Itamar Medical’s WatchPAT™ One, the First and Only Fully Disposable Home Sleep Apnea Test Receives FDA 510(k) Clearance

New system expands WatchPAT access to additional sleep centers by reducing infrastructure needs and eliminating capital requirements; also reduces infection risk for in-patient sleep apnea testing

CAESAREA, Israel, June 6, 2019 -- Itamar Medical Ltd. (Nasdaq:ITMR) (TASE:ITMR), a company that develops, manufactures and markets non-invasive diagnostic medical devices for sleep apnea with a focus on the cardiology market, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration for WatchPAT One, the latest innovation of its WatchPAT technology and the first and only fully disposable Home Sleep Apnea Test (HSAT). WatchPAT One incorporates the technology and comfort advances of WatchPAT 300, which received 510(k) clearance in August 2018 and was launched in March 2019.

“WatchPAT One is ideally suited for clinics and practices that recognize the value of HSAT but have limited resources, infrastructure or capital to invest in acquiring or managing our reusable WatchPAT products,” said Gilad Glick, President and Chief Executive Officer of Itamar Medical. “WatchPAT One offers patients and physicians the same simplicity, accuracy and reliability as WatchPAT 300 without the need for return shipping, downloading, cleaning or preparation for the next study. We expect the availability of a disposable WatchPAT system will improve patient access by increasing the number physicians able to offer our cutting-edge technology to their patients. Additionally, as a disposable HSAT, WatchPAT One may have particular utility in the inpatient setting, where transmission of infection through reusable medical devices is a significant concern.”

With WatchPAT One, patients pair the WatchPAT device to their smartphone using Itamar’s proprietary app. Sleep study data are collected during the test and automatically sent to CloudPAT™, Itamar’s secure server. Once the test is complete, a comprehensive report using WatchPAT’s True Sleep Time, Sleep Architecture and Central Plus algorithms is automatically generated and sent to the prescribing physician. The patient then disposes the WatchPAT device. WatchPAT One utilizes the same reimbursement codes as Itamar Medical’s other outpatient WatchPAT studies.

WatchPAT One will be unveiled at SLEEP 2019, the annual meeting of the Sleep Society®, which is taking place June 8-12 in San Antonio, TX. Meeting attendees can learn more about WatchPAT One and the WatchPAT family of products and services by visiting Booth #916 at 10:00 a.m. CDT on Monday, June 10th, 2019.

About Itamar Medical Ltd.

Itamar Medical is engaged in research, development, sales and marketing of non-invasive medical devices for the diagnosis of respiratory sleep disorders with a focus on the cardiology market. The Company offers a Total Sleep Solution™ to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare costs. Its flagship PAT-based product, the WatchPAT™ device, is a home-use diagnostic device for sleep breathing disorders. It also offers the EndoPAT™ system, an FDA cleared device to test endothelial dysfunction and to evaluate the risk of heart disease and other cardiovascular diseases. Itamar Medical is a public company traded on the Nasdaq and on the Tel Aviv Stock Exchanges, and is based in Caesarea, Israel with U.S. headquarters based in Atlanta, GA. For additional information visit www.itamar-medical.com.
Forward-Looking Statements

This Press Release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Statements preceded by, followed by, or that otherwise include the words "believes", "expects", "anticipates", "intends", "estimates", "plans", and similar expressions or future or conditional verbs such as "will", "should", "would", "may" and "could" are generally forward-looking in nature and not historical facts. For example, when we discuss expectations of improving patient access to WatchPAT™ by increasing the number of physicians able to offer it to their patients, we are using forward-looking statements. Because such statements deal with future events, they are subject to various risks, uncertainties and assumptions, including events and circumstances out of the Company's control and actual results, expressed or implied by such forward-looking statements, could differ materially from the Company's current expectations. Factors that could cause or contribute to such differences include, but are not limited to, risks, uncertainties and assumptions discussed from time to time by the Company in reports filed with, or furnished to, the U.S. Securities and Exchange Commission ("SEC") and the Israel Securities Authority ("ISA"), including the Company’s latest Form 20-F which is on file with the SEC and the ISA. Except as otherwise required by law, the Company undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

The contents of any website of hyperlinks mentioned in this press release are for informational purposes only and the contents thereof are not part of this press release nor is it incorporated herein by reference.

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