PharmaEssentia tirelessly commits to new drug development and through its Access of Medicine strategy plan, continuously promotes the acquisition of new drugs by patients worldwide. This enhances 'accessibility', ensures 'affordability', and improves 'availability'. These are our core philosophies and commitments. We follow the framework of the 2024 Access to Medicine Index to formulate the group's strategic guidelines, solely to address unmet medical needs.

6.1 Access to Healthcare Management

Materiality Assessment

1,332 patients

Global cumulative clinical trial patient usage

PharmaEssentia follows the framework of the 2024 Access to Medicine Index (ATMI). Under good access to healthcare governance, the company provides product development rooted in scientific innovation. By increasing medicine accessibility, accelerating the promotion of drug certification acquisition, and market distribution, PharmaEssentia helps more MPN patients obtain better treatment with Besremi, thereby improving their quality of life.

Materiality Assessment

Access to Healthcare

Impact Assessment

The core mission of the biotechnology industry is to promote human health and well-being. PharmaEssentia focuses on patient-centric care, achieving unmet patient needs through research and innovation. Before products are marketed, compassionate use therapies and clinical trial participation opportunities are provided; after marketing, the company accelerates drug certification in different markets through subsidiaries and strategic partners, enhancing the accessibility and equitable availability of medications.

Management Policies and Commitments

We are committed to providing high-quality medications to more patients whose medical needs are currently unmet. Through innovative research and development efforts, and by accelerating drug certification with market supply chain partners, we can meet the needs of more patients requiring solutions. Additionally, we are considering how to implement reasonable pricing strategies to reduce the burden of healthcare costs, demonstrating the cost-effectiveness of Besremi through cost analysis.

Governance Structure

- Taiwan headquarters along with the marketing departments and medical affairs teams of subsidiaries.
- Materiality Assessment: Managed and integrated by the members of the Access to Healthcare team from the Center for Sustainable Development.

Management Actions

Research and Development	Clinical Trial Participation	Compassionate Use Therapy	Marketing Authorization
Beyond MPN, PharmaEssentia is also investing in PEG-IL-2 technology for the treatment of inflammatory and immune diseases; and through external collaborations, jointly developing TCRT cell therapies.	In 2023, global clinical trials (multi-country, multi-ethnic) added 453 participants, bringing the total to 1,332 patients.	In 2023, a total of 43 patients received compassionate use therapy.	Obtained drug licensing in over 40+ countries.

Indicators and Goals

- In accordance with the spirit of the Access to healthcare guidelines, we use (1) the number of products developed/clinical trial participants, (2) the number of patients using Besremi, and (3) the timing of drug approvals in various countries as indicators to demonstrate how the company serves more unmet medical needs.

Practices to Ensure Effective Actions

- Continuously advancing milestones for various programs, including drug approvals, equitable access to healthcare strategies, and outcomes.
- Improving the affordability of new drugs: fair and reasonable pricing, pricing policies, drug delivery, and drug donations.

Performance in 2023

- Scientific innovation in product development: In 2023, global R&D expenses reached NT$2.22 billion, a 55.5% increase from the previous year, and marketing expenses amounted to approximately NT$2.13 billion, a 38.2% increase from last year. PharmaEssentia has recently accelerated the development of BESREMi® for various indications, in collaboration with partners for new drug development and expansion into new therapeutic areas, with four new indications currently under trial; additionally, six new drugs and drug combinations are being rapidly developed.
- Number of patients using the medication: In 2023, over 6,200 patients benefited from Besremi.
- Beneficiaries of compassionate use therapy: 43 patients.
- Drug approvals: Obtained in over 40 countries.

43 patients

Patients benefiting from compassionate use therapy

1. Committed to providing high-quality medicines to more patients whose medical needs are currently unmet.

Compassionate Use Therapy

For regions where the drug has not yet been approved and for patients who do not qualify for clinical trials but are in severe or life-threatening situations due to MPN, PharmaEssentia conducts internal reviews and complies with regulations and ethics committees to provide compassionate use therapy to eligible patients.

Mechanisms and Progress of Compassionate Use Therapy

Operating Mechanisms

PharmaEssentia has established a standard operating procedure (PEC-MA-SOP-001) to manage the provision and execution of medications under compassionate use. As of the end of 2023, 43 patients have utilized this program.

