

News release

Kyowa Kirin and Swixx BioPharma announce expansion of access to POTELIGEO® (mogamulizumab) for adults living with mycosis fungoides or Sézary syndrome in Central and Eastern Europe

- ***Second- and third-line treatment for adults with mycosis fungoides or Sézary syndrome reimbursed by Croatia's National Health Insurance Fund (NHIF), effective as of 15th November 2024.***
- ***Bulgaria's Ministry of Health also confirms positive second-line reimbursement, effective 2nd January 2025.***

Galashiels and Marlow, United Kingdom, and Baar, Switzerland, 30 January 2025 — Kyowa Kirin International (KKI), a wholly owned subsidiary of Kyowa Kirin Co. Ltd., and Swixx BioPharma AG today announced that the Croatian National Health Insurance Fund (NHIF) and the Bulgarian Ministry of Health have both approved the reimbursement of POTELIGEO® (mogamulizumab) for adult patients with mycosis fungoides (MF), and Sézary syndrome (SS).

MF and SS are two subtypes of cutaneous T-cell lymphoma (CTCL), a rare form of non-Hodgkin's lymphoma that presents and persists in the skin and can cause debilitating physical, emotional and social challenges.¹ MF—the most common CTCL subtype—accounts for approximately 60% of all CTCLs.²

With an average time to diagnosis of 3-4 years, MF is typically characterised by skin symptoms including patches or plaques, skin redness and tumours.^{3,4} SS is much rarer, accounting for around 5% of CTCLs,⁵ and is more aggressive, causing severe itching, erythroderma, intense scaling of the skin and frequent hair loss.⁶

Jeremy Morgan, President of Kyowa Kirin International, commented: "I am delighted that the Croatian and Bulgarian authorities have agreed to reimburse POTELIGEO for MF and SS patients. Both decisions are important milestones for people impacted by these rare and challenging forms of CTCL, and with mogamulizumab now reimbursed in more than 20 countries across the EMEA region we remain as committed as ever to delivering life changing value for people impacted by under-diagnosed and under-served diseases, and making more people smile."

Poteligeo is distributed in Central and Eastern Europe by Swixx, on behalf of KKI. The two companies signed a Promotion and Distribution Agreement in October 2022. Under the terms of the agreement, Swixx will exclusively market, promote and distribute mogamulizumab in both Croatia and Bulgaria, among other countries.

"At Swixx, our mission is to unlock access to innovative medicines, and the recent reimbursement approvals in Croatia and Bulgaria mark significant progress in improving therapeutic options for patients with MF and SS in those markets," said Dezso Martha, Chief Operating Officer of Swixx. "We will continue working closely with health authorities, the scientific community, and Kyowa Kirin to expand access to this important medicine, ensuring better outcomes for patients across our Central and Eastern European countries."

With Croatian reimbursement effective as of 15th November 2024, and Bulgaria's Ministry of Health confirming reimbursement as of 2nd January 2025, both decisions build on the inclusion of POTELIGEO® (mogamulizumab) in the Polish Ministry of Health's Drug Programme announced in July 2024 and the ongoing expansion of access to patients across Central and Eastern Europe (CEE).

End.

About Poteligeo (mogamulizumab)

Mogamulizumab is a first-in-class humanised monoclonal antibody directed against CC-chemokine receptor 4 (CCR4), a protein consistently expressed on cancerous cells seen in both MF and SS.⁷⁻⁹ Once mogamulizumab binds to CCR4, it increases attraction of immune cells from the immune system to destroy the cancerous cells.¹⁰

About MF and SS

MF and SS are two subtypes of CTCL, which is itself a rare form of non-Hodgkin's lymphoma that presents and persists in the skin.¹ CTCL is treatable, but is not generally considered to be curable, and there has been a clear unmet need for novel treatment options. As well as the obvious impact of symptoms upon patients, there can be significant erosions to quality of life for those caring for an individual living with CTCL.¹¹

MF and SS are characterised by localisation of cancerous white blood cells called T lymphocytes (T cells), to the skin.¹² These cancerous T cells consistently express a protein called CCR4, which enables them to move from the blood to the skin.⁷⁻⁹ When these cancerous T cells move to the skin, this results in the visible early skin symptoms of red patches or plaques which can resemble psoriasis or eczema in the early stages of the disease.⁶ Later, for some patients, skin involvement may evolve to include tumours or reddening of the majority of the skin's surface (erythroderma).

MF—the most common CTCL subtype—accounts for approximately 60% of all CTCLs² and is typically indolent, characterised by skin symptoms including patches or plaques, skin redness and tumours.^{3,4} SS is much rarer, accounting for around 5% of CTCLs,⁵ and is more aggressive,⁶ with high levels of blood involvement.⁵ It can cause severe itching, erythroderma, intense scaling of the skin and frequent hair loss.⁶ CTCL can take, on average, between 2 and 7 years for individuals to receive a confirmed diagnosis.⁶

About Kyowa Kirin

Kyowa Kirin aims to discover novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, we have invested in drug discovery and biotechnology innovation for more than 70 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients affected by severe and rare diseases. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our four regions – Japan, Asia Pacific, North America, and EMEA/International.

You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com>

About Swixx BioPharma AG

Swixx BioPharma is one of the fastest-growing, largest, intercontinental commercial platforms for the biopharmaceutical industry. Swixx operates subsidiaries across Central and Eastern Europe, Greece, Russia, several Eurasian countries, the Middle East, and via Biopas, a Swixx BioPharma company, in almost 20 Latin American countries. Swixx BioPharma Group has over 1,600 employees and sales likely to exceed a billion Euros in 2024. The company has gathered outstanding rare disease, oncology-hematology, specialty, vaccines and self-medication talent under one roof.

For more information about Swixx BioPharma, please visit: www.swixxbiopharma.com

Contacts for Kyowa Kirin Co., Ltd.:

Media

Stacey Minton

Email: Stacey.Minton@kyowakirin.com

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