

Material Information (6446 PEC)

SEQ_NO	1	Date of announcement	2025/10/06	Time of announcement	20:20:03
Subject	Hong Kong Department of Health has Approved the New Drug Registration of BESREMi (Ropeginterferon alfa-2b) for PV				
Date of events	2025/10/06	To which item it meets	paragraph 10		
Statement	<p>1.Date of occurrence of the event:2025/10/06</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:N/A</p> <p>5.Current development stage:</p> <p>(1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): Hong Kong Department of Health has approved the new drug registration of BESREMi (Ropeginterferon alfa-2b) 500mcg/mL solution for injection in prefilled syringe for adults with PV.</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: PharmaEssentia will initiate the sales and marketing activities for Ropeginterferon alfa-2b in Hong Kong as per the launch plan.</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:N/A</p> <p>(1) Estimated date of completion: N/A</p> <p>(2) Estimated responsibilities: None.</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. Patients with PV are at high risk of cardiovascular complications such as thrombosis, embolism and secondary myelofibrosis or leukemic transformation. There are around 500 patients living with PV in Hong Kong, and clinical treatments include phlebotomy, hydroxyurea (HU) and interferon.</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 around 50 countries worldwide, including major markets such as the European Union, the United States, and Japan.</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>				