



December 16, 2024

To Whom It May Concern

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KYORIN and Bayer Enter into License Agreement for Novel Obstructive Sleep Apnea (OSA) Treatment

KYORIN Pharmaceutical Co., Ltd. announced that it has entered into a licensee agreement on December 13, 2024, with Bayer AG (Berlin Germany, CEO: Bill Anderson), for the novel OSA treatment BAY2925976 and its backup compound discovered by Bayer AG.

Under this agreement, KYORIN have obtained the exclusive worldwide rights to manufacture, develop, and commercialize BAY2925976 and its backup compound. KYORIN will make an upfront payment of EUR 15 million to Bayer AG, along with milestone payments of up to EUR 70 million based on development progress. Additionally, royalties based on net sales and commercialization milestone payments will be provided to Bayer AG.

OSA impacts more than 1 billion individuals globally, including approximately 9 million moderate-to-severe cases in Japan that require treatment^{*1}. OSA is associated with significant health risks such as cardiovascular disease and diabetes, and it can lead to accidents due to drowsy driving or work-related incidents. Despite these risks, many suffers of OSA remain untreated or receive insufficient care. Through the development and commercialization of BAY2925976, KYORIN aims to expand treatment options available for OSA, contributing to enhance care and improve the quality of life for those patients.

BAY2925976 works as an ADRA2C (α 2-adrenergic receptors) antagonist, helping to centrally reduce upper airway collapse. It is expected to improve the temporary apneas and hypopneas commonly observed in patients with OSA. Bayer AG has completed the Phase1 clinical program for BAY2925976.

KYORIN aims to create high-value new drugs that meet medical needs and has prioritized “Expand development pipeline” under its long-term vision “*Vision 110*”. With this agreement, we are committed to advancing the development of new treatment options for OSA patients worldwide as soon as possible, contributing to people’s health.

The impact on the consolidated earnings forecast for the fiscal year ending March 2025 is expected to include the upfront payment to Bayer AG under this agreement, which will be recorded as SG&A expenses (R&D expenses) for the current fiscal year. Any matters requiring timely disclosure arise, KYORIN will make prompt announcements accordingly.

[Reference]

About Obstructive Sleep Apnea (OSA)*2,3,4

OSA is a condition characterized by repeated episodes of apnea or difficulty breathing during sleep, caused by the collapse of upper airway muscles, particularly the genioglossus. These episodes lead to interrupted breathing throughout the night, significantly reducing sleep quality. As a result, patients with OSA often experience excessive daytime sleepiness and fatigue, which can increase the risk of drowsy driving accidents and work-related accidents. In addition, the oxygen deprivation caused by OSA triggers increased cardiac activity, which can lead to hypertension. OSA is also associated with a higher risk of lifestyle-related diseases and conditions, including arteriosclerosis, heart attacks, strokes, and elevated blood sugar and cholesterol levels.

Globally, over 1 billion people are estimated to suffer from OSA, with more than 9 million moderate-to-severe cases in Japan requiring treatment. However, less than 10% of affected patients are currently receiving appropriate care, leaving a large number of untreated or inadequately treated patients.

Currently, the standard treatment for OSA is Continuous Positive Airway Pressure (CPAP) therapy. It is reported that a certain number of patients are either ineligible for insurance coverage of CPAP or find CPAP therapy difficult to use. Meanwhile, options for pharmacological treatment remain limited.

*1. Benjafield AV, Ayas NT, Eastwood PR, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. *Lancet Respir Med* 7: 687-698, 2019.

*2. Clinical Practice Guideline for Sleep Apnea Syndrome (SAS) 2020

*3. Sleep Apnea Syndrome : SAS, Website of The Japanese Respiratory Society (<https://www.jrs.or.jp/english/>)

*4. E-health net: Website of MHLW (<https://www.e-healthnet.mhlw.go.jp/information/>)