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Contribution to Access to Medicine

Summary of 2022

PharmaEssentia is dedicated to the pursuit of developing new drugs. Through its access to a medicine strategies program, it continues to promote access to new drugs for patients around the world. Our core philosophy, to which we are committed, is to enhance drug accessibility, ensure affordability, and promote availability. We have adopted the framework of the 2022 Access to Medicine Index to develop our group's strategy and policy to meet unmet medical needs.

Material Topic

- Governance on Access to Medicine
- Globalizing Local Capacity Building and Access to Healthcare

Highlights Performance

3,800+

Over 3,800 patients worldwide have used BESREMi®

No.1

The world's first long-acting interferon alpha drug approved for the treatment of PV /

Assist to establish the first MPN center and the Taiwan Myeloproliferative Neoplasms Association (TMPNA)

500+

Sponsoring underprivileged group patients to use BESREMi®

MPNiCare

Launched the MPN iCare interactive platform for patient education and support

NCCN

BESREMi® has been included in the US NCCN Guidelines

0

No incidents of adverse drug recall

5 Patient Groups

Support for over 8 events for 5 major North American patient groups

40

Patients who benefit from compassionate use

89

Effective patent certificates

3,200+

Patient Power Viewing Record in the US

4.1 Governance on Access to Medicine

Material Topic

PharmaEssentia is committed to continuous research and development of new drugs, and through the Access to Medicine program, we strive to promote access to medication for patients around the world. Our core philosophy, to which we are committed, is to enhance drug accessibility, ensure affordability, and promote availability. We have formulated our group strategy guidelines based on the 2022 Access to Medicine Index framework to address unmet medical needs. Our goal is to reduce the gap in drug accessibility for patients, so that they can obtain the drugs they need in a reasonable, affordable, correct, and convenient manner. Through a drug accessibility governance policy that is closely integrated with our business development strategy, we aim to create shared value for patients. We also hope to use the power of the PharmaEssentia group to achieve SDG 3- Good Health and Well-being by 2030.

GRI 3-3 / 203-1

Management Policy

Internal Policies

- Clinical Study Policy (Draft)
- Compassionate Use Policy (Draft)
- Standard Operating Procedures related to Clinical Trials
- Standard Operating Procedures for Compassionate Use
- Intellectual Property Management and Utilization Measures

External Guidelines

- International regulatory guidelines
- ICH E6 Good Clinical Practice
- Local country regulatory guidelines (e.g. Taiwan)
  - Pharmaceutical Affairs Act
  - Medical Care Act
  - Human Subjects Research Act
  - Personal Data Protection Act
  - Regulations Governing Human Research Ethics Review
  - Good Clinical Practice for Drugs
  - Regulations Governing Sample and Gift Offerings of Drugs

Management Commitment

PEC commits to adherence with relevant international and local laws and standards, and uses our strengths to implement the three approaches of access to medicine strategies from the Access to Medicine Index: Governance on Access to Medicine, Research & Development, and Product Delivery. We expect to contribute to the improvement of global health with our technology and expertise, and committed to following the 6 major aspects of access to medicine strategies:

- Enhance the management strategies of drug accessibility.
- Innovative medicine – addressing unmet medical needs
- Responsible and transparent intellectual property right management
- Provide stable and safe medicines.
- Leading the industry development to enhance the local capabilities.
- Committed to developing innovative drugs to treat rare and ultra rare diseases, benefiting vulnerable patients

Accountable Units

- At present, the Board of Directors and senior management functional taskforces of each subsidiary are responsible for issue management, and the implementation of access to medicine governance is integrated with our business strategy within the current system.
- ECCS - Access to Medicine team

Input Resource

- The resources allocated for access to medicine is concentrated on research and development expenses and marketing expenses. Global R&D expenses are expected to reach around NTD 1.43 billion, an increase of 12.5% compared to last year, and marketing expenses are expected to reach around NTD 1.54 billion, an increase of 63% compared to last year.
- To enhance product life cycle management, the company has hired an international biopharmaceutical intellectual property lawyer by the end of 2022.
- A quarterly demand-forecasting mechanism for commercial and clinical development will be managed using the SAP S4 system starting from 2023.
- Manage drug safety and supply shortage reporting systems with regulatory authorities in different countries.
- Maintain and operate the drug complaint system established by PharmaEssentia Headquarters.
- Panco Healthcare meets the medication needs of patients in hospitals, and manages the medication pickup process in various hospitals.

Targets

Short-term Targets for 2023

- Ropeg is used to treat polycythemia vera (PV), a condition in which the body produces too many red blood cells
  - Obtaining approval for the drug in Japan
  - Submit drug license applications for Ropeg in Malaysia, Singapore, and Hong Kong
- Apply for coverage of Tirbanibulin (KX01) kinase inhibitor for the treatment of actinic keratosis under Taiwan's National Health Insurance program
- Establish internal pricing policies that are reasonable and fair in order to achieve global operational goals
- Strengthen the management system of global logistics supply chains, effectively manage drug transportation and recycling, and ensure that high-quality products are delivered to patients at the right time
- Initiation and application of research protocol
  - Initiate human clinical trials related to TCRT cell therapy
  - Complete IND application for Ropeg in treating epithelioid hemangioendothelioma, a very rare disease, in Taiwan
- Improve the technology for scaling up production for biologic drug processes and pass PMDA inspections in Japan
- Collaborate with Taiwan's National Health Insurance system to obtain hospital contracts and expand the use of medications beyond Panco Healthcare
- Continue to protect the patented new drug BESREMi® with the most basic global patent protections, be involved in the R&D process of PharmaEssentia, and continue to file new patent applications
- Establish an international-level research institution to expand the breadth and depth of new drugs that can be developed, and apply for intellectual property patents in a timely manner

