SOTYKTU™
(deucravacitinib) 6 mg tablets

A first-line systemic treatment for moderate plaque psoriasis

Could a once-daily oral option be next for her moderate plaque psoriasis?

Patient portrayal.

INDICATION

SOTYKTU (deucravacitinib) is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Limitations of Use:

SOTYKTU is not recommended for use in combination with other potent immunosuppressants.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SOTYKTU is contraindicated in patients with a history of hypersensitivity reaction to deucravacitinib or to any of the excipients in SOTYKTU.

Please see additional Important Safety Information throughout and the U.S. Full Prescribing Information, including Medication Guide for SOTYKTU and Study Design.

Meet Jill: A baker and a SOTYKTU candidate

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"It's impossible to hide my hands from customers, and the flaking on my palms makes a simple handshake an ordeal."

- Age 55 with moderate plaque psoriasis
- Visible plaques with redness and scaling on lower extremities and forearms with flaking and dryness on hands
- Has been using topicals on and off for 10 years

See why SOTYKTU may be right for patients like Jill

Proven superior clearance vs apremilast[1-3†]

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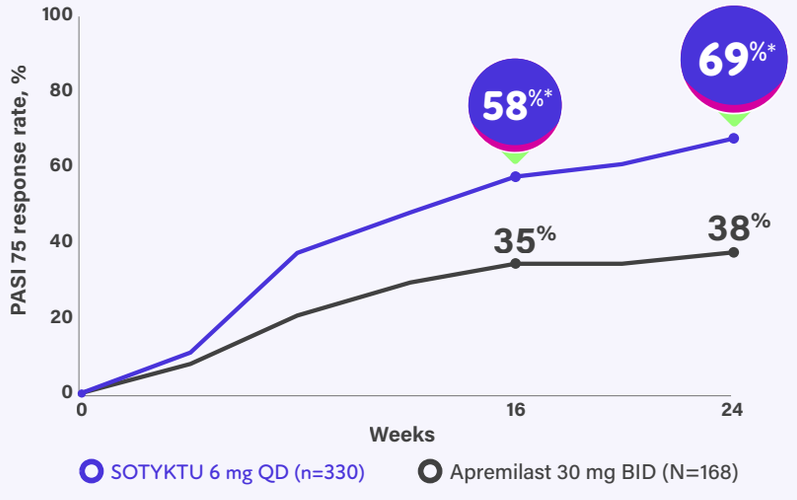
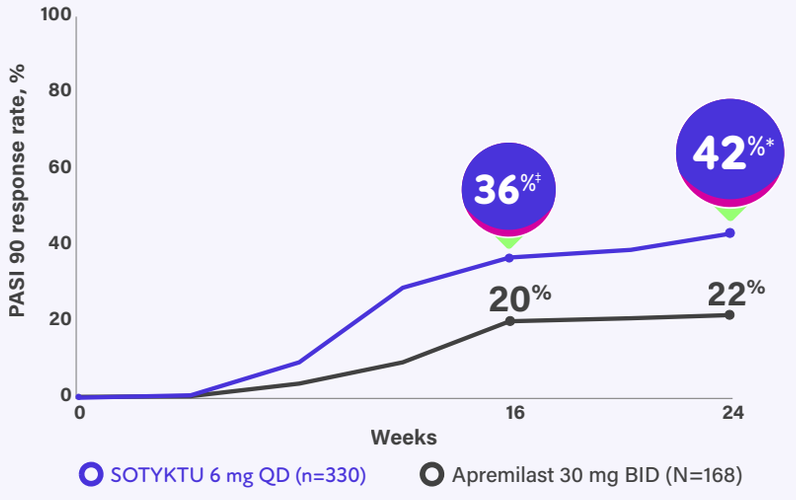
IN POETYK PSO-1

PASI 75 AND PASI 90 RESPONSE RATES AT WEEKS 16 AND 24 (SECONDARY ENDPOINTS) (NRI)[1,2]





~7 out of 10 patients achieved PASI 75 at Week 24[1,2]

Patients saw ~2x the PASI 90 response rate vs apremilast at Week 24[1,2]

