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KYORIN and Edesa Biotech Enter into License Agreement for EB05 for ARDS (Acute Respiratory Distress Syndrome)

KYORIN Pharmaceutical Co., Ltd. announced that it has entered into a license agreement on November 9, 2026, with Edesa Biotech, Inc. (Toronto, Canada, CEO: Par Nijhawan), for Edesa's ARDS treatment EB05 (paridiprubart).

Under this agreement, KYORIN has obtained the exclusive rights to develop and commercialize EB05 in Japan. KYORIN will make an upfront payment of USD 12 million to Edesa, along with milestone payments of up to USD 134 million based on the progress of development, NHI price listing, and the achievement of certain net sales targets. Additionally, royalties based on net sales will be paid to Edesa.

ARDS is a severe, life-threatening form of acute respiratory failure resulting from conditions such as pneumonia, sepsis, trauma and other serious conditions. Current management is primarily supportive, including mechanical ventilation, and there are limited pharmacologic treatment options shown to improve survival. Thus, ARDS continues to be associated with substantial mortality and represents a significant unmet medical need.

Paridiprubart is an investigational monoclonal antibody targeting Toll-like receptor 4 (TLR4), a key mediator of innate immune signaling and inflammation. By inhibiting TLR4 signaling, paridiprubart is designed to modulate excessive inflammatory responses that contribute to the pathophysiology of ARDS - with the goal of improving survival and clinical outcomes. Edesa and KYORIN intend to collaborate on future clinical development of EB05 in ARDS, with KYORIN responsible for clinical development activities in Japan.

KYORIN aims to create high-value new drugs that meet medical needs and has prioritized the "Expansion of development pipeline through in-licensing" under its medium-term vision, "Vision 110 －Stage2－". Through this agreement, we are committed to actively advancing development to deliver new treatment options to patients as soon as possible, thereby contributing to people's health.

The impact on the consolidated earnings forecast for the fiscal year ending March 2027 is expected to include the upfront payment to Edesa under this agreement, which will be recorded as SG&A expenses (R&D expenses) for the current fiscal year. For details, please refer to the "Notice Regarding Difference Between Financial Forecast and Actual Results for the First Half of FY2026 and Revision of Financial Forecasts for FY2026" announced separately today.

[Reference]

About Paridiprubart (EB05)

Paridiprubart is an investigational monoclonal antibody targeting Toll-like receptor 4 (TLR4), a key mediator of innate immune signaling and inflammation. By inhibiting TLR4 signaling, paridiprubart is designed to modulate excessive inflammatory responses that contribute to the pathophysiology of ARDS - with the goal of improving survival and clinical outcomes. Edesa has announced Phase 3 clinical trial data in patients with ARDS associated with SARS-CoV-2 infection, demonstrating that the group receiving EB05 in combination with standard of care showed a statistically significant reduction in Day 28 mortality compared to the placebo group in the patient population consisting of severely ill patients (WCSS score* of 6 and 7) receiving invasive mechanical ventilation (adjusted mortality risk: 39% vs. 53%, $p<0.001$). This therapeutic effect was durable out to Day 60 ($p=0.003$). A statistically significant reduction in mortality was also observed in the overall study population, which included patients with a broader range of disease severity. Exploratory analyses identified treatment effects in clinically relevant subgroups, including patients with sepsis, pneumonia, and acute kidney injury. Paridiprubart was generally well tolerated with a favorable safety profile. For further details, please refer to Edesa's press release (https://www.edesabiotech.com/news/news-archive-2025/).

*WCSS Score: WHO Clinical Progression Scale. A 7-point ordinal scale based on the clinical status and level of respiratory support in COVID-19 patients. WCSS 6: Intubation and mechanical ventilation; WCSS 7: Intubation + additional organ support (vasopressors, RRT/renal replacement therapy, ECMO/extracorporeal membrane oxygenation). Source: *WHO R&D Blueprint: novel Coronavirus COVID-19 Therapeutic Trial Synopsis, World Health Organization.*

About ARDS

Acute Respiratory Distress Syndrome (ARDS) is a severe, life-threatening form of acute respiratory failure that can develop following pneumonia, sepsis, major trauma and other serious conditions. ARDS is characterized by an excessive inflammatory response, increased pulmonary vascular permeability, pulmonary edema and severe impairment of oxygenation. Despite advances in supportive care, such as mechanical ventilation, ARDS continues to carry a high risk of mortality. There are currently limited pharmacological treatments specifically shown to improve survival, highlighting a significant unmet medical need.

About Edesa Biotech, Inc.

Edesa Biotech, Inc. (Nasdaq: EDSA) is a clinical-stage biopharmaceutical company developing innovative ways to treat inflammatory and immune-related diseases. Its clinical pipeline is focused on two therapeutic areas: Medical Dermatology and Respiratory. In Medical Dermatology, Edesa is developing EB06, an anti-CXCL10 monoclonal antibody, as a therapy for vitiligo, a common autoimmune disorder that causes skin to lose its color in patches. Its medical dermatology assets also include EB01 (1.0% daniluromer cream), a Phase 3-ready asset developed for use as a potential therapy for moderate-to-severe chronic Allergic Contact Dermatitis (ACD), a common occupational skin condition. The Company's most advanced Respiratory drug candidate is paridiprubart (EB05), which is being developed as a potential treatment for Acute Respiratory Distress Syndrome, a life-threatening form of respiratory failure. The paridiprubart program has been the recipient of two funding awards from the Government of Canada to support the further development of this asset, and is currently being evaluated in a U.S. government-funded platform study. Edesa is also pursuing additional uses for paridiprubart.

For more information, please visit https://www.edesabiotech.com/

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