Medium-term Targets for 2024-2026

- Ropeg
  - Obtain regulatory approval for the treatment of polycythemia vera (PV) in Southeast Asian and Central/South American countries
  - Obtain regulatory approval for the treatment of essential thrombocythemia (ET) after completing Phase 3 clinical trials in the United States, Taiwan, China, Japan, and South Korea
- Continue to strengthen drug life cycle management by continuously planning and applying for patents related to the substance and methods of the new drug, expanding exploration of new drug usage, collaborating with academic and research institutions in various countries, and enhancing social impact on the local biotech and biopharmaceutical industry with value chain partners
- Promote advocacy for issues related to access to medicine and collaborate fully with Panco Healthcare and subsidiaries to support the Group's new drug market launch process

Long-term Targets (2026 and beyond)

- Accelerate the application for drug approvals in each country, and integrate the prevalence of indications for the company's new drugs in developing countries for people with low to middle income into drug pricing strategies based on reasonable and fair pricing principles, while considering patients' ability to pay for the drug
- Ropeg
  - Obtain marketing authorization for the treatment of polycythemia vera (PV) in Eastern Europe, Central Asia, and Africa
  - Obtain marketing authorization for the treatment of essential thrombocythemia (ET) in Southeast Asia, Central and South America, Eastern Europe, Central Asia, and Africa
- Responsible and transparent intellectual property management
- When conducting patent layout, the company will gradually promote the use of drugs in low-income countries and developing countries based on the expansion of access to medicine in major industrialized countries, to ensure that the treatment needs of patients worldwide are met through licensing and external authorization as well as clinical trials and sales after launch conducted around the world

Evaluation of Management Policy

Management Evaluation Mechanism

- Rigorously comply with the laws and relevant regulations involved in the product cycle from research and development, production to sales
- Conduct drug supply, pricing, and international marketing in an ethical and responsible manner in accordance with internal policy

2022 Evaluation Results

- BESREMi® has obtained licenses in 38 countries and is expected to obtain a license in Japan in the first quarter of 2023.
- The board of directors has approved the drafting of a distribution and licensing agreement for Ropeg in Latin American with an international pharmaceutical company.
- Ropeg has been included in the reimbursement program of the largest hospital chain in the United States, the Kaiser Permanente.
- The Macau Health Bureau has granted approval for the import of Ropeg as a "pre-approved imported drug".
- The American NCCN treatment guidelines have listed BESREMi® as a treatment option for adult patients with polycythemia vera (PV).
- The Compassionate Use Program has benefited a total of 40 patients worldwide.
- A special import program for myeloproliferative neoplasms (MPNs) was executed in Hong Kong and Singapore.

3,800+

Over 3,800 patients worldwide have used BESREMi®

40

Patients who benefit from compassionate use

Key Strategies and Actions on Access to Medicine

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To meet the medical needs of patients with rare diseases around the world, not only does PharmaEssentia address key issues at each stage of the value chain, but we also follow the 2022 Access to Medicine Index framework to develop our strategies and policies as well as take concrete actions to promote the positive impact of drug repurposing.

Corporate Purpose and Strategy

To solve the pain of patients and promote the health and well-being of all mankind with our new drug products.

Core Vision and Commitments

Improve Accessibility	Provide drugs that can treat disease needs and supply them through legal and safe channels.
Ensure Affordability	Responsible, reasonable, and fair pricing mechanism.
Enhance Availability	Assist economically disadvantaged countries' patients in accessing the required drugs and reducing accessibility gaps.

Strategy and Accessibility Plan

Accessibility Governance

Access to medicine governance closely integrated with business strategies.
Promote access to medicine by the board of directors and senior management teams of subsidiaries.

Meet the access to medicine needs of vulnerable groups.
Focus on the medical needs of economically or resource-poor patients, and provide assistance in resolving medical burdens.

500+

Sponsoring underprivileged group patients to use BESREMi®

For Patients

Ensure access to medicine support for patients and eliminate economic barriers to using BESREMi®

For Healthcare Institutions

Accelerate patient treatment progress by providing support programs or other channels to prescribe BESREMi®

Value Chain	Issues	Strategy	Scope and Market	Impact	Correspond SDGs
New Drug Development	Early-stage research	Continuously develop innovative drugs	• Create value through innovation and improvement of existing drugs to reduce the risk of developing new drugs • Develop diverse products effectively using technology platforms	• Active investment in early R&D with NTD1.43 billion spent and over 120 R&D clinical staff globally	
	Intellectual Property Management	Actively collaborate with academia and industry for research	• Engage in industry-academia collaborations with pharmaceutical companies outside of Taiwan • Patent application considerations for access to drugs that are urgently needed in developing countries	• Accelerated clinical trials and market launch by licensing in and out • 89 effective patent certifications	
Clinical Development	Clinical Trials	Conduct global clinical trials	Conduct multi-country and multi-center clinical trials following relevant laws, regulations, and ethical guidelines	• Conducted over 20 clinical trials for the approval and prescription of new drugs, benefiting over 850 clinical patients	
	Compassionate Use	Provide stable and timely supply of drugs	Provide timely medical assistance to patients with serious or life-threatening diseases who cannot participate in clinical trials	• Continuously benefiting 40 people worldwide, improving medical access for vulnerable groups	
Production and Manufacturing	Product Quality	Produce and manufacture products in a strict and legal manner	• Production and manufacturing processes are approved and inspected according to international standards • GMP certification has been obtained from the FDA, EMA, TFDA, MFDS, and other regulatory bodies	• Passed Japan's PMDA plant inspection to ensure the safety of the production process and drug safety	
	Transport and Supply	Real-time stable drug supply	• Establish a secure and stable drug supply chain in Taiwan and globally • Develop international import/export and transportation procedures that meet PIC/S GDP requirements.	• Regularly reviewing and evaluating the execution of injection filling, logistics, and supply chain • In 2022, BESREMi® product shipments grew by 2.7 times compared to the previous year	
Drug Registration	Access Program	Actively obtain multiple national drug approvals	• Establish marketing task forces in multiple countries and strategic alliances with external partners • Plan short and medium-term drug approval applications around the world	• BESREMi® has obtained approval from more than 38 countries • Obtained the "pre-import license for imported drugs" for Ropeg from the Macau Pharmacology Administration • Obtained NHI pricing in Taiwan, benefiting more local patients	

