Bristol Myers Squibb Announces TGA Registration of *Sotyktu*® (deucravacitinib) in Australia for the Treatment of Active Psoriatic Arthritis in Adults

Sotyktu, *a once-daily oral treatment, is the first tyrosine kinase 2 (TYK2) inhibitor registered in Australia for this indication*

(MELBOURNE, Australia, Embargoed until 3 September, 2026) -- Bristol Myers Squibb Australia today announced that *Sotyktu* (deucravacitinib) has been registered by Australia's Therapeutic Goods Administration (TGA) for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response to, or who have been intolerant to, a prior disease modifying therapy (DMARD)[1]. It may be used as monotherapy or in combination with conventional synthetic DMARDs (csDMARDs). Sotyktu, a once-daily oral, selective tyrosine kinase 2 (TYK2) inhibitor, is the first TYK2 inhibitor to be registered in Australia for the treatment of active PsA. Sotyktu is not currently listed on the Pharmaceutical Benefits Scheme (PBS) for the treatment of active psoriatic arthritis.

"The TGA registration of Sotyktu for active psoriatic arthritis marks an important milestone, providing an additional treatment option for eligible adults living with this disease in Australia," said Owen Smith, General Manager, Bristol Myers Squibb Australia & New Zealand.

Psoriatic arthritis (PsA) is a chronic, immune-mediated, heterogenous disease with multiple musculoskeletal and skin manifestations, including inflammatory arthritis, enthesitis (inflammation where a tendon or ligament attaches to the bone), dactylitis (swelling in fingers and/or toes) and psoriatic skin and nail lesions. PsA can affect up to 30% of people living with psoriasis[2]. In addition to impairments in physical function, depression and fatigue caused by PsA, the disease can significantly impact the well-being of patients[3]. Patients with PsA are also at increased risk of serious comorbidities[3].

"Psoriatic arthritis can have debilitating joint and skin symptoms. The psoriatic arthritis patient and carer community in Australia has been waiting for additional treatment options," said Seth D. Ginsberg, Co-founder of GHLF Australia and CreakyJoints Australia. "We welcome this new treatment option for people living with psoriatic arthritis."

This TGA registration is based on positive results from the pivotal POETYK PsA-1 and POETYK PsA-2 Phase 3 clinical trials, which evaluated the efficacy and safety of *Sotyktu* 6 mg once daily in adults with active PsA. In both trials, treatment with *Sotyktu* resulted in a statistically significant improvement in disease activity, as measured by American College of Rheumatology (ACR) 20 (the primary endpoint) and Minimal Disease Activity (MDA) (key secondary endpoint)[4,5].

In POETYK PsA-1 and PsA-2, the overall safety profile of Sotyktu observed in patients with active psoriatic arthritis was generally consistent with the safety profile in patients with plaque psoriasis[6]. Common adverse drug reactions with Sotyktu include upper respiratory infections including nasopharyngitis and upper respiratory tract infections, herpes simplex infections, oral ulcers, acneiform rash, and folliculitis.

“Psoriatic arthritis presents differently from patient to patient, often combining widespread musculoskeletal inflammation and challenging skin symptoms with a debilitating impact on quality of life,” said Prof Paul Bird, Chief Medical Officer of Emeritus Clinical Research, NSW and VIC.

In clinical trials, health-related quality of life was assessed by the 36-Item Short Form Health Survey (SF-36). Patients treated with *Sotyktu* showed improvements in SF-36 Physical Component Summary (PCS) score at Week 16 compared to placebo (key secondary endpoint), with improvements maintained in both POETYK PsA trials up to Week 52[4,5].

Sotyktu was first registered in Australia in 2022 for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It was subsequently reimbursed via the PBS for the treatment of severe chronic plaque psoriasis in October 2023, with dermatologists, rheumatologists and general physicians being able to initiate the prescription for psoriasis. With this latest TGA registration, *Sotyktu* is now also indicated in Australia for the treatment adult patients with active psoriatic arthritis who have had an inadequate response to, or who have been intolerant to, a prior disease modifying therapy (DMARD). Sotyktu may be used as monotherapy or in combination with conventional synthetic DMARDs (csDMARDs).

Bristol Myers Squibb thanks the patients and investigators who participated in the POETYK PsA clinical trials around the world including those from Australia.

About the *Sotyktu* Phase 3 Psoriatic Arthritis Trial Program

The Phase 3 *Sotyktu* psoriatic arthritis (PsA) program included two Phase 3, multicenter, randomized, double-blind, placebo-controlled trials evaluating the efficacy and safety in adults 18 years of age and older with active PsA: POETYK PsA-1 (IM011-054; NCT04908202) and POETYK PsA-2 (IM011-055; NCT04908189).

