

**SLEEP DEPRIVATION AND OTHER SLEEP DISORDERS CAN HAVE A SERIOUS EFFECT ON HEALTH**

**SLEEP PROBLEMS MAY AFFECT PERFORMANCE AT WORK AND QUALITY OF LIFE, AS WELL AS HAVE AN IMPACT ON SOME CHRONIC DISEASES**

**THE “SLEEP & HEALTH” PROJECT DEDICATED TO GPs AND SPECIALISTS**

*Insomnia and disruption of the sleep-wake cycle start a cascade of events that involve different organs, and have been associated with a wide range of deleterious health consequences, including an increased risk of hypertension, diabetes and obesity: an early identification of patients with sleep problems and an optimal treatment planning and management have a major influence on the patient’s physical and mental condition*

**Milan, March 16, 2018** – Approximately **4 out of 5 diabetic patients**<sup>1</sup> and **2 out of 5 hypertensive patients**<sup>2</sup> show symptoms of insomnia. Findings from recent studies have demonstrated the close relationship between sleep disorders and cardiometabolic diseases, such as **hypertension**<sup>3</sup> and **type II diabetes**. According to these studies, diabetes is a major comorbid condition in sleep-deprived individuals<sup>4</sup>, and people suffering from sleep disorders have a higher risk of developing hypertension, namely 300-500% higher with respect to non-insomniacs (independently of age, body mass index, diabetes, alcohol consumption, and smoking).<sup>5,6,7</sup>

*“Such work has led to further confirmation of the key role exerted by sleep in maintaining a good mental and physical health: changes in the so-called internal clock may also have an impact on other crucial physiological functions, such as hormone levels, body temperature, blood pressure, mood, and energy metabolism – says Prof. Lino Nobili, Scientific Coordinator of the Sleep & Health Project, (Progetto Sonno & Salute), Secretary of the European Sleep and Research Society and Head of the Centre of Sleep Medicine, Niguarda Hospital, Milan, Italy - Sleep disturbances, hypertension and diabetes are frequently associated with lower secretion of melatonin, a naturally occurring hormone mainly released by the pineal gland in the head, that regulates circadian rhythm and maintains the internal clock balanced within a 24-hour schedule. Besides regulating the sleep-wake cycle, melatonin plays a decisive role in modulating energy and glucose metabolism over 24 hours. In addition, by influencing the circadian rhythm – hence, blood pressure - melatonin may also affect the cardiovascular system.”*

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1. Aiding sleep in type 2 diabetes: therapeutic considerations Tan X et al. Lancet Diabetes Endocrinol 2017; 6: 60-68.

2. Effect of melatonin on nocturnal blood pressure: meta-analysis of randomized controlled trials Grossman E et al. Vasc Health Risk Manag. 2011;7:577-84.

3. Sleep and Cardio-Metabolic Disease Cappuccio FP et al. Curr Cardiol Rep. 2017; 19(11):110.

4. Efficacy and safety of prolonged-release melatonin in insomnia patients with diabetes: a randomized, double-blind, crossover study Garfinkel D. et al. Diabetes Metab Syndr Obes. 2011; 4: 307–313.

5. Insomnia and Hypertension Vgontzas AN et al. Sleep. 2009; 32(12): 1547.

6. Insomnia with objective short sleep duration and incident hypertension: the Penn State Cohort. Fernandez Mendoza J. et al. Hypertension. 2012;60(4):929-35.

7. Insomnia With Physiological Hyperarousal Is Associated With Hypertension Li Y. et al. Hypertension 2015;65:644-650.

Based on this evidence, and thanks to the contribution of the Italian pharma company **Fidia Farmaceutici**, the second edition of the **Sleep & Health Project** (Progetto Sonno & Salute) will be launched this month, focusing on the cardiometabolic comorbidities of insomnia. Starting March 24, 2018, 18 CME courses will take place throughout Italy, involving local GPs and specialists (cardiologists, endocrinologists, geriatric physicians, diabetologists, neurologists, internists, and psychiatrists).