Value Chain	Issues	Strategy	Scope and Market	Impact	Correspond SDGs
Marketing and Sales	Academic Exchange	Demonstrate medical value	• Collaborate with partners to expand the social impact of local biopharmaceutical industries • Promote access to medical initiatives and sponsor related organizations and activities	• Assisted in establishing the first MPN treatment center in Taiwan and the Taiwan Myeloproliferative Neoplasm Care Association • Provided support for five major North American patient-related group activities	3, 17
	Fair Pricing	Witness the economic value of products	Assess the value of products in different countries' medical and economic systems based on pharmacoeconomics and health technology assessments (HTAs)	• Achieved legitimate and sustainable pricing strategies • BESREMi® has been included in the NCCN in the United States and the ELN guideline in Europe	3
	Patient Support	Provide resources to remove barriers	Host multiple health education activities to enhance patient awareness of disease treatment and support patient support programs to remove medical barriers	• Taiwan MPN iCare Program • The patient support SOURCE Program in the United States • The Patient Power program in the United States, patient advocacy groups and education activities for MPN advocacy and education, and the MPN Research Foundation's clinical trial search engine	1, 3
	Medical Contribution	Reduce disparities in medical use	Provide medicine to patients with MPN through various channels and sponsor medication for disadvantaged patient groups	• Over 3,800 patients have been treated with BESREMi® • The medicine has been provided in 20 hospitals in Taiwan to support local needs • Sponsored BESREMi® for more than 500 disadvantaged patients in the United States, Taiwan, South Korea, Singapore, and other places	1, 3
Patient Safety	Pharmacovigilance	Multi-channel pharmacovigilance	• Establish a mailbox for reporting adverse drug reactions and a market notification management center • Establish a database to ensure local clinical data generation and quality	• Mailbox for reports ▶ 5.4Patient Safety Management • Regular publication of PSUR reports for real-time monitoring of drug safety	3, 17
	Product Tracking	High-tech serialization of products	Implement drug serialization to comply with the US Drug Supply Chain Security Act regulations	• The US drug packaging plant we have partnered with implements drug packaging and serialization correctly • Establishment of a drug traceability system for continuous monitoring of drug flow and usage records	3
	Product Recall	Recall management mechanism	Establish a comprehensive product traceability mechanism	• No drug recall incidents occurred in 2022 • No product-related deaths were reported to the FDA in 2022	3

4.2 Globalizing Local Capacity Building and Access to Healthcare

Material Topic

PharmaEssentia adheres to a patient-centered approach, and plans various actions and support programs to implement access to medicine and meet patients' health-related needs. Through activities such as health education, financial and medical support, academic exchanges and more, we provide patients with a comprehensive and integrated plan that covers every stage of their treatment.

Management Policy

Internal Policies

- HCP& HCO Interaction Policy
- Promotional Material Policy

External Guidelines

- World Health Organization (WHO)
- International Research-Based Pharmaceutical Manufacturers Association (IRPMA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- National Council for Prescription Drug Programs (NCPDP)

Management Commitment

Implement various action plans related to patient health

- Ensure complete collection and timely reporting of safety data through multiple channels for adverse drug events in compliance with laws and regulations
- Ensure that all patients using PharmaEssentia's drugs have clear knowledge of the disease's characteristics, the effects of the drug, and treatment outcomes
- Promote disease-related knowledge as well as provide treatment consultation and referral services
- Provide health care and follow-up for patients during the treatment period
- Promote local medical care and social participation to expand PharmaEssentia's external social influence

Responsibility Unit

- Marketing departments and medical affairs teams at PharmaEssentia Headquarters and our subsidiaries
- ECCS – Access to Medicine team and Product Quality and Patient Safety Taskforce

Input Resource

- Taiwan Patient Education Support Program, assisting the establishment of the first MPN treatment center and the Taiwan Myeloproliferative Neoplasms Association (TMPNA)
- An interactive patient education platform "MPN iCare Program" in Taiwan, providing educational information to patients and their families
- Providing Besremi® to medical institutions participating in clinical trials through the PharmaEssentia Can Help project
- Commissioning a professional management consulting company to set up a toll-free hotline for a medical information consultation center, notifying those in departments relevant to hospital and factory pharmacovigilance who are in charge of monitoring and quality assurance (QA). The email address for receiving drug safety reports has been announced on the company's website in Taiwan
- Establishing an electronic mailbox representing PharmaEssentia in collaboration with a drug safety research institution to receive reports on drug safety from countries where the drug is marketed

Targets

Short-term Targets for 2023

- Implement MPN education program: Increase awareness of MPN and provide education to help patients understand the disease or get proper diagnosis and treatment, such as sponsoring the MPN Asia International Symposium and American Society of Hematology (ASH)
- Continue to promote the patient support SOURCE program to serve US patients
- Participate in local medical, educational and academic-related seminars and events to build positive connections with the local community
- Continue to collaborate with TMPNA to hold patient education activities
- Collaborate with the Chiayi Chang Gung Memorial Hospital to provide assistance for occasional health education activities
- Provide the latest health information through MPN iCARE
- Initiate clinical research and development of BESREMi® in the field of tumors