Superior PASI 75 response rates vs apremilast in PSO-2 (secondary endpoints)[1,3]

- 53% for SOTYKTU (n=511) vs 40% for apremilast (n=254) at Week 16 (*P*=0.0004)
- 58% for SOTYKTU (n=511) vs 38% for apremilast (n=254) at Week 24 (*P*<0.0001)

Superior response rates vs placebo at Week 16 (co-primary endpoints)[1-3]

PASI 75

- 58% for SOTYKTU (n=330) vs 13% for placebo (n=166) in PSO-1 (*P*<0.0001)
- 53% for SOTYKTU (n=511) vs 9% for placebo (n=255) in PSO-2 (*P*<0.0001)

sPGA 0/1

- 54% for SOTYKTU (n=330) vs 7% for placebo (n=166) in PSO-1 (*P*<0.0001)
- 50% for SOTYKTU (n=511) vs 9% for placebo (n=255) in PSO-2 (*P*<0.0001)

Superior PASI 90 response rates vs apremilast in PSO-2 (secondary endpoints)[1,3]

- 27% for SOTYKTU (n=511) vs 18% for apremilast (n=254) at Week 16 (*P*=0.0046)
- 32% for SOTYKTU (n=511) vs 20% for apremilast (n=254) at Week 24 (*P*=0.0002)

Please click here to see POETYK PSO-1 and PSO-2 study designs.

*P<0.0001 vs apremilast.[2]
†Comparison between SOTYKTU and apremilast was a secondary endpoint.[1]
‡P=0.0002 vs apremilast.[2]
NRI=non-responder imputation; PASI=Psoriasis Area and Severity Index; PASI 75=≥75% reduction from baseline PASI; PASI 90=≥90% reduction from baseline PASI; sPGA 0/1=static Physician's Global Assessment, patients achieving clear (0) or almost clear (1) skin.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions such as angioedema have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue SOTYKTU.

Palmoplantar response rates[4,5]

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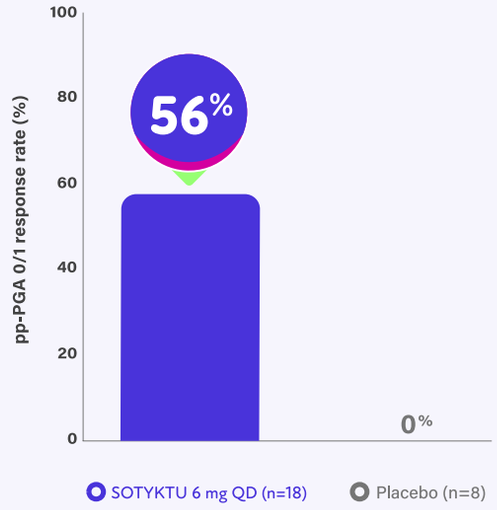
"Because of my job, I would prefer a treatment that I don't need to apply to my hands."

IN POETYK PSO-1

pp-PGA 0/1 (CLEAR OR ALMOST CLEAR) RESPONSE RATES AT WEEK 16 (ADDITIONAL ENDPOINT)[4*†]



Additional endpoint

- In PSO-2, the pp-PGA 0/1 response rates were 46% for SOTYKTU (n=39) and 24% for placebo (n=17)[5*†]
- pp-PGA 0/1 for SOTYKTU and placebo at Week 16 was not a ranked primary or secondary endpoint and was analyzed descriptively[6]

*Included patients with a baseline PGA-F score of ≥3.6.[4]
†**Analysis limited by small sample size.**[5]

pp-PGA=palmoplantar Physician's Global Assessment; pp-PGA 0/1=score of 0 (clear) or 1 (almost clear); QD=once daily.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Infections: SOTYKTU may increase the risk of infections. Serious infections have been reported in patients with psoriasis who received SOTYKTU. The most common serious infections reported with SOTYKTU included pneumonia and COVID-19. Avoid use of SOTYKTU in patients with an active or serious infection. Consider the risks and benefits of treatment prior to initiating SOTYKTU in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis
- with a history of a serious or an opportunistic infection
- with underlying conditions that may predispose them to infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment. A patient who develops a new infection during treatment should undergo prompt and complete diagnostic testing, have appropriate antimicrobial therapy initiated and be closely monitored. Interrupt SOTYKTU if a patient develops a serious infection. Do not resume SOTYKTU until the infection resolves or is adequately treated.

