

Material Information (6446 PEC)					
SEQ_NO	1	Date of announcement	2025/04/01	Time of announcement	14:25:13
Subject	The Company Announces Submission of Marketing Authorization Application of BESREMi (Ropeginterferon alfa-2b) for PV in Vietnam				
Date of events	2025/04/01	To which item it meets	paragraph 10		
Statement	<p>1.Date of occurrence of the event:2025/04/01</p> <p>2.New drug name or code:BESREMi (Ropeginterferon alfa-2b, P1101)</p> <p>3.Indication:Treatment of adults with Polycythemia Vera (PV)</p> <p>4.Planned development stages: Submission of marketing authorization application in Vietnam</p> <p>5.Current development stage: (1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): The marketing authorization application of BESREMi 500 mcg/mL solution for injection in prefilled syringe for PV has been submitted in Vietnam.</p> <p>(2)Risks and mitigation measures to be taken by the company upon disapproval of the competent authority:N/A</p> <p>(3)Strategies to be taken by the company upon approval by the competent authority: N/A</p> <p>(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.</p> <p>6.Upcoming development plan: Review of the marketing authorization application in Vietnam.</p> <p>(1)Estimated date of completion: The actual review time and approval shall be subject to the decision of Drug Administration of Vietnam (DAV).</p> <p>(2)Estimated responsibilities: N/A.</p> <p>7.Market situation: Polycythemia Vera (PV) is a chronic, progressive myeloproliferative neoplasm (MPN). Although the overproduction of red blood cells is most dramatic; however, in most cases, there are elevated white blood cells and platelets as well. PV patients are at high risk of cardiovascular complications such as thrombosis and embolism and secondary myelofibrosis or leukemic transformation. According to the market research, there are around 15,000 PV patients in Vietnam, and the current treatment includes phlebotomy, hydroxyurea (HU), interferon and JAK2inhibitors.</p> <p>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.): 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 Polycythemia Vera (PV) in more than 40 countries worldwide, including major markets such as the United States, Japan, China and European Union.</p> <p>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.:</p>				