Medium-term Targets for 2024-2026

- Continuously promote various BESREMi®/Pacritinib® related health education activities with patient groups from different countries to give them accurate information about disease treatment
- Continuously strengthen diverse activities and stakeholder negotiations, and expand to more local medical organizations
- Promote other BESREMi®-related patient support programs in countries where BESREMi® is already on the market to comprehensively expand global coverage
- Accelerate research and development of BESREMi® for other MPN-related diseased, and expand BESREMi® to other disease treatments
- Monitor related advocacy issues around the world, and examine available resources and benefits
- Assist Taiwanese patient groups to connect with patient groups from all over the world, and share their experiences in treatment

Long-term Targets (2026 and beyond)

- Expand BESREMi® to all countries where it is on the market, and establish a system for giving medical care to those need it. With comprehensive care for those with rare diseases and community participation, we will enhance the company's positive contributions and influence on the global medical system for treating rare diseases and for society in general
- Assist Taiwanese patient groups to connect with international patient groups and share treatment experiences

Management Evaluation Mechanism

- Evaluation of the budget goals and execution of various marketing and seminar activities by the marketing departments and medical affairs task forces at PharmaEssentia Headquarters and the subsidiaries

2022 Evaluation Results

- Continuation of the operation of Taiwan's first MPN treatment center in collaboration with Chiayi Chang Gung Memorial Hospital
- Continuation of the operation of the MPN iCare platform for patient education and interaction in Taiwan
- Panco Healthcare organized four educational events and invested more than 28+ person-times with a total participation of nearly 800 people. One such session was to increase physicians' knowledge of MPN and the effectiveness of long-acting interferon therapy
- The "PharmaEssentia Can Help" project provides BESREMi®
- Initiated the patient support SOURCE Program in the United States to serve American patients
- Assisted the Taiwan Myeloproliferative Neoplasms Association (TMPNA) in establishing and held the first national patient education seminar in collaboration with Chiayi Chang Gung Memorial Hospital's MPN center
- Organized special blood disease education events with a total of 40 participants
- Initiated the patient support SOURCE Program in the United States to serve American patients
- Sponsored the MPN Asia International Medical Symposium regularly each year, but was suspended due to the pandemic. The plan is to continue hosting physical conferences in Taiwan in 2023

Value Chain Empowerment Program

GRI 413-1/413-2

PharmaEssentia's value chain empowerment program focuses on key activities and training programs for each stage of the value chain. The company has not assessed any negative impact of its operations on the local community. To improve access to medicine for patients in need of financial assistance, the company has developed initiatives. For patients already using BESREMi, a series of health promotion activities have been planned to extend their medication duration and improve overall treatment outcomes.

Capacity building programs related to the value chain

Research and Manufacturing

- **PharmaEssentia Innovation Research Center:**
  Establish an innovation research center (PIRC) in Boston, Massachusetts, recruiting 25 researchers to develop a more diverse product line. Artificial intelligence and machine learning will be combined to provide information for new research targets and indications, expanding the field of disease research
- **New drug development strategy - Taiwan Biotech Academy in-person and online seminars:**
  The course shares the process that takes place from new drug development to approval and marketing, development strategy, and practical problems that need to be solved. It is also hoped that after the course can stimulated more ideas for R&D ideas and pass on experiences of successful development of new drugs in Taiwan
- **2022 summer internship program:**
  Combining the advantages of schools and industry practices, students will receive 1-2 months of project lectures and training before being assigned to related departments such as R&D or clinic testing for practical operations, which helps to cultivate professional talents for the biopharmaceutical industry from the source

Drug licenses application process

- **Regulatory considerations and experience-sharing on the use of overseas data in the development of new drugs in Taiwan :**
  Development of new drugs in Taiwan targets the global market, and is based on R&D strategy and international collaboration; pivotal trials are often conducted overseas. This session will be about strategies on using overseas data for approval of new drugs in Taiwan

Medical education and outreach

- **Assistance in the establishment of the Taiwan Myeloproliferative Neoplasms Awareness Association (TMPNA) and the organization of health education events in collaboration with the MPN Center at Chiayi Chang Gung Memorial Hospital:**
  Aimed at enhancing patient awareness and understanding of the disease and its treatment, as well as reducing information gap between patients and healthcare providers

- **Cooperation and Academic Exchange in Taiwan:**
  Collaboration with the Taiwan Hematology Society and the Young Pharmacists Association to hold health education events aimed at enhancing physician knowledge of MPN and the efficacy of interferon treatment, with a cumulative attendance of over 700
- **Medical education programs in the US:**
  Sponsorship of medical education programs by the US subsidiary, including conferences and on-demand educational content
- **Participation in the Patient Power Program in the US:**
  Aimed at providing support to PV patients and promoting the correct information about the disease's treatment through online digital content, with over 3,200 viewings recorded. The project not only facilitates dialogue between patients and physicians, but also enhances public understanding of the disease
- **Assistance to MPN patient groups and international education events:**
  Support for over 8 events for 5 major North American patient groups, including the MPN Research Foundation, Canadian MPN Research Foundation, MPN Advocacy & Education International, Patient Power, and PV Reporter. These events include both online events and 2 in-person events whose aim is to enhance patient knowledge and facilitate the exchange of opinions, as well as promote diagnosis of the disease, treatment goals, and related information, while also increasing awareness of the medical benefits of BESREMi among the MPN community

