



PRESS RELEASE

March 17, 2017 is the World Sleep Day

SLEEP DISORDERS MAY AFFECT HEALTH, PERFORMANCE AT WORK AND QUALITY OF LIFE

*Management of sleep disorders may result in significant improvement of general health.
The first step is talk to the primary care provider.*

Abano Terme (PD), March 16, 2017 – Social media use is rapidly increasing, as well as daytime and bedtime use of computers, including devices such as smartphones, tablets and laptops. Work, stress, menopause, advancing age or a variety of underlying medical conditions affecting the general population, may be responsible for those nights of missed sleep, until getting back to a normal pattern becomes increasingly difficult. An estimated 9 million people in Italy suffer from sleep disorders, that partially contribute to poorer work performance, general health and quality of life.

A cross-national study¹ of sleep problems conducted in 5 European countries, including Italy, involved 62,000 adults with a diagnosis of insomnia, with or without medication, and a control group. A significant association was observed between the presence of insomnia and health-related quality of life, work productivity loss, and healthcare resource use (i.e., visits/hospitalization). Specifically, patients with insomnia reported greater overall work impairment (38.74% vs. 14.86%), significantly more absenteeism and activity impairment, as well as healthcare resource use and more physician visits in the past 6 months (9.10 vs. 4.08).

A good night's sleep is a key factor for good health and well-being. *'Sleep –possibly quality sleep - is as important to our health and well-being as good nutrition and exercise - says Prof. Lino Nobili, Specialist in Neurophysiopathology and Neuropsychiatry, Scientific Coordinator of the Sleep&Health Project (Progetto Sonno&Salute). Situations affecting the quality and quantity of sleep, especially for long periods of time, may have an impact on mental state and detrimental effects on cognitive function, and may result in endocrine, immunologic and cardiovascular alterations. Early intervention on sleep disorders is also recognised as being essential to improve general health status of patients'*

The choice of treatment should be individualized according to the type of sleep disturbance and the patient's general condition. The first step in treatment for insomnia involves consulting with the healthcare provider to discuss and treat the underlying cause that may be contributing to the disorder. However, insomnia may sometimes persist after the underlying condition is treated. Then, the two main treatment

¹ DiBonaventura M. et Al., The Association between Insomnia and Insomnia Treatment Side Effects on Health Status, Work Productivity, and Healthcare Resource Use, PLOS One, October 1, 2015

options are medical (medical includes medications, and PAP therapy for insomniacs due to sleep apnea) and behavioral. "A number of approaches have been taken to modify unwanted behaviors that can cause or worsen insomnia. Generally, they aim at identifying and changing the thoughts, habits and behaviors that interfere with sleep, as well as lowering overall levels of anxiety and worry related with sleep ("the fear of not being able to sleep"). International treatment guidelines for the treatment of sleep disorders recommend sedative-hypnotic medications with a short half-life and prolonged-release melatonin (PRM) 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, including driving and operating machinery. Therefore, optimal treatment should use the lowest effective dose. Prolonged-release melatonin 2 mg may be used short-term to improve quality of sleep in people ≥ 55 years, but can be also used in adult patients younger than 55 years. Melatonin is a naturally occurring hormone mainly released from the pineal gland in the head. It has a key role in regulating the sleep-wake cycle, thereby melatonin facilitates the feeling of sleepiness and the ability to induce and maintain sleep. Clinical studies have demonstrated that the prolonged-release formulation of melatonin, PRM 2mg, significantly decreases time getting to sleep, and improves quality of sleep and next-day alertness. Treatment for 13 consecutive weeks ensures a continued effect of PRM 2 mg, with no evidence of dependence and no impact on daytime performance." summarizes Prof. Nobili.

The SONNO & SALUTE project was born within this context, thanks to the contribution of an Italian pharma company, **Fidia Farmaceutici**: April through September 2017, the Project will be touring in several regions across Italy, namely Veneto, Lombardy, Piedmont, Liguria, Friuli Venezia Giulia, Emilia Romagna, Tuscany, Lazio, Abruzzo, Apulia, Calabria, Sardinia and Sicily. The project is part of the awareness activities of the World Sleep Day 2017 and falls under the aegis of the World Sleep Society. It has been developed by sleep scientists and experts and is dedicated to GPs, with the aim to advance, also in Italy, knowledge about sleep health and disorders. The goal and purpose of this Project is the early recognition of patients with insomnia or other sleep disorders, to expedite most appropriate treatment approach.

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, which have many applications in the biomedical field, in areas such as rheumatology, orthopaedics, wound care, tissue repair and dermo-aesthetics, with worldwide leadership in viscosupplementation. Fidria Farmaceutici is part of the Milanese P&R Holding group. The company is well established in Italy, with R&D activities carried out both in Abano (where the company's headquarter is located) and at the Research Unit in Noto (Sicily, Italy). The turnover will amount over 300 million Euros in 2017, of which 70% generated in international markets. Fidria Farmaceutici's products are marketed in over 100 countries, through wholly-owned subsidiaries - in USA, Kazakhstan, 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-honoured legacy of products, with over 900 patents to its name.