Announcement

November 9, 2026

Update on New Drug Application (NDA) in Japan

Aiming to accelerate access to this therapy for patients, families, and caregivers by leveraging overseas clinical data without additional clinical trials in Japan

LinDo K.K. (Head Office: Tokyo, Japan, President: Jun Katsura) announces that, following a consultation with the Pharmaceuticals and Medical Devices Agency (PMDA), the company has decided to proceed with an application for manufacturing and marketing approval in Japan for its oral solution containing Glycopyrronium Bromide currently under development (the "Product"). The application will utilize clinical data from studies conducted overseas, without conducting new clinical trials involving Japanese participants.

Through consultations with the PMDA, the company has engaged in careful discussions regarding the development strategy for the Product. The company has carefully evaluated multiple factors, including extensive overseas clinical experience, scientific validity, and critical unmet medical needs in Japan. The evaluation also considered the potential value of data obtained from a new clinical trial involving Japanese participants, the time required to conduct such a trial, and the importance of providing the Product to patients as early as possible. Based on these discussions, the company has decided to make full use of clinical data from overseas studies and proceed with an early application for manufacturing and marketing approval in Japan, without conducting a new clinical trial involving Japanese pediatric patients.

The Product was developed by Proveca Ltd. (Headquarters: UK) as a pediatric treatment for severe chronic sialorrhea associated with chronic neurological disorders and was granted marketing authorization in the EU in 2016.
In Japan, however, the Product has remained unavailable for nearly a decade, a situation commonly referred to as "drug loss." To address this gap, the company acquired exclusive development and commercialization rights for the Product in Japan in July 2026. The company expects this decision to represent an important step toward making the Product available in Japan.

Sialorrhea associated with chronic neurological disorders such as cerebral palsy is a serious symptom that not only impairs the quality of life of pediatric patients but also increases the caregiving burden on their families and poses a risk of serious respiratory complications, including aspiration pneumonia. The company will continue to make steady progress toward regulatory submission, aiming to bring the Product to pediatric patients suffering from sialorrhea associated with chronic neurological disorders, as well as their families and caregivers, as soon as possible.

Comment from Jun Katsura, President:

“This decision paves the way for bringing the Product to patients and caregivers in Japan sooner. We believe it represents a meaningful step toward achieving our company goal. In recent years, regulatory authorities in Japan have been steadily reviewing pharmaceutical regulations and implementing initiatives to promote drug development in an effort to address “drug loss”. In light of these initiatives, our mission is to deliver medications to patients as promptly as possible by rigorously examining clinical trial results and experience with clinical use overseas, while thoughtfully determining development plans appropriate for Japan's healthcare environment and patients. We will continue to advance preparations for the regulatory submission through ongoing discussions with the PMDA and other relevant organizations, contributing to efforts to address "drug loss." *1) in Japan.”

About the oral solution containing glycopyrronium bromide:

The Product is an oral solution containing glycopyrronium bromide, a peripheral anticholinergic agent, as its active ingredient. By antagonizing muscarinic receptors in the salivary glands, glycopyrronium bromide suppresses excessive saliva secretion. The Product is being developed to treat severe sialorrhea associated with chronic neurological disorders such as cerebral palsy.

*1): "Drug Loss" refers to a critical situation where innovative medicines approved globally remain unavailable in Japan due to a lack of local clinical development. Moving beyond the historical issue of "drug lag" (delayed approval), this has emerged as a severe challenge directly impacting patient access to healthcare, as patients in Japan are entirely deprived of the opportunity to receive global standard treatments. This is particularly observed in oncology, rare diseases, and pediatrics, and is widely recognized as a challenge that needs to be addressed.

References:

- Ministry of Health, Labour and Welfare: "Report of the Expert Committee on Comprehensive Measures for the Swift and Stable Supply of Pharmaceuticals" (in Japanese) (https://www.mhlw.go.jp/stf/newpage_33548.html)
- Ministry of Health, Labour and Welfare: "Report of the Committee on Regulatory Affairs for Strengthening Drug Discovery Standards and Ensuring Stable Supply" (in Japanese) (https://www.mhlw.go.jp/stf/newpage_39934.html)

About LinDo K.K.:
At LinDo, we address vital medical needs that extend beyond mere patient numbers or market size, striving to realize a society where medical choices are not limited by country or disease. Our mission is to address the "drug loss" by in-licensing, developing, and commercializing therapies that are approved globally but remain unavailable in Japan. Through strategic partnerships both locally and worldwide, we advance our unique "New Business Model to Overcome Drug Loss," enhancing healthcare access to ensure that essential medical value reaches the people who need it most.
Corporate Website: https://lindosi.com/