The courses aim at promoting the cultural perceptions about sleep disorders and the adverse health outcomes associated with inadequate sleep, in the attempt to better recognize the patients who suffer from sleep disturbances and provide the most appropriate diagnosis and treatment. The courses feature an expert Faculty composed of specialists in Sleep Medicine, Diabetology, Cardiology/Internal Medicine: **Prof. Lino Nobili**, Scientific Coordinator of the Sleep & Health Project, Secretary of the European Sleep Research Society and Head of the Centre of Sleep Medicine, Niguarda Hospital, Milan, Italy; **Dr. Raffaele Ferri**, President of AIMS and Director of the Head of the Centre of Sleep Medicine, Department of Neurology at the Oasi Institute for Research on Mental Retardation and Brain Aging (IRCCS), Troina, Italy; **Dr. Dario Arnaldi**, Centre of Sleep Medicine, Neurology Clinic – Department of Neuroscience (DiNOGMI) – University of Genova, Italy; **Prof. Nicola Montano**, Department of Clinical Sciences and Community Health, University of Milan, Department of Internal Medicine, Ca' Granda IRCCS Foundation, Ospedale Maggiore Policlinico, Milan, Italy; **Prof. Bruno Trimarco**, Department of Clinical Medicine, Cardiovascular and Immunological Sciences, Federico II University, Naples, Italy; **Dr. Giovanni Sartore**, Department of Medicine (DIMED) – Diabetology and Dietetics Service, University of Padua, Italy.

The Project is being supported by **AIMS** (*Associazione Italiana Medicina del Sonno* - Italian Association of Sleep Medicine), **SIN** (*Società Italiana Neurologia* - Italian Society of Neurology), **SIHA** (*Società Italiana dell'Ipertensione Arteriosa* - Italian Society of Hypertension), **SIMI** (*Società Italiana Medicina Interna* - Italian Society of Internal Medicine), and **AMD** (*Associazione Medici Diabetologi* - Italian Association of Diabetologists).

In addition, the Sleep & Health Project is part of the awareness activities of the **World Sleep Day 2018** and falls under the aegis of the **World Sleep Society** for the second consecutive year.

*“The first step in managing insomnia involves treating the underlying causes that may be contributing to the disorder and modify unwanted behaviors that can cause or worsen insomnia. Most frequently recommended pharmacological treatments include sedative-hypnotic medications with a short half-life and prolonged-release melatonin 2 mg approved as a drug. Treatment with hypnotics should be short-term and not exceed 4 weeks. In fact, they tend to gradually lose their efficacy when taken on a nightly basis in the long-term, as well as have side effects that can further disrupt sleep. We must also keep in mind that these medications can have residual negative daytime effects, such as sleepiness and alterations of cognitive performance (memory loss, attention deficits) that may interfere with activities of daily living – says Prof. Nobili. Prolonged-release melatonin 2 mg may be used short-term to improve quality of sleep in people ≥ 55 years. Clinical studies have demonstrated that the prolonged-release formulation of melatonin 2mg, by getting the sleep-wake cycle back in sync, significantly decreases time getting to sleep, and improves quality of sleep and next-day alertness. Treatment is approved for 13 consecutive weeks, with no evidence of dependence and no impact on daytime performance, also when combined with other therapies in patients with comorbidities, such as hypertensive and diabetic subjects.”*



## **Fidia Farmaceutici**

*Fidia Farmaceutici is an Italian company founded in 1946 with proven expertise in Neuroscience, acquired over the years thanks to an activity of Research and Development unique in the Italian pharmaceutical scenario. It is also a top leading company in marketing products based on hyaluronic acid and its derivatives, which have many applications in the biomedical field, in areas such as rheumatology, orthopedics, wound care, tissue repair, ophthalmology, dermo-aesthetics, and regenerative medicine, with worldwide leadership in viscosupplementation. The company is well established in Italy, with R&D activities and manufacturing activities carried out both in Abano Terme (where the company's headquarter is located) and at the Research Unit in Noto (Sicily, Italy). Current turnover amounts to 300 million Euros, 50% generated in international markets. Fidia Farmaceutici's products are marketed in over 100 countries, through wholly-owned subsidiaries – in USA, Germany, Spain, Russia and the Middle East – and a comprehensive network of international partners and distributors. Thanks to its investment in R&D, it has managed to create a time-honored legacy of products, with over 900 patents to its name, 600 of which on hyaluronic acid with different molecular weights.*