Ko-Chung Lin – Founder, CEO & US General Manager, PharmaEssentia



Our ambition has always been to build a fully integrated global pharmaceutical company

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For nearly 30 years, patients with essential thrombocythaemia had no new FDA-approved treatment. PharmaEssentia's BESREMi has now changed that, and it adds a second US indication for the drug after polycythaemia vera. Founder and CEO Dr Ko-Chung Lin explains how the Taiwanese company collaborated with the FDA to achieve the key indication expansion, and how it is working to get BESREMi to patients beyond specialist centres. He also covers a Phase III trial that could take BESREMi into all three classical myeloproliferative neoplasms. With more than USD 800 million in cash, the company is looking for a second commercial product, as part of an aim to build a global pharma company.

How has PharmaEssentia evolved since our last interview in 2017, and what have been the key milestones in its international expansion?

We have grown considerably over the past decade, with more than 300 employees in the US and a global workforce expected to approach 1,000 by the end of 2026. A major turning point was the European approval of ropeginterferon alfa-2b (BESREMi) for polycythaemia vera (PV) in February 2019, followed by FDA approval in November 2021. Since then, we have successfully commercialised BESREMi, which is now approved in more than 50 countries worldwide. Our commercial strategy combines direct operations in major markets, including the US, Japan, South

Korea and China, with established partnerships such as AOP Health in Europe and Pint-Pharma in Latin America.

We have also strengthened our presence in North America through the acquisition of FORUS Therapeutics, our former Canadian commercialisation partner, which is now a wholly owned subsidiary. More recently, we established a subsidiary in Australia, where we see opportunities to expand patient access while benefiting from the country's strong clinical research environment. Although its healthcare system differs from those in the US and Canada, we believe Australia can contribute meaningfully to our future development programmes.

What does the FDA approval of BESREMi for essential thrombocythaemia mean for patients, and how did PharmaEssentia navigate the clinical and regulatory process?

The approval of BESREMi for essential thrombocythaemia (ET) is a major achievement for us and, more importantly, for patients, as it represents the first new FDA-approved treatment for this rare blood cancer in nearly three decades. Although ET and PV are closely related myeloproliferative neoplasms (MPNs), they have important clinical differences. PV is characterised by excessive red blood cell production, often accompanied by elevated white blood cell and platelet counts, whereas ET is primarily associated with elevated platelet counts. When we first approached the FDA, the agency was understandably cautious about extending BESREMi's development into a distinct disease. With guidance from international experts, we spent approximately two and a half years refining the clinical protocol before agreeing on SURPASS-ET, a Phase III trial comparing BESREMi with anagrelide in patients who were resistant or intolerant to hydroxyurea. The study began in 2020, during the COVID-19 pandemic, making recruitment particularly challenging, and took more than four years to complete. Nevertheless, the results were compelling, with 42.9 percent of patients receiving BESREMi achieving a durable response, compared with 6.0 percent receiving anagrelide, demonstrating clear superiority.

Given the recruitment challenges in the US and the predominantly Asian population enrolled in SURPASS-ET, we also worked with the FDA to develop EXCEED-ET, a Phase IIb study conducted in the US and Canada to provide additional evidence in a broader North American population. We initially planned to recruit 64 patients but ultimately enrolled 91, including 67 treatment-naïve patients and 24 previously treated with hydroxyurea. The study achieved a durable response rate of approximately 60 percent, providing further encouraging evidence across different patient populations and molecular subtypes. Together, SURPASS-ET and EXCEED-ET formed a

comprehensive clinical package, with the former providing pivotal Phase III evidence and the latter offering supportive and confirmatory data. This was an important example of how closely we worked with the FDA to ensure the clinical evidence could support a meaningful treatment option for patients.

That collaboration ultimately enabled us to secure approval for adults with ET without restrictions based on prior lines of treatment, including patients who have not previously received cytoreductive therapy. For decades, hydroxyurea has remained a mainstay of ET treatment, while anagrelide has been another established option, although its tolerability profile, particularly cardiovascular adverse effects, can limit its use. Some patients also do not respond adequately to hydroxyurea or cannot tolerate it, leaving a clear need for additional options. With BESREMi, we can now offer physicians and patients an important alternative after nearly 30 years without a new FDA-approved treatment for ET.