Mean PASI percentage improvement from baseline[7,8,9]

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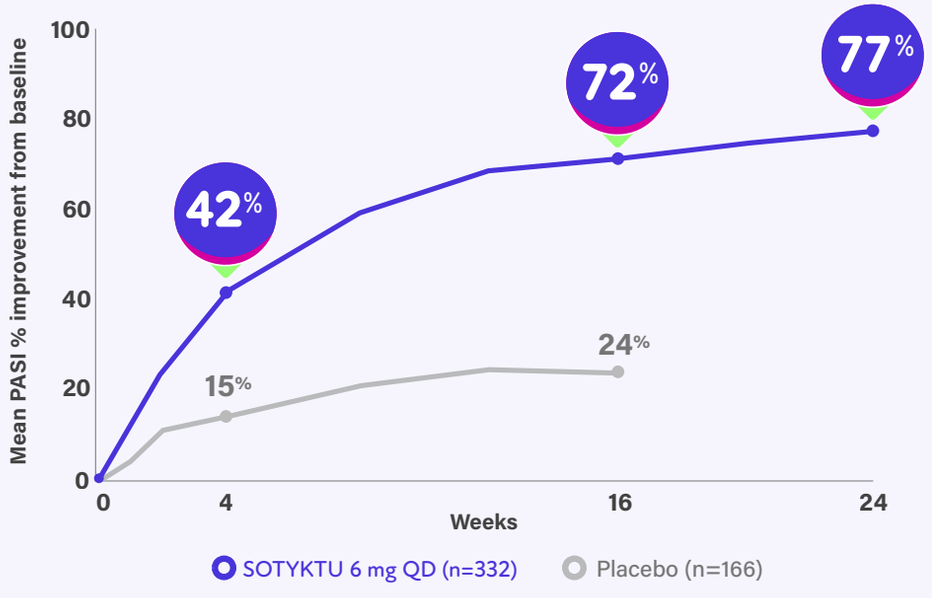
PSO-1: MEAN PASI % IMPROVEMENT FROM BASELINE (mBOCF) (ADDITIONAL ENDPOINTS)[7,8*]



Graph has been inverted from its original presentation.[7]

- Mean percentage improvement from baseline PASI was not a ranked primary or secondary endpoint and was analyzed descriptively[6]
- In POETYK PSO-2, mean PASI percentage improvement from baseline (mBOCF) was 40% at Week 4, 69% at Week 16, and 71% at Week 24† for SOTYKTU (n=511) and was 20% at Week 4 and 22% at Week 16 for placebo (n=255)[9]

*Analysis includes 2 patients in the SOTYKTU arm who were excluded from primary and secondary endpoint analyses.[1]

†At Week 24, post-hoc analysis not predefined in the protocol.

mBOCF=modified baseline observation carried forward.

How would you tell your patients about SOTYKTU?

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Infections (cont.)

Viral Reactivation

Herpes virus reactivation (e.g., herpes zoster, herpes simplex) was reported in clinical trials with SOTYKTU. Through Week 16, herpes simplex infections were reported in 17 patients (6.8 per 100 patient-years) treated with SOTYKTU, and 1 patient (0.8 per 100 patient-years) treated with placebo. Multidermatomal herpes zoster was reported in an immunocompetent patient. During PSO-1, PSO-2, and the open-label extension trial, the majority of patients who reported events of herpes zoster while receiving SOTYKTU were under 50 years of age. The impact of SOTYKTU on chronic viral hepatitis reactivation is unknown. Consider viral hepatitis screening and monitoring for reactivation in accordance with clinical guidelines before starting and during therapy with SOTYKTU. If signs of reactivation occur, consult a hepatitis specialist. SOTYKTU is not recommended for use in patients with active hepatitis B or hepatitis C.