MPN RESEARCH FOUNDATION

- **The MPN Research Foundation and Clinical Trial Search Engine in US:**
  Helped establish the MPNRF clinical trial search tool, which provides a good matchmaking channel for MPN patients and their physicians. The search engine helps MPN patients and their physicians find suitable clinical trials to initiate subsequent treatment

Supply Chain Management

- **Supply Chain and Healthcare System Enhancement:**
  Collaborate with external CMO companies that have obtained qualified certifications to complete the final filling of BESREMi and sell it directly to local markets, ensuring that all patients can access the medication in a timely manner

Pharmacovigilance

- **Establishment of Special Task Forces:**
  PharmaEssentia has established an active drug surveillance task force with a global presence, assigning dedicated personnel in each subsidiary region and collaborating with external partners to monitor drug use safety

Data Generation and Quality Improvement

- **Data Maintenance:**
  Establish dedicated medical affairs task forces and quality management task forces to handle issues related to clinical data collection, ensuring the generation and quality improvement of clinical data

Finance and Medical Assistance

- **Compassionate Use:**
  Provide medical solutions to patients with severe or immediately life-threatening diseases who do not qualify for clinical trials. After internal review, compliance with regulations and ethics committees, eligible patients can apply to use experimental new drugs that have been researched but not yet approved for marketing worldwide, and start treatment courses. Currently, 40 patients around the world continue to receive medical assistance through the Compassionate Use program.
- SOURCE Program:
  Applicable to patients using BESREMi as a prescription drug, it provides comprehensive support, including insurance information, medication-related guidance, and the process of the continued prescription of the medication. It helps provide more convenience for patients who cannot access the medication due to insurance payment delays or insufficient insurance coverage, as well as free medication for patients without insurance or has insufficient insurance coverage, aiming to provide a stable supply of Pharmigene drugs and reduce financial burden.

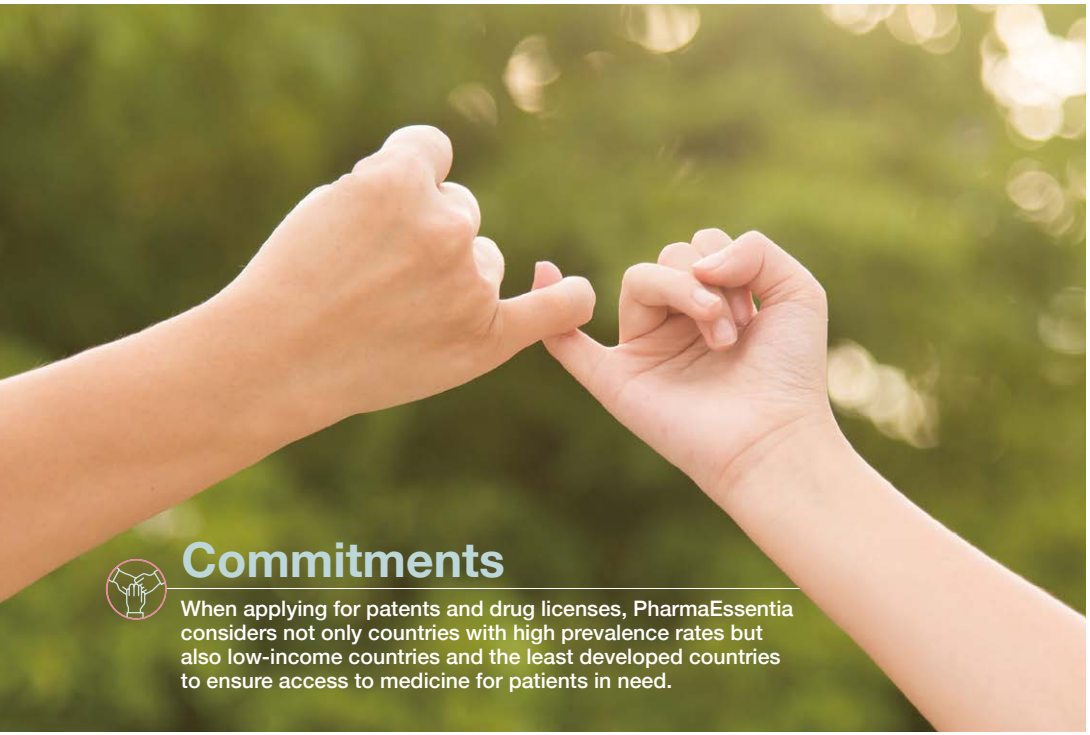
PharmaEssentia SOURCE
Your resource for patient support & education

Cross-Value Chain

- National Biotechnology Park Investment and Talent and Technology Matchmaking Conference:
  Participate in jointly organizing the National Biotechnology Research Park Investment and Talent and Technology Matchmaking Conference, including trend forums, investment matchmaking meetings, talent matchmaking, and biomedical startup exhibitions, etc., as well provide an integrated resource platform to assist biotech startup talents and task forces in accelerating the process of productization
- 2022 Taiwan Biopharmaceutical Industry Analyst Training Course:
  The course aims to cultivate professional new drug analysts, and Pharmigene was invited to jointly teach the course, with the aim of establishing a professional knowledge exchange platform for domestic finance and biotechnology industries and cultivating students as professionals in the field of biomedicine.

Intellectual Property Sharing Promotes Access to Medicine

Based on the differences in medication adherence and demand, PharmaEssentia adjusts its operational strategies when entering local markets where it has obtained patents. To prevent the penetration of intellectual property rights in the least developed countries and the reluctance of the international biopharmaceutical industry towards the right to access to medicines, not only are the countries where patent applications for important new drugs are filed investigated for the global prevalence of the new drug indications but special considerations are given to developing countries with high total demand and relatively low national income, as well as low-income countries and least developed countries, to meet the needs of patients in less advanced countries and their access to medicine. When faced with a trade-off between patent rights and humanitarian aid, medical needs are given priority, and patented new drugs are made available to patients at affordable prices and through convenient channels.