Drawing on your experience with BESREMi in polycythaemia vera, how are you approaching its launch in essential thrombocythaemia and its potential across other MPNs?

We have seen encouraging initial uptake of BESREMi among academic specialists, who tend to be well informed about the latest treatment developments, although reaching physicians in community practice remains a challenge. After nearly five years of commercialising BESREMi in the US for PV, we have gained valuable experience that we can now apply to ET. Both are chronic blood cancers that often progress slowly, meaning physicians may not always feel the same urgency to initiate treatment as they would with more aggressive cancers, particularly when patients have few or no symptoms. Nevertheless, these diseases can progress and lead to serious complications, making it important to raise awareness of the potential benefits of earlier intervention. We are making progress in this regard, supported by a growing body of evidence, particularly in PV, suggesting that earlier treatment may improve long-term disease control. Scientific publications, real-world evidence, subgroup analyses and investigator-initiated studies are all helping us strengthen physician education and support more informed treatment decisions.

Looking ahead, our next major focus is primary myelofibrosis (PMF), the third of the classical MPNs, where we believe there is considerable potential to improve outcomes through earlier treatment. For patients with early or lower-risk PMF, observation has traditionally been a common approach, but Professor Richard Silver of Weill Cornell Medicine, who devoted decades to studying MPNs, was

instrumental in encouraging us to investigate whether earlier intervention could make a difference. Following extensive discussions with the FDA, we developed HOPE-PMF, a placebo-controlled Phase III study evaluating BESREMi in this patient population. We initially planned to enroll 150 patients, but recruitment exceeded our expectations, ultimately reaching 160 patients across several markets, including the US, Japan, South Korea, China and Singapore. The study is progressing well, with the independent Data and Safety Monitoring Board recommending its continuation as planned, and we anticipate topline results in 2027, with the possibility of pursuing regulatory submissions in 2028 if the findings are positive.

Our broader ambition is to establish PharmaEssentia as a leader in the MPN field, building on the strong position we have established with BESREMi in PV and ET. With an estimated 160,000 and 170,000 patients, respectively, in the US, these represent the two largest classical MPN patient populations and offer significant opportunities to expand access to treatment. Incyte has demonstrated the potential of this field through ruxolitinib (Jakafi), which is approved for myelofibrosis and certain patients with PV, and we see an opportunity to establish a similarly strong presence across the MPN spectrum. If HOPE-PMF delivers positive results and ultimately secures regulatory approval, we could extend our reach to all three classical MPNs, marking an important milestone in our long-term growth strategy.

How do you assess the impact of evolving US drug pricing policies on rare-disease innovation, particularly for smaller biotechnology companies?

When discussing orphan drugs, it is worth remembering that nearly half of the FDA’s recent novel drug approvals have been for rare diseases, yet more than 10,000 rare diseases have been identified, many of which still have no approved treatment. Large pharmaceutical companies naturally tend to focus on larger patient populations, which is why I believe smaller biotechnology companies like PharmaEssentia have an important role to play in addressing these unmet needs. At the same time, the evolving US policy environment presents challenges, particularly around most-favoured-nation (MFN) pricing and the Inflation Reduction Act (IRA), making it important to maintain a framework that supports continued innovation in rare diseases. At PharmaEssentia, we have worked extensively with the Centers for Medicare & Medicaid Services (CMS) to understand and address how the IRA’s provisions for smaller manufacturers apply to us. This has required considerable effort, but we have taken a proactive approach to navigating these regulatory challenges. While there is only so much we can do to influence government policy, our priority is to understand the regulations, engage constructively with the relevant agencies and find practical

ways forward while remaining focused on developing treatments for patients with rare diseases.

What role does the US play in PharmaEssentia's global strategy, and how are you strengthening your presence in this market?

