

Material Information (6446 PEC)					
SEQ_NO	1	Date of announcement	2025/01/02	Time of announcement	19:28:10
Subject	Update on the Company's IND Application of Phase I Clinical Trial of TCRT-ESO-A2-TW in Patients with Advanced Solid Tumors to TFDA				
Date of events	2025/01/02	To which item it meets	paragraph 10		
Statement	<p>1.Date of occurrence of the event:2025/01/02</p> <p>2.New drug name or code:TCRT-ESO-A2-TW</p> <p>3.Indication:Advanced solid tumors</p> <p>4.Planned development stages:Phase I clinical trial</p> <p>5.Current development stage:</p> <p>(1)Application submission/approval/disapproval/each of clinical trials (include interim analysis):</p> <p>The Company received the review opinions on the IND application of the phase I clinical trial of TCRT-ESO-A2-TW, a T Cell Receptor T cell therapy (TCR-T) developed in collaboration with Axis Therapeutics Limited (Axis), in patients with advanced solid tumors from the Taiwan Ministry of Health and Welfare (MOHW) that MOHW was not able to agree to the implementation. The Company will submit the supplementary information as MOHW advised within the timeline.</p> <p>(2)Risks and mitigation measures to be taken by the company upon disapproval of the competent authority:</p> <p>The Company will submit the supplementary information as MOHW advised within the timeline.</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:</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:</p> <p>Phase I clinical trial</p> <p>(1)Estimated date of completion:</p> <p>Disclosure will be made according to the regulations.</p> <p>(2)Estimated responsibilities: N/A.</p> <p>7.Market situation:</p> <p>According to the GLOBOCAN 2020 released by the International Agency for Research on Cancer (IARC), there were 19,292,789 new cancer patients and 9,958,133 cancer deaths in 2020 worldwide.</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>TCRT-ESO-A2-TW is a TCR-T therapy targeting solid tumors that are NY-ESO-1 positive in HLA-A*02:01 positive patients. Through a research collaboration agreement, PharmaEssentia and Axis will collaborate to conduct the initial clinical study of TCRT-ESO-A2-TW in Taiwan. The agreement also grants PharmaEssentia the right of first negotiation with Axis for licensing opportunities related to TCRT-ESO-A2-TW.</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>				