Commitments

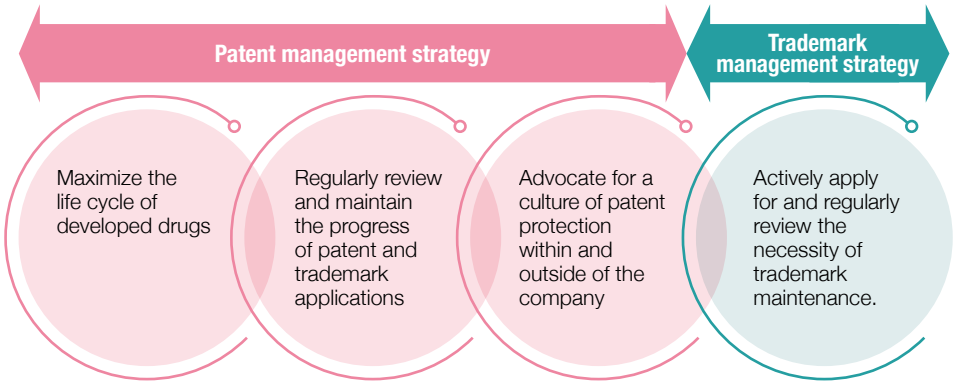
When applying for patents and drug licenses, PharmaEssentia considers not only countries with high prevalence rates but also low-income countries and the least developed countries to ensure access to medicine for patients in need.

Well-Established Patent Management and Application Policies

89	202	112	29
Effective patents	Valid patents cover 202 sovereign states	Effective registered trademarks	Valid registered trademarks cover 29 countries/regions

PharmaEssentia has formulated the "Intellectual Property Management and Utilization Measures" to regulate intangible assets such as patents, trademarks, copyrights, and trade secrets. The measures are closely linked to R&D cycle regulations and asset acquisition or disposal procedures to ensure the protection of the company's intellectual property and its widespread application and registration in the world. This allows more people in need to be informed about and have the opportunity to use new drugs.

PharmaEssentia has a strong global presence in terms of R&D patents and has proactively implemented a global intellectual property strategy for obtaining multiple country-specific drug licenses. As of 2022, the company has obtained a total of 89 (an increase of 6) valid patents in 202 sovereign countries. In addition, the company has registered 112 trademarks in 29 countries/regions, with 8 new certificates in 2022. The Intellectual Property Department reports annually to the board of directors on the implementation of the intellectual property management plan and includes the management of intellectual property in the internal control procedures, in accordance with the Corporate Governance Guidelines for Listed and OTC Companies, to ensure the protection of the company's intellectual property rights.



Technology Licensing can Maximize the Value of Intellectual Property

To accelerate the promotion of access to medicine, the company has collaborated with external partners to license its patents to others. Additionally, the company has also collaborated with pharmaceutical companies outside of Taiwan to obtain licensing for patents and technology, enabling further development and commercialization. In the future, we plan to establish a systematic management mechanism for external collaboration and technology transfer, maximizing the social value of our intellectual property management.

Out-licensing

AOP Orphan has been granted a license to market Ropeg for the treatment of rare blood disorders in Europe, the Middle East, and the Commonwealth of Independent States. In 2019, the drug received European Union marketing approval, and the company has been promoting its marketing and sales in the region.

Licensing In

- Licensing of Tirbanibulin (KX 01) from Athenex Inc. in the regions of Taiwan, Singapore, China, Malaysia, Japan, and Korea, with indications expanded to include skin cancer and all dermatologic indications.
- Exclusive licensing of the cancer drug Oraxol® from Athenex Inc. for sales in Taiwan, Singapore, and Vietnam, with ongoing efforts to obtain market approval in the US, Taiwan, Singapore, and Vietnam.
- Collaborating with licensing partner Axis Therapeutics on the technology transfer and clinical trials of a new TCRT-ESO-A2 cell therapy product for solid tumor treatment.

The company has obtained the exclusive rights to sell Tirbanibulin in certain regions.

The company has obtained the exclusive rights to sell Oraxol® in certain regions.

Short-to-Medium-Term Drug License Registration Plan

The company has successfully obtained licenses for Ropeg, a product used to treat rare blood disorders, for the treatment of polycythemia vera (PV) in over 38 countries, including the European Union, Israel, Taiwan, South Korea, and the United States, and continues to submit applications for PV licenses to other regulatory authorities. Phase III clinical trials for essential thrombocythemia (ET) are also underway in various countries, and the trial results will support the ET licensing plan, benefiting more patient communities suffering from MPN-related diseases.

2023

- **Ropeg for treatment of polycythemia vera (PV):** Obtained drug approvals in Japan, Malaysia, Hong Kong, Singapore, and Macau
- **Ropeg for treatment of essential thrombocythemia (ET):** Completed phase 3 clinical trials in the United States, Taiwan, China, Japan, and South Korea

2024 -2026

- **Ropeg for treatment of polycythemia vera (PV):** Obtained drug approvals in Southeast Asia and Central/South America countries
- **Ropeg for treatment of essential thrombocythemia (ET):** Obtained drug approvals and market authorization in multiple countries after completing phase 3 clinical trials in Southeast Asia, Central/South America, Eastern Europe, Central Asia, and Africa

2027

- **Ropeg for treatment of polycythemia vera (PV):** Obtained drug approvals in Eastern Europe, Central Asia, and Africa
- **Ropeg for treatment of essential thrombocythemia (ET):** Obtained drug approvals and market authorization in Southeast Asia, Central/South America, Eastern Europe, Central Asia, and Africa

Global Marketing and Market Promotion

To improve services for local patients and comply with local market regulations, in addition to AOP Orphan's responsibility for the European, Middle Eastern, and CIS markets, PharmaEssentia has deployed subsidiaries in the Asia-Pacific region and throughout the United States, and established professional marketing task forces to accelerate local market sales. In 2022, no complaints were received regarding sales activities from regulatory authorities or voluntary complaints.

