Press Release

Itamar Medical Reports Success in Clinical Study Validating WatchPAT for Central Sleep Apnea Differentiation, Submits Application for FDA Clearance of New WatchPAT™ Version

New version of WatchPAT distinguishes between different subtypes of Sleep Apnea, ensuring a suitable therapeutic solution for patients

CAESAREA, Israel, June 9, 2016 – Itamar Medical Ltd. (TASE.ITMR), which develops, manufactures, and markets non-invasive diagnostic medical devices for cardiology and sleep related breathing disorders, reported success in a comprehensive clinical study based on initial results reported this week, and an FDA submission for a new WatchPAT version.

The new version enables, for the first time, distinction between Central and Obstructive Sleep Apneas and provides detailed identification of breathing patterns characteristic of heart failure patients. In light of the great importance of distinguishing between the different subtypes of Sleep Apnea in this market (patient population), the success of the study, and pending future clearance to market this new version of WatchPAT, will give the Itamar Medical an additional significant advantage in the cardiology market.

The new WatchPAT version incorporates a new Snoring and Body Position (SBP) sensor which, when combined with the proprietary PAT signal and a new advanced algorithm, enables distinction between Central and Obstructive Sleep Apneas. In Obstructive Sleep Apnea events, the patient tries to breath, but physical obstruction of the airways prevents the entry of air into the lungs (inability to breath); in Central Sleep Apnea, the respiratory command is not given and the relevant muscles (diaphragm and thorax) are not activated; hence, there is no breathing.

The Company’s multicenter study that took place in the U.S, Europe and Israel, validated the WatchPAT results against the gold standard Polysomnography (PSG). WatchPAT was successful in automatically distinguishing Central Sleep Apnea events from other events, when compared to the PSG, where the analysis is done manually by a technician. In addition, identification of Cheyne-Stokes respiration, a specific pattern of Central Sleep Apnea typical for heart failure patients, was facilitated. Initial results from the study have been submitted and approved for publication, and will be presented by Prof. Thomas Penzel of Charité Medical University, Berlin, at the upcoming annual convention of the American Sleep Association (APSS), to be held this June in Denver Colorado.

Central Sleep Apnea originates from the central nervous system and manifests in its failure to activate the respiratory muscles for short periods of time (as opposed to Obstructive disorders which result from physical obstruction of the upper airways). The relevance and significance of diagnosing Central Sleep Apnea among cardiac patients, was demonstrated in the SERVE-HF study recently published in the New England Journal of Medicine. The study showed that appropriate treatment is especially important
for these patients, and that certain treatments are liable to not only fail in improving the clinical outcomes, but may even lead to an increased rate of mortality.¹

“The success of the study and the new capabilities of our WatchPAT device significantly strengthen Itamar Medical’s strategic position in the cardiology market in the U.S (Pending 510k clearance) and around the world. It opens important new opportunities for the company as we enter the Sleep Apnea therapeutic world. The new WatchPAT capability, alongside Itamar’s unique distributed line of PAP therapy solutions, make Itamar Medical’s diagnostic and therapeutic solutions first of their kind, and position Itamar Medical at a significant competitive advantage. With the increase in the number of cardiology patients, the prevalence of Central Sleep Apnea and its severity are growing steadily. With the new WatchPAT product, patients suspected of having sleep related breathing disorders can be diagnosed with a non-invasive, simple to operate home-use device, and benefit from an optimized treatment that does not put them at risk,” said Gilad Glick, CEO of Itamar Medical.

As part of promoting a Total Sleeping Solution (TSS) for diagnosis and treatment of Sleep Apnea, Itamar Medical is reinforcing its direct sales organization in the U.S, deployed over most of the main population centers. It has also announced the continuation of the co-marketing agreement with Medtronic, a leading provider in the Cardiology market. These strategic moves further strengthen the company’s connection with both patients and doctors, and leverage its sales capabilities.

**About the Company’s WatchPAT™ Product**

WatchPAT, the FDA-approved flagship product developed by Itamar Medical, is used for diagnosis of sleep apnea in the home environment. What makes the device so unique are its advanced capabilities combined with an unmatched ease-of-use for the patient, and its ability to automatically decipher test results and produce a full sleep report. The device provides a variety of respiratory indices, distinguishes between sleep and wakefulness and provides a complete sleep architecture that includes analysis of sleep stages (light sleep, deep sleep and REM sleep) as well as snoring volume and body position information throughout the night.

**About Itamar Medical Ltd.**

Itamar Medical Ltd., a publicly traded medical device Company (TASE:ITMR) develops, manufactures and markets diagnostic products based on its proprietary PAT® technology which provides an innovative solution to diagnosing Sleep Breathing Disorders and cardiovascular conditions. More information about Itamar Medical can be found online at [www.itamar-medical.com](http://www.itamar-medical.com).

**Itamar Medical Forward Looking Information**

This press release contains “forward-looking statements” as defined in the Securities Law, 5728-1968. Forward looking information is uncertain information regarding the future, which is based on existing information or assessments in the company and includes intentions or assessments of the Company, as at the date of publishing this press release or that is not solely dependent on the Company. It is possible that all or some of this information, will not materialize (at all) or will materialize in a different manner.

¹ Heart Failure and Sleep-Disordered Breathing — The Plot Thickens, Ulysses J. Magalang, M.D., and Allan I. Pack, M.B., Ch.B., Ph.D., N Engl J Med 2015; 373:1166-1167
manner, among other things, because of changes in the Company's strategy, regulatory changes in the target market, competition and competitors in the target market, the degree of acceptance and the rate of penetrating WatchPAT by the medical community in the US, delay in obtaining or failure to obtain the FDA clearance for the new WatchPAT version and/or changes in the Company's financial situation and its business.

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