

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 expanded 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.