European Market

30+ countries

Providing nearly a thousand patients in over 30 countries in Europe with access to treatment

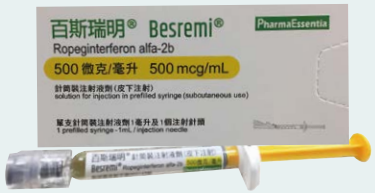
BESREMi® sold in Europe

Available in the European Union since 2019, the drug is currently sold in more than 30 countries in Europe, with nearly 1,000 patients using the drug. In 2022, sales in Europe continued to grow and tripled from the previous year, spreading the positive influence brought by the access to the medicine.

Taiwan and Asia-Pacific Market

Sales and distribution in Asia-Pacific

Expanding sales and distribution in the Asia-Pacific region with Taiwan at the center



百斯瑞明®sold in Taiwan

With Taiwan as its central base, Ropeg has established professional marketing task forces in South Korea and Japan to devise marketing strategies that increase the drug's visibility and sales, ultimately providing better clinical outcomes for patients. In 2020, Ropeg's BESREMi® was approved by Taiwan's Food and Drug Administration for the treatment of polycythemia vera (PV), making it an official medication covered by Taiwan's National Health Insurance. In 2021, BESREMi® received its second drug license in Asia from South Korea's MFDS, and in 2022, it was also approved for PV treatment in Macau. As of early 2023, Ropeg has successfully passed an inspection by Japan's PMDA, and plans to obtain regulatory approvals in other Asia-Pacific regions such as China, Hong Kong, Singapore, Malaysia, and Vietnam are ongoing.

US Market

Expanding the US market penetration

Expanding market penetration and insurance coverage to benefit more patients

BESREMi® sold in the U.S.

Ropeg has been expanding its market penetration in the US and increasing insurance coverage to benefit more patients since BESREMi® was granted approval in 2021. The drug has received enthusiastic responses from US physicians and patient communities, and the US subsidiary task force has gradually expanded market penetration and increased medical insurance coverage to reach 100% and commercial insurance coverage to 85%. Promotion in leading myeloproliferative neoplasms (MPN) medical centers has exceeded 80%. To address the challenges of the US supply chain and market marketing, the task force regularly reviews the execution of injection filling, logistics, and supply chain, and actively discusses process and process optimization solutions with partners to ensure the drug's logistics and supply chain are safe and stable, and to continue expanding the US business market.

4.3 Tackling Medical Costs

Improving Product Medical Efficiency

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

Improving medical efficiency by providing innovative drugs that contribute to healthcare is a goal that PharmaEssentia strives to achieve. We have completed a comprehensive economic evaluation, including cost-effectiveness, cost-utility, and cost-benefit analysis, for BESREMi® upon its launch in Europe, to analyze the product's impact on medical costs. BESREMi® has achieved a coverage rate of 100% and has already been included in the European LeukemiaNet (ELN) guidelines in 2021. As for the US market, although BESREMi® has not yet been evaluated by any Health Technology Assessment (HTA) organization, it has been included in the National Comprehensive Cancer Network (NCCN) guidelines, a global authority on cancer clinical treatment standards. BESREMi® can be used as a suggested treatment for polycythemia vera (PV) in adults, regardless of previous treatment or high-risk population status. The guidelines also include details on recommendations, providing comprehensive advice for medical practitioners on diagnosis, treatment, and patient management. We are actively collecting relevant data as the basis for future medical technology evaluations to certify the medical value of BESREMi®.

*Note 1: The European LeukemiaNet (ELN) is a platform that includes 44 countries, 220 institutions, and over 1000 researchers and clinical professionals. Its goal is to integrate 120 pioneering leukemia clinical trial groups in Europe, as well as relevant services and resources provided by agencies, industries and enterprises, to jointly promote the importance of leukemia treatment.

*Note 2: The National Comprehensive Cancer Network (NCCN) is a non-profit organization in the United States that is composed of 31 cancer centers, most of which are designated by the National Cancer Institute as comprehensive cancer centers. BESREMi® has been included in the NCCN guidelines, which provide comprehensive recommendations for the diagnosis, treatment, and management of patients with polycythemia vera (PV).

Fair and Reasonable Pricing

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

BESREMi® is the first interferon approved by the US FDA for the treatment of polycythemia vera (PV), a rare blood disorder, and is eligible for orphan drug licenses. It has also been included in the NCCN guidelines for PV treatment. Due to the difficulty in developing orphan drugs, significant research and financial resources are required. To realize our pursuit of expanding access to medicine, we are still willing to invest substantial resources to ensure that patients who need these drugs can access the drugs when they are first approved for market.

When pricing our drugs, patient interests are our top priority. We take into consideration various factors, such as the investment in research and development, the number of patients who would benefit from the treatment during the patent period, the pricing of competing products, expected profits, third-party insurance claims, and health insurance coverage provided by regulatory authorities. We then use these factors to determine a fair price, taking into account the ability of different countries to afford the medication, their level of economic development, and the cost of manufacturing the drug. We also refer to the WHO Guideline on Country Pharmaceutical Pricing Policies published by the World Health Organization to determine reasonable and fair drug prices.