Demonstrated safety profile through Week 16[1]

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ARs THAT OCCURRED IN ≥1% OF PATIENTS TREATED WITH SOTYKTU, AND MORE FREQUENTLY THAN IN PATIENTS TREATED WITH PLACEBO, THROUGH WEEK 16 FROM PSO-1 AND PSO-2[1]

AR, (%) Category	SOTYKTU n=840	Placebo n=419
Upper respiratory infections*	**19.2%**	14.8%
Blood CPK increased	**2.7%**	1.2%
Herpes simplex†	**2.0%**	0.2%
Mouth ulcers‡	**1.9%**	0.0%
Folliculitis	**1.7%**	0.0%
Acne§	**1.4%**	0.2%

- Adverse reactions that occurred in <1% of patients in the SOTYKTU group were herpes zoster[1]
- Serious infections through Week 16 were reported in 5 patients (2.0/100 PY) treated with SOTYKTU, and 2 patients (1.6/100 PY) treated with placebo[1]
- Malignancies (excluding non-melanoma skin cancer) through Week 52 (total exposure of 986 PY with SOTYKTU) were reported in 3 patients treated with SOTYKTU (0.3/100 PY)[1]
- During clinical trials, including an open-label extension trial, 3 SOTYKTU patients (0.1/100 PY) developed lymphoma[1]

*Includes upper respiratory tract infection (viral, bacterial, and unspecified), nasopharyngitis, pharyngitis (including viral, streptococcal, and unspecified), sinusitis (includes acute, viral, bacterial), rhinitis, rhinotracheitis, tracheitis, laryngitis, and tonsillitis (including bacterial and streptococcal).[1]
†Includes oral herpes, genital herpes, herpes simplex, and herpes virus infection.[1]
‡Includes mouth ulceration, aphthous ulcer, tongue ulceration, and stomatitis.[1]
§Includes acne, acne cystic, and dermatitis acneiform.[1]
AR=adverse reaction; CPK=creatine phosphokinase; PY=patient years.

Additional tolerability data[6]

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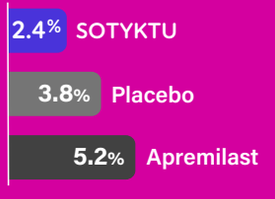
AEs OCCURRING IN ≥5% OF PATIENTS IN ANY ACTIVE TREATMENT GROUP WEEKS 0-16 FROM POOLED CLINICAL TRIALS (PSO-1 AND PSO-2)[6]

AE Category, (%)	SOTYKTU n=842*	Apremilast n=422	Placebo n=419
Nasopharyngitis	9.0%	8.8%	8.6%
URTI	5.5%	4.0%	4.1%
Headache	4.5%	10.7%	4.5%
Diarrhea	4.4%	11.8%	6.0%
Nausea	1.7%	10.0%	1.7%

DISCONTINUATION RATES DUE TO AEs AT WEEK 16[6]



Studies were not designed to compare the safety of apremilast to SOTYKTU. Some of the observed safety rates for apremilast may differ from those previously reported. Please refer to the apremilast Full Prescribing Information.

*Includes 2 patients in SOTYKTU arm that were excluded from primary and secondary endpoint analyses.[1]
AE=adverse event; URTI=upper respiratory tract infection.

THREE REASONS TO CHOOSE SOTYKTU

for your patients with moderate plaque psoriasis

1. ONCE-DAILY PILL[1]
2. UP TO 2X EFFICACY VS APREMILAST[1-3*]
3. SAFETY DATA AVAILABLE THROUGH 3 YEARS WITH ~3300 PATIENT YEARS[1,11,12†]

Patient portrayal.

