Material Information (6446 PEC)					
SEQ_NO	2	Date of announcement	2025/09/05	Time of announcement	21:48:01
Subject	PharmaEssentia Files for an Additional Indication of Besremi (Ropeginterferon alfa-2b) for the Treatment of Essential Thrombocythemia (ET) with TFDA				
Date of events	2025/09/05	To which item it meets	paragraph 10		
Statement	1.Date of occurrence of the event:2025/09/05 2.New drug name or code:Besremi (Ropeginterferon alfa-2b, P1101) 3.Indication: Adult patients with essential thrombocythemia (ET) who are resistant or intolerant to hydroxyurea (HU) 4.Planned development stages:Application of indication addition 5.Current development stage: (1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): PharmaEssentia has submitted a Post-Approval Change Application to the Taiwan Food and Drug Administration (TFDA) for Besremi (Ropeginterferon alfa-2b) to add a new indication for adult patients with essential thrombocythemia (ET) who are resistant or intolerant to hydroxyurea (HU). (2)Risks and mitigation measures to be taken by the company upon disapproval of the competent authority: N/A (3)Strategies to be taken by the company upon approval by the competent authority: N/A (4)Accumulated investment expenditure incurred: In consideration of the future marketing strategy and to protect the rights of the company and investors, no public disclosure will be made for the time being. 6.Upcoming development plan: Review of indication addition application in Taiwan (1)Estimated date of completion: According to the Application Processing Timetable of TFDA, review time for an indication addition is 180 days, and time for further documents request is not included. The actual review time and approval shall be subject to the decision of TFDA. (2)Estimated responsibilities: N/A. 7.Market situation: Essential thrombocythemia (ET) is a myeloproliferative neoplasm (MPN) characterized by an overproduction of platelets in the blood resulting from a genetic mutation. The patient number of ET is similar to that of polycythemia vera (PV). According to a study using Taiwan’s National Health Insurance database, there are around 4,500 patients with ET in Taiwan (the prevalence of ET in Taiwan was approximately 20 cases per 100,000 people). Currently, the first-line drug for ET is HU, which is used off-label, and the second-line drug for ET is anagrelide, approved by the U.S. FDA in 1997. 8.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 8 of the Securities and Exchange Act Enforcement Rules, which brings forth a significant impact on shareholders rights or the price of the securities on public companies.): (1)The Taiwan Ministry of Health and Welfare (MOHW) approved the marketing authorization for Besremi 500 mcg/mL and 250 mcg/0.5mL solution for injection in prefilled syringe for the treatment of adult patients with polycythemia vera (PV) without symptomatic splenomegaly in 2020. In 2022, the National Health Insurance Administration included Besremi in Taiwan’s national health insurance coverage. (2)Ropeginterferon alfa-2b is an innovative monopegylated, long-acting interferon invented and manufactured by PharmaEssentia. Ropeginterferon alfa-2b is approved to treat adult patients with PV in around 50 countries in the world, including major markets such as the United States, Japan, China and European Union. 9.New drug development requires long process, vast investments and with no guarantee in success which may pose investment risks.The investors are advised to exercise caution and conduct thorough evaluation.:				