The US has always been central to PharmaEssentia's development, particularly because our chairperson and co-founder, Dr Ching-Leou Teng, and much of our founding team gained extensive experience in the American pharmaceutical industry before returning to Taiwan. This gave us a strong understanding of the entire pharmaceutical development process, from drug discovery and clinical development to manufacturing and commercialisation. We also recognise that the US offers one of the most established environments for pharmaceutical innovation, with a healthcare system that, despite its complexity, is commercially oriented and rewards companies bringing innovative medicines to market. Our ambition has always been to build a fully integrated global pharmaceutical company, and Takeda is one example we look to in this regard. It has taken more than two centuries to establish its global presence, but we believe we can build something comparable over the next 50 years, and we are already making good progress towards that goal.

Our US journey began around 14 years ago with just two employees, initially to support the Phase III development of BESREMi and establish the regulatory foundations for its eventual commercialisation, particularly in the orphan-drug space. Following the positive Phase III results, we secured our Board's support to establish a fully functioning commercial operation in Burlington, Massachusetts, and subsequently opened the PharmaEssentia Innovation Research Center (PIRC) in nearby Bedford. Both facilities have supported our continued expansion, and we have also recently announced the acquisition of our own building in Lexington as we prepare for the next stage of growth. Beyond our approved indications in MPNs, we are also investigating the potential of BESREMi in other cancers, including solid tumours and cutaneous T-cell lymphoma (CTCL). An investigator at Moffitt Cancer Center in Florida has been studying BESREMi in CTCL, with findings presented at the American Society of Hematology (ASH) annual meeting, while additional research is exploring its potential in solid tumours. We also see opportunities in cell therapy and are considering establishing small-scale manufacturing capabilities in the Boston area to support future candidates as they advance through development.

Alongside these initiatives, we have committed USD 46 million to establishing a manufacturing facility in Puerto Rico, primarily to support BESREMi production and strengthen our supply chain. Together, these investments reflect the importance we place on the US, both as a commercial

market for our existing portfolio and as a centre for future research, development and manufacturing. By continuing to expand these capabilities, we are laying the foundations for PharmaEssentia's next phase of growth and our ambition to become a fully integrated global pharmaceutical company.

How is PharmaEssentia expanding its oncology pipeline beyond BESREMi, and what are your strategic priorities for the next three to five years?

We have built a strong team of scientists with extensive expertise in monoclonal antibody discovery and development, providing a solid foundation for expanding into ADCs. We are also developing bispecific immunocytokines targeting pathways such as PD-1 and IL-2, where we have seen encouraging preclinical results and hope to advance candidates into Phase I clinical trials. Building on our existing antibody platform, we are progressing several promising programmes, including an ADC candidate that we aim to bring into clinical development in the first half of 2027. These developments represent an important next step in broadening our oncology pipeline and building on the scientific capabilities we have established over the years.

From a strategic perspective, we are fortunate to have a strong financial position, with more than USD 800 million in cash, and we intend to put those resources to good use. We have already made several strategic investments and acquisitions, and are actively exploring further opportunities, particularly late-stage Phase III assets with the potential to reach the market within the next three to five years. Our immediate priority is to identify a promising candidate that could become our second commercial product beyond BESREMi. Although we have not yet completed an acquisition of this kind, discussions are ongoing, and we are optimistic about making progress in the near future. Looking further ahead, over the next five to ten years, we expect our internal pipeline to advance towards potential commercialisation, supported by a talented team that includes many young scientists who are passionate about their work. I believe this combination of internal innovation and strategic acquisitions will be important to our continued growth and, most importantly, in bringing new treatments to patients.

Looking further ahead, what kind of company do you hope PharmaEssentia will become, and what will be most important in achieving that vision?

As scientists, our goal has always been to apply our knowledge to developing medicines for patients who need them, and patients remain our first priority. Our employees are equally

important, and we want them to be happy, motivated and able to contribute their talents, while the continued support of our shareholders is essential to achieving our long-term ambitions. I also want to express my appreciation to the Taiwanese government for its efforts to foster biotechnology as another important pillar of the country's economy, building on the success of Taiwan Semiconductor Manufacturing Company (TSMC) in the semiconductor industry. We have been fortunate to be among the front-runners in this development and to establish PharmaEssentia as one of Taiwan's leading biotechnology companies. However, our ambition extends well beyond Taiwan, and we want to continue building PharmaEssentia into one of the world's leading biotechnology companies, recognised for the medicines we develop and the difference we make for patients.

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