*Comparisons between SOTYKTU and apremilast were secondary endpoints. In POETYK PSO-1 at Week 24, 42% of SOTYKTU patients (n=330) achieved PASI 90 vs 22% of apremilast patients (n=168); *P*<0.0001. At Week 16, 36% of SOTYKTU patients (n=330) achieved PASI 90 vs 20% of apremilast patients (n=168); *P*=0.0002. In POETYK PSO-2, PASI 90 response rates at Week 24 were 32% for SOTYKTU (n=511) and 20% for apremilast (n=254); *P*=0.0002. At Week 16, 27% of SOTYKTU patients (n=511) achieved PASI 90 vs 18% of apremilast patients (n=254): *P*=0.0046. POETYK PSO-1 (N=664) and POETYK PSO-2 (N=1020) were two, 52-week, multicenter, randomized, double-blind, placebo- and active (apremilast 30 mg twice daily)-controlled, Phase 3 studies to evaluate the safety and efficacy of SOTYKTU (6 mg once daily) in adult patients with moderate-to-severe plaque psoriasis.[1-3] Please click here to see additional study design descriptions.[1]

†Patients had varying lengths of treatment exposure.[11]

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Tuberculosis (TB): In clinical trials, of 4 patients with latent TB who were treated with SOTYKTU and received appropriate TB prophylaxis, no patients developed active TB (during the mean follow-up of 34 weeks). One patient, who did not have latent TB, developed active TB after receiving 54 weeks of SOTYKTU. Evaluate patients for latent and active TB infection prior to initiating treatment with SOTYKTU. Do not administer SOTYKTU to patients with active TB. Initiate treatment of latent TB prior to administering SOTYKTU. Consider anti-TB therapy prior to initiation of SOTYKTU in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during treatment.

Malignancy including Lymphomas: Malignancies, including lymphomas, were observed in clinical trials with SOTYKTU. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with SOTYKTU, particularly in patients with a known malignancy (other than a successfully treated non-melanoma skin cancer) and patients who develop a malignancy when on treatment with SOTYKTU.

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To learn more visit SOTYKTUHCP.COM

Please see additional Important Safety Information throughout and the U.S. Full Prescribing Information, including Medication Guide for SOTYKTU.

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POETYK PSO-1 and POETYK PSO-2 STUDY DESIGNS

POETYK PSO-1 (N=664) and POETYK PSO-2 (N=1020) were two, 52-week, multicenter, randomized, double-blind, placebo- and active (apremilast 30 mg twice daily)-controlled, Phase 3 studies to evaluate the safety and efficacy of SOTYKTU (6 mg once daily) in adult patients with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Patients had a body surface area (BSA) involvement of ≥10%, a PASI score ≥12, and a sPGA ≥3 (moderate or severe). Both studies assessed the responses at Week 16 compared with placebo for the 2 co-primary endpoints[1]:

- The proportion of patients who achieved an sPGA score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline
- The proportion of patients who achieved at least a 75% improvement in PASI scores from baseline (PASI 75)

Comparisons between SOTYKTU and apremilast were made for multiple ranked secondary endpoints, including[1]:

- The proportion of patients who achieved PASI 75 and PASI 90 at Week 16 and Week 24 vs apremilast
- The proportion of patients who achieved ss-PGA 0/1 at Week 16 vs apremilast

Statistical significance was not met for the following secondary endpoints[13,14]:

- The PGA-F 0/1 (score of clear or minimal disease) vs placebo (BL ≥3) at Week 16, PSSD symptom score of 0 vs apremilast (BL ≥1) at Week 16

STUDY RESULTS

Co-primary endpoints: percentage of patients achieving PASI 75 at Week 16 vs placebo and percentage of patients achieving sPGA 0/1 vs placebo at Week 16. The results were achieved for PASI 75 (POETYK PSO-1: 58% vs 13%; POETYK PSO-2: 53% vs 9%) and sPGA 0/1 (POETYK PSO-1: 54% vs 7%; POETYK PSO-2: 50% vs 9%).[1] Statistical significance was achieved for secondary endpoint PASI 75 vs apremilast at Week 16 (POETYK PSO-1: 58% vs 35%; POETYK PSO-2: 53% vs 40%).[1,15,16]

