Material Information (6446 PEC)					
SEQ_NO	2	Date of announcement	2025/05/24	Time of announcement	08:16:48
Subject	Announcement of the Topline Results from the Phase I Clinical Trial of PharmaEssentia's Long-acting GCSF, P2203				
Date of events	2025/05/23	To which item it meets	paragraph 10		

Statement

1.Date of occurrence of the event:2025/05/23
2.New drug name or code:
Pegylated Methionine Human Granulocyte-Colony Stimulating Factor (PEG-MetHuG-CSF, also known as P2203)
3.Indication:
Chemotherapy-induced neutropenia, Multiple Myeloma (MM), Chronic Myelogenous Leukemia (CML), Acute Myeloid Leukemia (AML), Myelodysplastic Syndromes (MDS)
https://e-sub.fda.gov.tw/ClinicalTrialInfo/home
Protocol No.: F23-101
4.Planned development stages:
Phase I clinical trial and sequential clinical trials
5.Current development stage:
Topline results from the phase I clinical trial
(1)Application submission/approval/disapproval/each of clinical trials (include interim analysis):
The topline results from the Phase I clinical trial of P2203 demonstrated that P2203 has a favorable safety and tolerability profile and was observed to increase white blood cell counts in healthy subjects.
A.Study design
a.Study title:
A Phase 1, Randomized, Open-label Study to Evaluate the Safety, Tolerability, and Pharmacokinetics/ Pharmacodynamics of PEG-MetHuG-CSF (P2203) in Healthy Volunteers
b.Objectives:
To evaluate the safety and tolerability of P2203
c.Phase of development:
Phase I clinical trial
d.Name of investigational drug:
P2203
e.Indication:
Chemotherapy-induced neutropenia, Multiple Myeloma (MM), Chronic Myelogenous Leukemia (CML), Acute Myeloid Leukemia (AML), Myelodysplastic Syndromes (MDS)
f.Endpoints:
Primary Endpoints: To evaluate the safety and tolerability of P2203
Secondary Endpoints: To characterize the PK, PD, and immunogenicity of P2203
g.Number of subjects:
30 healthy subjects
B.The statistical results (including but not limited to P value) and statistical significance (including but not limited to whether statistical significance is achieved) of the primary and secondary endpoints. If the Company cannot disclose statistical data due to other important reasons, the reasons should be stated.
a.Primary endpoint: The topline results demonstrated that P2203 has a favorable safety and tolerability profile.
18 healthy volunteers who received P2203 (6 healthy volunteers received 2 mg and 12 healthy volunteers received 6 mg doses) demonstrated good tolerability. No serious adverse events (SAEs) occurred during the trial, and no unacceptable side effects were observed. Additionally, there were 12 healthy volunteers in the control group who received the comparator drug.
During the clinical trial, a Safety Review Committee (SRC) was regularly convened to review safety data. The committee confirmed that the 18 healthy volunteers who received P2203 did not experience any drug-related, unacceptable side effects and expressed their approval of P2203's safety profile.
b.Secondary endpoints:
In terms of pharmacokinetics, at the 6 mg dose, P2203 demonstrated significantly greater area under the concentration–time curve (AUC) values for both AUC0–t and AUC0–inf compared to the control group.

In terms of pharmacodynamics, administration of P2203 at 6 mg led to a gradual increase in neutrophil counts, peaking around Day 4, followed by a slow decline. Overall, P2203 exhibited a more sustained neutrophil-stimulating effect and a slower decline in neutrophil levels compared to the control group.
In terms of immunogenicity, among the 12 subjects who received P2203 6 mg, one subject tested positive for anti-drug antibodies (binding antibodies) at pre-dose, while two other subjects tested positive on Day 15 and Day 29, respectively.

C.If statistical results of the phase III clinical trial of the new drug is disclosed, the marketing plan of the Company:N/A

D.The results of a single clinical trial (including the statistical P-values of t the primary and secondary endpoints and whether they are statistically significant) are not sufficient to fully reflect the success or failure of the launch of the new drug. Investors are advised to exercise caution and conduct thorough evaluation.

(2)Once disapproved by competent authority or each of clinical trials (include interim analysis) results less than statistically significant sense, the risks & the associated measures the Company may occur:
N/A

(3)After obtaining official approval or the results of statistically significant sense, the future strategy:
PharmaEssentia has completed the Phase I clinical trial of P2203 on healthy subjects. The top-line results indicate that P2203 demonstrates good safety and tolerability, with preliminary signs of efficacy observed. In the future, based on the analysis of the complete data, the Company will continue discussions with relevant experts and regulatory authorities to plan the subsequent development strategy.

(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:
Under Company’s internal evaluation
(1)Estimated date of completion: N/A
(2)Estimated responsibilities: None

7.Market situation:
Neutrophil is a type of white blood cell, and G-CSF agents have been the standard of care for neutropenia, a condition where patients have a low number of neutrophils in their blood. G-CSF agents can shorten the period of neutropenia and reduce the risk of infection. Sales of currently marketed long-acting G-CSF agent, Neulasta (pegfilgrastim), reached USD 710 million in the U.S. in 2023, and the global biosimilar drugs market of Neulasta reached USD 1.41-1.59 billion in 2023 according to market research.

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.):None.

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.: