the patient has been using and responding to treatment between reviews, rather than on subjective patient self-reporting and a snap-shot lung function test taken at the time of the review.

**Ultimately, by enabling continually optimized and remote care, the eMDI has the potential to significantly improve outcomes and reduce burdensome healthcare costs**

Evidence

The clinically validated connected health platform (BreatheSmart from Cohero Health) has been proven to engage and empower pulmonary patients, leading to dramatically improved adherence and reduced hospitalizations.

- 2.5x
  - 2.5 times increase in medication adherence over standard of care
- 100% reduction in hospitalizations
- Reaching over 1 million children and adults with asthma, COPD and cystic fibrosis
About Asthma and COPD: Burden and Poor Adherence

What is asthma and COPD?

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<tr>
<th><strong>Asthma</strong></th>
<th><strong>Chronic Obstructive Pulmonary Disease (COPD)</strong></th>
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<td>A very common, potentially life-threatening chronic condition of the airways, causing difficulty breathing, chest tightness, wheezing or coughing.\cite{1,2} Symptoms arise when a person with asthma comes into contact with an asthma trigger, causing the airways to become inflamed, narrower and irritated\cite{1}</td>
<td>A progressive, disabling and life-threatening chronic lung disease that includes chronic bronchitis and emphysema.\cite{6,7} COPD is a condition where the airways become inflamed, scarred and narrowed making it hard to breathe.\cite{8} It causes coughing that produces large amounts of phlegm, wheezing, breathlessness and chest tightness\cite{9}</td>
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<td>Asthma attacks are typically triggered by exposure to environmental allergens, such as pollen, dust mites or smoke, changes in weather, exercise, or by certain respiratory illnesses\cite{4}</td>
<td>Potentially life-threatening exacerbations (a sudden worsening of symptoms) are primarily triggered by infections, but also industrial allergens and pollution\cite{10}</td>
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<td>The severity and risk of a potentially life-threatening attack can vary day by day, season by season, and across someone's lifetime\cite{5}</td>
<td>Typically diagnosed in middle-aged or older adults\cite{8}</td>
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<td>Affects people of all ages and is the most common chronic disease of children\cite{3}</td>
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**Asthma and COPD: A significant global burden**

- **300 million people have asthma worldwide** – a figure set to rise to nearly 400 million by 2025.\cite{11} It is the most common chronic disease in children\cite{12} affecting 9.4% of children in the EU\cite{13} and 8.6% in the US\cite{14} – and its prevalence is increasing\cite{3}
- **Uncontrolled symptoms affect quality of life**, limiting daily life, work and school performance, while asthma attacks can be fatal\cite{3}
- **Responsible for 250,000 deaths every year**, of which 90% are avoidable\cite{11}
- **65 million people have been diagnosed with COPD** and prevalence is increasing\cite{15,16}
- **COPD exacerbations can result in severe limitations** in quality of life and daily living as well as a significant reduction in physical activity\cite{17}
- **COPD is now the third leading cause of death globally**\cite{18}, responsible for 3 million deaths per year.\cite{15} Deaths are predicted to increase by more than 30% in the next 10 years\cite{15}

Uncontrolled asthma and COPD represent a significant economic burden in terms of healthcare costs and lost productivity\cite{2,17}

The cost of healthcare and lost productivity for asthma and COPD:

- **US** $92 billion\cite{19,20}
- **Europe** €82.3 billion\cite{10}

Asthma attacks and COPD exacerbations are the main cost driver, leading to emergency room visits and inpatient or intensive care\cite{21,17}

According to one UK study, an asthma attack more than triples the cost of healthcare\cite{21}

Exacerbations are one of the main cost drivers in COPD, particularly in terms of hospital emergency room visits and inpatient or intensive care\cite{17}
Adherence to preventer inhalers is vital in asthma and COPD

Preventer and reliever inhalers are the mainstay of treatment for people with asthma and COPD. Daily adherence to preventer inhalers is vital in asthma and COPD to improve quality of life, control symptoms, and prevent asthma attacks and COPD exacerbations.21

