A Look at SOTYKTU™'s Safety Profile

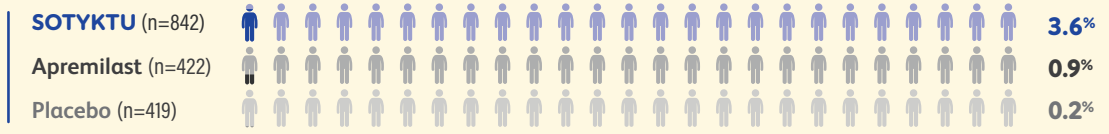
POETYK PSO-1 and PSO-2 studies

Adverse reactions occurring in ≥1% of the SOTYKTU group with higher rates than placebo, through Week 16 (pooled data)[1]

Gastrointestinal disorders

Infections and infestations

Skin and subcutaneous tissue disorders



Adapted from Product Monograph.
*Includes aphthous ulcer, mouth ulceration, tongue ulceration and stomatitis.
†Includes nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, pharyngitis, sinusitis, acute sinusitis, rhinitis, tonsillitis, peritonsillar abscess, laryngitis, tracheitis, and rhinotracheitis.
‡Includes oral herpes, herpes simplex, genital herpes, and herpes viral infection.
§Includes acne, dermatitis acneiform, rash, rosacea, pustule, rash pustular, and papule.

- No new adverse reactions were identified with SOTYKTU through Week 52 and the incidence of common adverse reactions did not increase compared to those observed during the first 16 weeks of treatment
- Discontinuation rate due to adverse events was 2.4% for SOTYKTU vs. 3.8% for placebo and 5.2% for apremilast. The majority of events leading to treatment discontinuation occurred in single patients[1]

SOTYKTU (deucravacitinib tablets) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

ONCE-DAILY
SOTYKTU™
deucravacitinib tablets

Less Common Adverse Reactions Reported[1,2]

Herpes zoster | **SOTYKTU** (n=842)

0.2%

During the 0-to-52-week treatment period of the two controlled psoriasis clinical studies (total exposure of 969 person-years with SOTYKTU)

Malignancies (excluding non-melanoma skin cancers) | **SOTYKTU** (n=1364)

0.2%

This included one lymphoma. Lymphomas were also reported with SOTYKTU in the open-label, long-term extension and in an open-label regional study. The potential role of SOTYKTU in the development of malignancies is unclear.

Clinical Use:

There are no data in pediatric patients, therefore, Health Canada has not authorized an indication for pediatric use.

Relevant Warnings and Precautions:

- No studies on the effects of SOTYKTU on ability to drive and use machinery. Exercise caution when driving or operating a vehicle or potentially dangerous machinery.
- Contains lactose. SOTYKTU should not be administered in patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption.
- Increased risk of infections. SOTYKTU should not be initiated in patients with any clinically important active infection until it resolves or is adequately treated.
- Pre-treatment evaluation of tuberculosis (TB). Do not administer SOTYKTU to patients with active TB.
- Avoid use of live vaccines with SOTYKTU. The response to live or non-live vaccines has not been evaluated.
- Insufficient data to inform on risk in pregnant women.
- It is unknown if SOTYKTU is excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.
- Not recommended in patients with severe hepatic impairment (Child-Pugh Class C).

For More Information:

Please consult the Product Monograph at https://www.bms.com/assets/bms/ca/documents/productmonograph/SOTYKTU_EN_PM.pdf for adverse reactions, drug interactions, and dosing information. The Product Monograph is also available by calling 1-866-463-6267.

References:
1. SOTYKTU Product Monograph. Bristol-Myers Squibb Canada Co. November 23, 2022.
2. Data on file, Bristol-Myers Squibb Co. [POETYK Clinical Study Report]

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