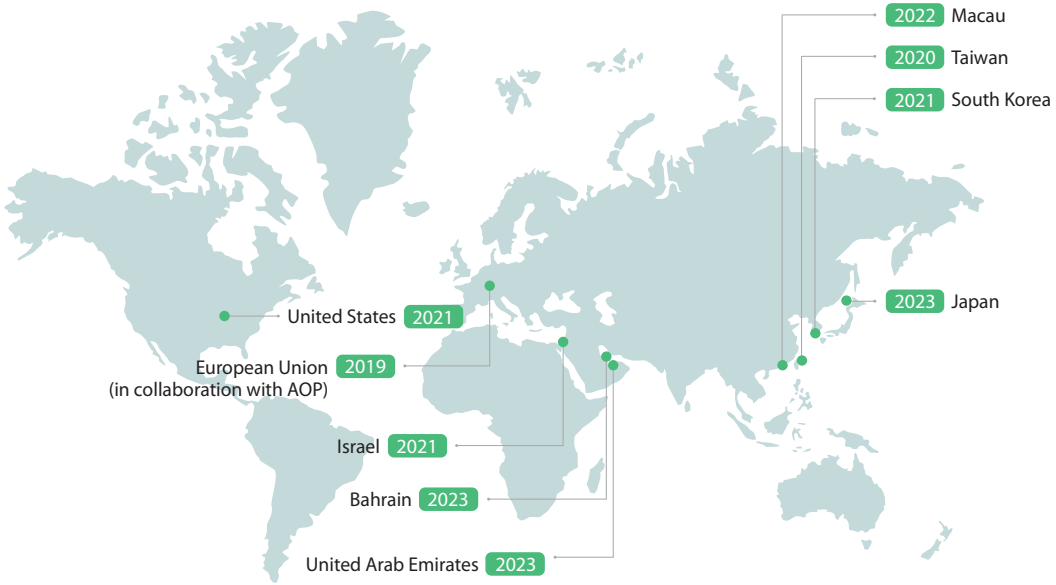
	Type of Donated Medications	Indications	Cumulative Number of Benefiting Patients
2020	P1101	• MPN (PV, ET, MF)	38
2021	P1101	• Taiwan : MPN (PV, ET, MF) • South Korean : ECD	40
2022	P1101	• Taiwan : MPN (PV, ET, MF) • South Korea : ECD	40
2023	P1101	• Taiwan : MPN (PV, ET, MF), EHE • Singapore and Malaysia : PV	43

Note: For content related to clinical trials, please refer to Section 3.1, New Drug Research and Innovation Management.

Accelerating Drug Registration

BESREMi® has obtained marketing authorization in over 40 countries globally since its first drug license in 2018. This includes multiple European countries, as well as the United States, Japan, South Korea, Israel, and Taiwan where it is already on the market; drug licenses are currently being applied for in China, Singapore, and Malaysia. Through the establishment of subsidiaries and partnerships with strategic partners, PharmaEssentia continues to expand its global market share, providing new options for the treatment of rare diseases and reducing the burden of such treatments.

Year and Countries of BESREMi® Drug Registration



Year	Indications	Countries
2019	PV	European Union (in collaboration with AOP)
2020	PV	Taiwan
2021	PV	United States, South Korea, Israel
2022	PV	Macau
2023	PV	Japan, United Arab Emirates, Bahrain

Product Delivery

Product delivery is equally important under the premise of access to healthcare; given the different regulations on drug packaging and labeling in various countries, PharmaEssentia collaborates with local stakeholders. In countries like the USA, Germany, and Japan, PharmaEssentia has signed outsourcing manufacturing contracts with local manufacturers who comply with GMP standards to enhance the smooth delivery of products. Additionally, measures are taken to combat counterfeiting. (For more details, see 3.4 Sustainable Supply Chain Management).

Product Donation

Given that Besremi (P1101) can be applied in multiple disease areas, we actively collaborate with governments and the academic community to make an impact. During the severe COVID-19 pandemic, considering patient needs, PharmaEssentia donated medication to the Health and Welfare Department's Shuang Ho Hospital for clinical use in treating mild to moderate COVID-19 patients. Out of 22 patients, 21 successfully recovered and were discharged after their test results changed from positive to negative. Based on this success, PharmaEssentia invited National Taiwan University Hospital to lead a Phase III multicenter clinical trial of P1101 for treating COVID-19, aimed at providing treatment options for mild to moderate cases. Although the pandemic subsided and the trial was not completed, PharmaEssentia will continue to adhere to its patient-centered philosophy and spirit, investing in research and collaborating with medical professionals to provide drug donations for independent clinical research based on clinical needs, accelerating the expansion of the drug's potential benefits to help more patients in need.

Focusing on patient needs, providing comprehensive support

- Patient Support SOURCE Program: Applicable to patients currently using BESREMi® prescription medication. This program provides comprehensive support, from insurance information and self-pay discount programs to medication guidance and ongoing medication ordering processes. It aims to offer more convenience to patients who might not use the medication due to insurance payment delays or insufficient insurance coverage, including providing free medication for uninsured or underinsured patients. The goal is to ensure a stable supply of PharmaEssentia medications to patients, reducing their financial burden.

PharmaEssentia SOURCE™
Your resource for patient support & education

- In Japan, beginning in 2024, a patient support program will be established, including a website, professional medical education, and customer service centers. This program will also cover insurance and self-pay discount programs to medication guidance, assisting patients in reducing their out-of-pocket financial burdens.

