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KYORIN Enter into Distribution and Promotion Agreement with Johnson & Johnson for SIRTURO®

KYORIN Pharmaceutical Co., Ltd. announced today that it has entered into an exclusive distribution and promotion agreement with Johnson & Johnson (the legal entity for the prescription pharmaceuticals business in Japan, operating as Janssen Pharmaceutical K.K., headquartered in Chiyoda-ku, Tokyo; President: Christopher Rieger; hereafter "J&J") on March 25, 2026, for SIRTURO® (Bedaquiline; hereafter "the Product"). The Product is currently marketed by J&J as a part of combination therapy in patients with multidrug-resistant pulmonary tuberculosis (MDR-TB). Furthermore, J&J is currently conducting Phase 2/3 clinical trials in patients with treatment-refractory *Mycobacterium avium* complex-lung disease (MAC-LD) to expand its approved indications.

Under this agreement, KYORIN will commence sole promotional activities for the Product from June 2026. Furthermore, upon obtaining approval for the additional indication of MAC-LD, KYORIN will receive product supply from J&J and exclusively distribute and promote the Product.

The Product is a diarylquinoline antimycobacterial drug marketed globally by J&J. It specifically inhibits ATP synthase, which is essential for the energy production of *Mycobacterium tuberculosis*, and exhibits antibacterial activity against both actively replicating and dormant cells. In Japan, it has been available since 2018 for the treatment of MDR-TB, with strains of *Mycobacterium tuberculosis* susceptible to the Product as the indicated bacterial species. As an oral medication, the standard dosage for adults is 400 mg once daily for the first two weeks, followed by 200 mg three times per week (with at least 48 hours between doses) from the third week onwards, to be taken with food. Furthermore, it is required that the Product always be used in combination with other antimycobacterial drugs.

In its medium-term business plan, "Vision 110 – Stage1 –", KYORIN aims for the "expansion of development pipeline through in-licensing", focusing on products that are expected to contribute

early to business results. Under the “Franchise Customer (FC) Strategy”, which concentrates resources on the specialized areas of respiratory, otolaryngology, and urology. KYORIN strives to contribute to the treatment of patients suffering from infectious diseases by adding this drug to product lineup.

The impact on business performance for the fiscal year ending March 31, 2026 is expected to be negligible.

There are no capital, personnel, or business relationships between KYORIN and J&J, and neither party is considered a related party to the other.

[Reference]

About SIRTURO®

SIRTURO® is a diarylquinoline antimycobacterial drug marketed globally by J&J. It specifically inhibits ATP synthase, which is essential for the energy production of *Mycobacterium tuberculosis*, and exhibits antibacterial activity against both actively replicating and dormant mycobacteria. SIRTURO® was approved in the United States in 2012 and Europe in 2014. In Japan, it has been available since 2018 as part of combination therapy of MDR-TB.

About MDR-TB

MDR-TB refers to pulmonary tuberculosis that is resistant to at least isoniazid (INH) and rifampicin (RFP), which are primary first-line antimycobacterial drugs. Issues in treatment, such as treatment interruption or irregular medication adherence, drive the development of drug resistance and, consequently, multidrug resistance in *Mycobacterium tuberculosis*.

According to the 2024 Annual Report on Tuberculosis Survey in Japan, out of 6,423 newly registered sputum smear-positive pulmonary tuberculosis patients, 45 were reported as having MDR-TB (resistant to both INH and RFP) [1].

About MAC-LD

MAC-LD is a chronic infection caused by nontuberculous mycobacteria (NTM), specifically where *Mycobacterium avium* complex is the causative pathogen. MAC-LD is reported to account for 80% to 90% of all pulmonary NTM cases. Cases are diagnosed as refractory if bacteriological efficacy remains insufficient even after at least six months of multidrug therapy, the standard of care. The incidence rate of pulmonary NTM disease in 2017 was reported to be 19.2 per 100,000 people [2].

J&J is currently conducting Phase 2/3 clinical trials in patients with treatment-refractory MAC-LD [3].

1. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000175095_00016.html
2. Hamaguchi Y, et al. *ERJ Open Res* 2025; 11: 00337-2024
3. NCT04630145 / jRCT2031200268