

Material Information (6446 PEC)					
SEQ_NO	1	Date of announcement	2025/06/18	Time of announcement	06:00:42
Subject	Argentina ANMAT has Approved the Marketing Authorization Application of BESREMi (Ropeginterferon alfa-2b) for PV				
Date of events	2025/06/17	To which item it meets	paragraph 10		
Statement	<p>1.Date of occurrence of the event:2025/06/17</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):</p> <p>Argentina National Administration of Drugs, Food and Medical Devices (ANMAT) has approved the marketing authorization application of BESREMi (Ropeginterferon alfa-2b) 500mcg/mL and 250mcg/0.5mL solution for subcutaneous 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:</p> <p>PharmaEssentia has entered into an exclusive commercial license agreement with Pint-Pharma GmbH for the registration and commercialization of Ropeginterferon alfa-2b in Brazil, Argentina, Colombia, Chile, Peru, Ecuador, and Mexico.</p> <p>(4)Accumulated investment expenditure incurred:</p> <p>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:</p> <p>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.</p> <p>According to the market research, there are more than 100,000 PV patients in Latin America, 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.):</p> <p>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 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>				