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[C2H2209] Summary of cost-effectiveness evaluation of deucravacitinib (Sotyktu®)

1. Indications

Patients with plaque psoriasis (an inflammatory disease causing red, scaly patches on the skin) not responding sufficiently to existing treatments.

2. Price of the drug

Deucravacitinib (Sotyktu®) has been reimbursed from November 2022 at JPY 2,770.90 (as of April 2024). This price is calculated using a similar efficacy comparison method, with a usefulness premium (I) of 5%. This product is designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for the treatment of plaque psoriasis patients who are not sufficiently responding to existing treatments. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

Population	Plaque psoriasis patients who are not sufficiently responding to existing treatments (a) Patients who are not sufficiently responding to non-biologic systemic treatments with no prior biologic treatments (b) Patients with no prior systemic treatments
Comparator	(a) Biologics (ixekizumab, risankizumab, and bimekizumab) with the lowest price (b) Apremilast

4. Evaluation of additional benefits

[Plaque psoriasis patients who are not sufficiently responding to non-biologic systemic treatments with no prior biologic treatments] The manufacturer noted that no randomized controlled trials (RCTs) that directly compared deucravacitinib and risankizumab were identified. The manufacturer identified 96 RCTs by conducting a systematic review and performing a network meta-analysis (NMA). The manufacturer asserted that deucravacitinib had additional benefits over risankizumab because the NMA using only Asian patient data showed an improvement in the odds ratio of achieving psoriasis area and severity index (PASI) for deucravacitinib over risankizumab at 10–16 weeks compared to the global NMA using all literature. However, in both cases, the odds ratio was less than 1. Thus, the ATAG rated deucravacitinib as having "no additional benefit" (inferior efficacy) over risankizumab.

[Patients with plaque psoriasis with no prior systemic treatments] Randomized POETYK-PSO-1 and POETYK-PSO-2 trials were included in the ATAG's systematic review. Deucravacitinib showed significantly higher response rates than apremilast at week 16 in POETYK-PSO-1 (PASI 75 was achieved in 58.4% vs. 35.1%) and POETYK-PSO-2 (53.0% vs. 39.8%) patients. The ATAG concluded that deucravacitinib has additional benefits over apremilast owing to its significantly higher percentage of achieving PASI at 16 weeks in the randomized POETYK-PSO-1 and POETYK-PSO-2 trials.

5. Results of the cost-effectiveness analysis

The manufacturer conducted a Markov cohort simulation analysis based on the structure of the York model. The model assumed that all patients would initiate treatment with either deucravacitinib or apremilast, and patients who achieved PASI 75 would transition to a maintenance phase consisting of three states (PASI 100, PASI 90–99, and PASI 75–89). Patients who did not achieve PASI 75 or discontinued the primary treatment were assumed to transition to a secondary treatment. In the event of discontinuation of the tertiary treatment, all patients were assumed to transition seamlessly to best supportive care (BSC), which would be continued for the rest of their lives. The ATAG conducted a re-analysis due to the identification of several challenges in the manufacturer's analysis. First, the manufacturer used pooled EQ-5D-3L data from POETYK trials and the previous technology appraisals conducted by the National Institute for Health and Care Excellence. The ATAG judged that using EQ-5D-3L, which was not converted

by Japanese tariff, was inappropriate. Therefore, the ATAG conducted a re-analysis using the pooled EQ-5D-3L data converted by Japanese tariff from POETYK trials. Additionally, the manufacturer assumed that patients who received BSC would be hospitalized once a year. The ATAG revised the hospitalization charges for BSC based on the annual hospitalization risk compiled in the National Database. The ECCEE accepted the following results:

Population	Comparator	Additional benefits	ICER (JPY/QALY)
(a) Plaque psoriasis patients who are not sufficiently responding to non-biologic systemic treatments with no prior biologic treatments	Risankizumab	No additional benefit (inferior efficacy)	
(b) Plaque psoriasis patients with no prior systemic treatments	Apremilast	Additional benefit	6,045,505

The ATAG rated deucravacitinib as having "no additional benefit" (inferior efficacy) over risankizumab and did not examine its cost-effectiveness.