1 Tiered pricing

The sales regions are categorized based on the level of economic development of each country, and the drug prices are set accordingly.

3.a Drug prices are approved by national insurance agencies

In the Asian region (using Taiwan as an example)

Drug pricing is based on the principles of the National Health Insurance drug payment pricing system, taking into account clinical opinions, efficacy evidence, current treatment costs, national budget criteria for reimbursement, and other factors. A payment standard, drug price plan, 5-year budget, financial impact analysis, and pharmacoeconomic analysis are proposed to develop a pricing strategy for drugs that benefit the most patients.

STEP 1 → STEP 2 → STEP 3.a → STEP 3.b

2 Determine whether national insurance covers the drug

If the sales region has a national unified medical insurance coverage, then move on to step 3.a for pricing evaluation. If not, proceed to step 3.b for the next pricing evaluation stage.

Note: It is a special qualification set by drug regulatory agencies in advanced countries such as European countries and the United States to encourage pharmaceutical companies to develop drugs for rare and difficult-to-treat diseases. It has advantages such as reducing the size of clinical trials and fast-tracked reviews, and the drug is granted market exclusivity for 10 years in Europe and 7 years in the United States from the approval date, to protect the pharmaceutical company's patent rights.

3.b Private medical insurance pricing strategy

- **Affordability:** Price set according to each country's affordability
- **Economic data:** Referring to each country's gross domestic product, private medical insurance expenses, and prices of drugs with similar indications.
- **Product value analysis:** Using pharmacoeconomic analysis, health technology assessment (HTA) and other methods.
- **Medical contribution evaluation:** Analyzing the benefits and risks of the product in various countries' healthcare and economic systems.

Europe and the United States

BESREMi®'s marketing and exclusive sales rights in the European market are licensed to AOP Orphan, and the "value-based pricing method" is used to set the drug price. The 2022 list price of BESREMi® in the United States is $7,507.

4.4 Contributions Throughout a Patient's Treatment

PharmaEssentia not only stops at the development of new drugs but takes concrete action to improve patient care throughout their treatment.

Patient education

As polycythemia vera (PV) is a hematopoietic stem cell mutation and is basically unpreventable, PharmaEssentia conducts various advocacy activities and collaborates with partners on programs to raise awareness and educate people on the disease as well as corresponding treatment methods.

- **Taiwan Myeloproliferative Neoplasms Association (TMPNA):**
  PharmaEssentia helped establish the TMPNA to gather information about the patients' concerns about treatment.
- **MPN iCare:**
  As one of Taiwan's main MPN-related disease information platforms, MPN iCare shares information about new treatments and advice on care.

Disease Treatment

- **National Health Insurance coverage in Taiwan:**
  BESREMi® has been officially included in the National Health Insurance coverage in Taiwan, benefiting more patients who need treatment.
- **Patient support activities in the United States:**
  Yung Shin offers many patient support activities related to treatment, which can be found on BESREMi.com and SOURCE Program.

End-of-life care

- **Taiwan Case Management Care:**
  Follow-up on the treatment and subsequent medication response of individual patients through a project-based approach.
- **US Medication Adherence Tracking:**
  If patients stop taking the medication due to adverse drug reactions, PharmaEssentia can receive cessation information through specialized pharmacy databases and record it in the drug monitoring program for subsequent follow-up.

Disease Diagnosis

- **MPN Center at Chiayi Chang Gung Memorial Hospital:**
  Both PharmaEssentia and Chiayi Chang Gung Memorial Hospital have been deeply involved in the field of MPN for many years. In addition to promoting the importance of disease treatment through the center, they also conduct genetic mutation testing through clinical research to improve disease diagnosis accuracy and techniques.
- **WHAT'S NEXT PV:**
  As a major health education website in the United States, it allows the public to learn about the disease and recognize risks. By leveraging the power of the platform to connect the patient community, the goal is to provide comprehensive physical, mental and spiritual support for each patient in the treatment process, and to promote smooth communication with medical practioners. Clinical education for healthcare professionals is expected to be added in 2023, which will help with accurate diagnosis and judgment of PV symptoms in the future.

4.5 Ethical Pharmaceutical Marketing

Marketing Ethics Policy and Commitment

GRI 417-3 | HC-BP-270a.2 / 510a.2

Our company strictly adheres to all applicable industry regulations and stipulated provisions in marketing and sales, ensuring that all relevant personnel receive appropriate training and comply with ethical standards. All employees of PharmaEssentia who interact with internal staff and healthcare professionals are subject to marketing ethics policies. All activities, marketing materials, and daily operations are subject to review processes based on the following principles:

Principle 1

Prioritize patient healthcare and welfare as the top priority.

Principle 2

Meet the high standards of quality, safety, and efficacy required by regulatory authorities.

Principle 3

Interact with relevant agencies or individuals in an ethical, appropriate, and professional manner. Do not provide or supply any goods or services that may directly or indirectly cause undue influence.

Principle 4

Provide accurate, balanced, and scientifically valid product information.

Principle 5

Ensure that product marketing activities are ethical, correct, and balanced, and avoid any misleading information. Product marketing materials must include a correct assessment of the product's risks and benefits and appropriate usage instructions.

Principle 6

Respect patient privacy and personal information.

Principle 7

Sponsor/support clinical trials or scientific research for the purpose of pursuing new knowledge, enhancing patient benefits, and promoting the advancement of medical technology. Maintain transparency in human clinical trials sponsored by the industry.

The US subsidiary currently uses policy manuals and PhRMA industry standards as core guiding principles for marketing and sales. In 2022, there were no violations of any marketing and communications-related regulations, and the company adhered to ethical pharmaceutical marketing practices.