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<th>Preventer (controller) inhalers</th>
<th>Reliever (rescue) inhalers</th>
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<td>Taken daily on a long-term basis to help minimize or prevent symptoms. Deliver medication such as inhaled corticosteroids (ICS) or long-acting beta-agonists (LABAs) to the lung.</td>
<td>For on-the-spot relief from symptoms and attacks, but may not always help during an asthma attack or COPD exacerbation. Deliver medication such as beta-2-agonists to open up the airways. Frequent use of reliever medication is a marker of poorly controlled asthma or COPD.</td>
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Key unmet needs in the management of asthma and COPD

Poor adherence
- Despite significant advances in inhalers for the treatment of asthma and COPD, many patients continue to experience poor disease control, with poor adherence being a key factor²¹,²³.
- Only 50% of patients receiving long-term treatment for chronic diseases adhere to treatment and adherence rates in asthma and COPD have been shown to vary from 22% to 78% (2²,²³,²⁴,²⁵).
- Non-adherence is associated with poor symptom control, higher healthcare utilization and healthcare costs, and reductions in health-related quality of life²¹.
- A growing number of national efforts have developed strategies aimed at improving medication adherence. For example, under a new initiative from the US Centers for Medicare & Medicaid Services (CMS), insurance companies are being offered incentives to boost adherence.

Patient self-management challenges
Self-management of asthma and COPD can be complex. It requires adherence to daily preventer and utilisation of reliever medications in an emergency, actively monitoring symptoms and recognizing worsening conditions, adjusting treatment, and determining if and when to contact a doctor. Moreover, for asthma, it also involves identifying and avoiding triggers.

Challenges faced by HCPs
Close partnership and good communication between patients, caregivers and healthcare professionals is essential for optimal management of asthma and COPD.¹,²⁶ However patients may only be reviewed once in a year by a healthcare professional in line with the minimum requirements of disease guidelines. This means healthcare professionals have to base treatment plans on subjective patient self-reporting and a snap-shot lung function test taken at the time of the review. Healthcare professionals aim to deliver the best care and motivate good self-management, but this can be complex and time-consuming and so often is not possible in the allotted time.⁵

The economic burden of non-adherence across all diseases:⁵

United States: $100 - 300 billion²⁶
Europe: €125 billion²⁷

1 Asthma UK website. What is asthma? Available at: https://www.asthma.org.uk/advice/understanding-asthma/what-is-asthma/  
2 Asthma UK website. Symptoms of asthma. Available at: https://www.asthma.org.uk/advice/understanding-asthma/symptoms/  
4 American College of Allergy, Asthma & Immunology website. Asthma Attack. Available at: http://acaaai.org/asthma/symptoms/asthma-attack  
7 WHO website. Chronic obstructive pulmonary disease (COPD). Available at: http://www.who.int/respiratory/copd/en/  
9 NIH website. What is COPD. Available at: http://www.nhlbi.nih.gov/health/topics/copd  
10 ERS White Book, 2014  
12 Global Atlas of Asthma, 2014  
17 Anzueto A. Impact of exacerbations on COPD. European Respiratory Review 2010; 19: 113-118  
18 Global Burden of Disease Study 2015  
20 CDC, CDC Vital Signs: Asthma in the US, May 2011  
21 Makela. Adherence to inhalaed therapies, health outcomes and costs in patients with asthma and COPD. Respiratory Medicine (2013) 107, 1481 - 1290  
27 EFPIA website. Patient adherence – 50% of patients don’t take their medicine properly. Available at: http://www.efpia.eu/topics/people-health/patient-adherence  
28 NICE Clinical Guideline (CG101), June 2010. Available at: https://www.nice.org.uk/Guidance/cg101
Combining the strength of two industry leaders

The partnership combines Cohero Health’s expertise in digital innovation with H&T Presspart’s 40 years’ experience of MDI design and component manufacture. The companies are currently collaborating with pharmaceutical manufacturers who are leveraging the technology for pipeline development and value-added product differentiation.

About H&T Presspart

H&T Presspart (a division of the German-based Heitkamp and Thumann group) is the world’s leading manufacturer of medical devices and pharmaceutical components. It was founded in 1970 and acquired by the Heitkamp and Thumann group in 2002.

The company offers pharmaceutical customers high-precision injection moulded plastic components, and deep drawn metal canisters for respiratory drug delivery systems. H&T Presspart’s Inhalation Product Technology Centre (IPTC) supports the development of new products and strategic initiatives with its customers. H&T Presspart has 3 European manufacturing sites in Germany, Spain and the UK, with Sales offices in China, India, South America and the USA.

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