POETYK PsA-1 included 670 patients with active PsA who were not previously treated with a biologic disease-modifying antirheumatic drug (bDMARD naïve). POETYK PsA-2 included 624 patients with active PsA who were bDMARD naïve or had previously received TNFα inhibitor treatment. Patients met the CASPAR criteria for PsA, with ≥3 swollen and ≥3 tender joints and had an active or documented history of plaque psoriasis. Both trials include a 52-week treatment period comprised of a placebo-controlled treatment period through Week 16, followed by a reallocation and continued active treatment period from Week 16 to Week 52. POETYK PsA-2 also included an apremilast safety reference arm.

The primary endpoint of both trials was the proportion of participants achieving an ACR20 response at Week 16. Key secondary endpoints were also assessed at Week 16 across measures of PsA disease activity.

Patients in both trials completing 52 weeks of treatment were potentially eligible to enroll in open-label extensions.

In both POETYK PsA-1 and POETYK PsA-2 trials, treatment with *Sotyktu* resulted in significant improvement in disease activity, as measured by American College of Rheumatology (ACR) 20 (the primary endpoint) and Minimal Disease Activity (MDA) (key secondary endpoint).

About *Sotyktu* (deucravacitinib)

Sotyktu is an oral, selective, tyrosine kinase 2 (TYK2) inhibitor with a unique mechanism of action. It is the first selective TYK2 inhibitor in clinical studies across moderate-to-severe plaque psoriasis and active psoriatic arthritis. Bristol Myers Squibb scientists designed *Sotyktu* to selectively target TYK2, thereby mediating the signaling of interleukin (IL)-23, IL-12 and Type 1 interferons (IFN), key cytokines involved in the pathogenesis of plaque psoriasis and psoriatic arthritis. *Sotyktu* achieves a high degree of selectivity by binding to the regulatory domain of TYK2, resulting in inhibition of TYK2 and mediation of its downstream functions. *Sotyktu* has been shown to have high selectivity for TYK2 at physiologically relevant concentrations and has not been shown to inhibit JAK1, JAK2 or JAK3 in *in vitro* assays. The precise mechanism linking inhibition of TYK2 enzyme to therapeutic effectiveness is not currently known.

Sotyktu is registered in Australia for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response to, or who have been intolerant to, a prior disease modifying therapy (DMARD).

SOTYKTU may be used as monotherapy or in combination with conventional synthetic DMARDs (csDMARDs).

The efficacy and safety of *Sotyktu* in patients with moderate-to-severe plaque psoriasis were evaluated in POETYK PSO-1 and POETYK PSO-2, multi-national, randomized, double-blind, placebo- and active comparator-controlled 52-week Phase 3 studies. In total, 664 patients were enrolled in POETYK PSO-1, and 1,020 patients were enrolled in POETYK PSO-2.

Sotyktu is associated with the following special warnings and precautions for use: hypersensitivity; infections; pre-treatment evaluation for tuberculosis; malignancies; immunisations; potential risks of JAK inhibition; laboratory abnormalities including elevated CPK and rhabdomyolysis, triglyceride elevations and liver enzyme elevations, use in elderly and paediatric use. Pregnancy: Category B1 [6].

Australian Product Information and Consumer Medicine Information for SOTYKTU.

References

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Bristol Myers Squibb: Pioneering Paths Forward in Immunology to Transform Patients' Lives

Bristol Myers Squibb is inspired by a single vision — transforming patients' lives through science. For people living with immune-mediated diseases, the debilitating reality of enduring chronic symptoms and disease progression can make simple tasks and daily life a challenge. Driven by our deep understanding of the immune system that spans over 20 years of experience, we continue to pursue bold science as we work to deliver life-changing medicines that elevate new standards of care across rheumatology, dermatology and pulmonology. Our sequential immunotherapy research framework aims to address the root cause of disease by controlling inflammation, resetting the immune system and promoting immune homeostasis with the goal of achieving transformational efficacy. By continuously pushing the boundaries of scientific knowledge, we strive to bring forward tailored approaches, treatments and combinations that may lead to durable remissions, improved quality of life and functional cures. Our collaborations with patients, caregivers, healthcare providers and researchers inform our patient-centric approach as we aim to break efficacy ceilings and deliver what matters most — the promise of living a better life.

About Bristol Myers Squibb: Transforming Patients' Lives Through Science
At Bristol Myers Squibb, our mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. We are pursuing bold science to define what's possible for the future of medicine and the patients we serve. For more information, visit us at BMS.com and follow us on LinkedIn, X, YouTube, Facebook and Instagram.
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