NCCN

BESREMi® upgraded in the U.S. NCCN Treatment Guidelines to PV2A category preferred drug for patient

2. Responsible Pricing Strategy, Creating Medical Value and Cost-Effectiveness

Equitable Access to Healthcare Strategy and Outcomes: Enhancing product medical efficiency

GRI 416-1 SASB HC-BP-240a.1

Providing innovative drugs with medical contributions to alleviate the burden on healthcare insurance systems and meet medical needs is a crucial goal for PharmaEssentia. The medical value of BESREMi® has been included in the guidelines of the European LeukemiaNet (ELN) [Note 1] since 2021. Additionally, the National Comprehensive Cancer Network (NCCN) [Note 2] has also incorporated BESREMi® into its guidelines as the preferred medication for treating adults with Polycythemia Vera (PV), regardless of previous treatments or high-risk status. We have completed a comprehensive health economic evaluation (including cost-benefit, cost-utility, and cost-effectiveness analysis) of BESREMi® upon its launch in Europe to analyze its impact on healthcare costs. We are actively collecting data to support subsequent health technology assessments, thereby certifying the medical value of BESREMi®.

Note 1: ELN is a platform of 44 countries and 220 institutions involving over 1,000 researchers and clinical personnel, aimed at integrating pioneering leukemia clinical trial groups across Europe. ELN's goal is to integrate 120 pioneering leukemia clinical trial groups in Europe, along with associated service cooperation institutions, industry, and corporate resources to promote the importance of treating leukemia.

Note 2: NCCN is a nonprofit organization in the USA, comprised of a coalition of 31 cancer centers, most of which are designated as Comprehensive Cancer Centers by the National Cancer Institute.

Improving New Drug Affordability: Fair and Reasonable Pricing

SASB HC-BP-240b.2, b.3

BESREMi® is the first interferon approved by the U.S. FDA for Polycythemia Vera (PV) and has been granted orphan drug status. It is also listed as the preferred medication in the U.S. NCCN guidelines. Developing orphan drugs requires significant investment in research and financial resources. Based on the principle of accessibility, we have committed substantial resources to ensure that patients can access the necessary medication as soon as it becomes available on the market.

Step 1 Tiered pricing

Implement tiered pricing for sales regions based on the level of national development.

Step 2 Evaluate the registration results

Evaluate the registration results and decide on a strategy for Step 3a or 3b

Step 3.a The prices of medications determined by national insurance agencies

For example, in Taiwan, pricing is set according to the principles established by the National Health Insurance. This involves considering clinical opinions, evidence of efficacy, current treatment costs, and other factors. A payment standard is proposed along with a five-year budget plan for drug pricing, an analysis of financial impact, and a pharmacoeconomic analysis. The goal is to establish medication prices that benefit the maximum number of patients.

Step 3.b Pricing Strategy for Private Health Insurance Systems

1. Affordability: Set prices based on affordability of each country.
2. Economic Data: Refer to each country's domestic GDP, private medical insurance costs, and drugs with the same indications.
3. Product Value Analysis: According to pharmacoeconomics, health technology assessment (HTA) and other methods.
4. Medical Contribution Assessment: Analyze the benefits and risks of products on the medical and economic systems of various countries.

Responsible Pricing Strategy

PharmaEssentia prioritizes patient interests in its drug pricing, also considering factors such as research and development costs, the number of patients targeted during the patent period, competitive product pricing, expected profits, reimbursements from third-party insurance companies, and health insurance payments by regulatory authorities in different countries. Prices are then set based on each country's ability to afford medical costs, economic development, pharmaceutical costs, and referencing the "WHO Guideline on Country Pharmaceutical Pricing Policies" to establish fair and reasonable drug prices.

Evidence-Supported Reasonable Pricing

PharmaEssentia evaluates the impact of its products on medical costs using health economics assessment methods (such as cost-benefit, cost-utility, and cost-effectiveness analyses) to assess the costs associated with using Besremi versus standard therapies and other competitive innovative products. This approach has been validated in its major markets.

Ireland

BESREMi has passed the HTA review in Ireland, analyzing the drug's safety, efficacy, and quality of life data, confirming it is more cost-effective compared to standard treatment options.

U.S.

In the U.S. market, the U.S. subsidiary has conducted cost-effectiveness analyses from the perspective of U.S. healthcare payers, also confirming greater cost-effectiveness compared to standard treatments.

Japan

PharmaEssentia subsidiary in Japan is analyzing the cost-effectiveness of BESREMi to submit to the Japanese Ministry of Health, Labour and Welfare (MHLW) as evidence for HTA. Strengthening the treatment with Besremi offers more reasonable cost-effectiveness compared to traditional therapies and competitive products.