FDA 510(k) clearance granted to PneumaCare's ground-breaking Thora-3DI™ product for non-contact respiratory measurement

Cambridge 16 March 2016 – PneumaCare Ltd (Cambridge, UK) announced that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for its Thora-3DI™ imaging device.

Thora-3DI™ is a non-invasive, non-contact device that uses a patented technology known as structured light Plethysmography (SLP) to measure breathing through detection of movement of the chest and abdomen. The technology can be used to accurately measure respiratory status in patients with a wide range of respiratory conditions, including asthma, chronic obstructive pulmonary disease (COPD), pneumonia and lung failure, and to assess patients before and after surgery. The SLP technology uses safe white light to project a grid pattern onto the chest, and record accurate 3D images of chest wall movements over time. The measurements are converted into visual and numerical outputs, which can help clinicians to make faster diagnoses and treatment decisions, and continually monitor patients in real time, without direct patient contact or intervention. The Thora-3DI™ is mobile, and can easily be moved between wards, or dismantled for transport and use in the community or in clinics.

Stringent bench and clinical validations required for the FDA 510(k) clearance have demonstrated that the Thora-3DI™ system can detect movements as small as 0.25 mm, and can accurately measure respiratory rate to within less than one breath per minute when compared with the FDA gold standard reference device. The device is indicated for hospital or clinical use and is intended to be operated by clinicians and medically qualified personnel.

Mark Harwood, PneumaCare's CEO, stated, *"We are delighted to receive FDA approval for our revolutionary product, which brings benefits for doctors and patients alike. Thora-3DI™ is a first-in-class product that will be of wide interest to respiratory physicians worldwide. 510(k) clearance builds on the success of our CE mark authorisation for the product in Europe, achieved in 2012. A number of clinical trials continue to demonstrate major benefits of respiratory assessment using the* Thora-3DI™, and *publication of trial data are in progress. We believe that these results will have significant implications for patient care in a range of clinical areas."*

Dr. Bill Mason, Chairman of PneumaCare *said, "FDA 510(k) clearance for* Thora-3DI™ *is a very exciting moment in our company history, but even more so for respiratory physicians globally, who will now have access to our product for the first time. The Company has met and surpassed the stringent criteria imposed by FDA for clearance to market medical technology, through a process that has taken nearly two years of hard work and intense consultation with the regulatory authority. I am very proud of our team for attaining this*

major achievement and also extend much gratitude to our shareholders, who have supported the company throughout the development of this innovative approach to an unmet clinical need."

About PneumaCare

PneumaCare Ltd is a Cambridge, UK-based company that is leveraging its patented structured light Plethysmography (SLP) technology to develop and market innovative respiratory imaging systems. PneumaCare's flagship Thora-3DI™ device is a respiratory imaging and assessment platform that enables clinicians to evaluate patients and their response to treatment in real time, and so gain a better understanding of respiratory status.

Representing a breakthrough in patient care, the Thora-3DI™ device achieved CE mark approval in Europe in 2012, and is being used in hospitals across non-US territories including the UK, France, Italy, Denmark, Sweden, Middle East, Hong Kong, China and Malaysia. With a first FDA 510(k) clearance for the Thora-3DI™ granted in March 2016, PneumaCare is now working with its strategic partners to make the device available in the US and in other markets that recognise 510(k) authorisation.

The PneumaCare systems are highly enabling for clinicians working in a wide range of specialties, from pulmonary physicians treating ventilated patients, to rehabilitation, acute and chronic disease areas, pre- and post-surgery assessment, asthma, COPD, pneumonia. The company has also recently launched a version of Thora-3DI™, using identical SLP technology, for paediatric applications.

For more information about PneumaCare and its products and technologies, please visit our website, www.pneumacare.com, or contact:

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