BL=baseline; PASI=Psoriasis Area and Severity Index; PASI 75=≥75% reduction from baseline in PASI; PASI 90=≥90% reduction from baseline in PASI; PGA-F=Physician's Global Assessment of Fingernail; PSSD=Psoriasis Symptoms and Signs Diary; sPGA 0/1=static Physician's Global Assessment, patients achieving clear (0) or almost clear (1) skin; ss-PGA 0/1=scalp severity Physician's Global Assessment, patients achieving clear (0) or almost clear (1) skin.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Rhabdomyolysis and Elevated CPK: Treatment with SOTYKTU was associated with an increased incidence of asymptomatic creatine phosphokinase (CPK) elevation and rhabdomyolysis compared to placebo. Discontinue SOTYKTU if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Instruct patients to promptly report unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Laboratory Abnormalities: Treatment with SOTYKTU was associated with increases in triglyceride levels. Periodically evaluate serum triglycerides according to clinical guidelines during treatment. SOTYKTU treatment was associated with an increase in the incidence of liver enzyme elevation compared to placebo. Evaluate liver enzymes at baseline and thereafter in patients with known or suspected liver disease according to routine management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt SOTYKTU until a diagnosis of liver injury is excluded.

Immunizations: Prior to initiating therapy with SOTYKTU, consider completion of all age-appropriate immunizations according to current immunization guidelines including prophylactic herpes zoster vaccination. Avoid use of live vaccines in patients treated with SOTYKTU. The response to live or non-live vaccines has not been evaluated.

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IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Potential Risks Related to JAK Inhibition: It is not known whether tyrosine kinase 2 (TYK2) inhibition may be associated with the observed or potential adverse reactions of Janus Kinase (JAK) inhibition. In a large, randomized, postmarketing safety trial of a JAK inhibitor in rheumatoid arthritis (RA), patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of all-cause mortality, including sudden cardiovascular death, major adverse cardiovascular events, overall thrombosis, deep venous thrombosis, pulmonary embolism, and malignancies (excluding non-melanoma skin cancer) were observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. SOTYKTU is not approved for use in RA.

ADVERSE REACTIONS

Most common adverse reactions (≥1% of patients on SOTYKTU and more frequently than with placebo) include upper respiratory infections, blood creatine phosphokinase increased, herpes simplex, mouth ulcers, folliculitis and acne.

SPECIFIC POPULATIONS

Pregnancy: Available data from case reports on SOTYKTU use during pregnancy are insufficient to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Report pregnancies to the Bristol-Myers Squibb Company's Adverse Event reporting line at 1-800-721-5072.

Lactation: There are no data on the presence of SOTYKTU in human milk, the effects on the breastfed infant, or the effects on milk production. SOTYKTU is present in rat milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SOTYKTU and any potential adverse effects on the breastfed infant from SOTYKTU or from the underlying maternal condition.

Hepatic Impairment: SOTYKTU is not recommended for use in patients with severe hepatic impairment.

SOTYKTU is available in 6 mg tablets.

Please see U.S. Full Prescribing Information, including Medication Guide for SOTYKTU.

References: 1. SOTYKTU [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2022. **2.** Data on file. BMS-REF-DEU-0020. Princeton, NJ: Bristol-Myers Squibb Company; 2021. **3.** Data on file. BMS-REF-DEU-0021. Princeton, NJ: Bristol-Myers Squibb Company; 2021. **4.** Data on file. BMS-REF-DEU-0075. Princeton, NJ: Bristol-Myers Squibb Company; 2023. **5.** Data on file. BMS-REF-DEU-0076. Princeton, NJ: Bristol-Myers Squibb Company; 2023. **6.** Armstrong AW, et al. Oral presentation at: AAD 2021, session S033. September 29-October 2, 2021: Virtual Meeting. **7.** Warren RB, et al. Oral presentation at: EADV 30th Congress; September 29 to October 2, 2021: Virtual Meeting. **8.** Data on file. BMS-REF-DEU-0011. Princeton, NJ: Bristol-Myers Squibb Company; 2022. **9.** Data on file. BMS-REF-DEU-0012. Princeton, NJ: Bristol-Myers Squibb Company; 2022. **10.** Data on file. BMS-REF-DEU-0096. Princeton, NJ: Bristol-Myers Squibb Company; 2023. **11.** Armstrong AW, et al. Oral presentation at EADV 32nd Congress; October 11 to 14, 2023; Berlin, Germany. **12.** Warren RB, et al. Poster presented at: European Academy of Dermatology and Venereology Spring Symposium; May 12-14, 2022; Ljubljana, Slovenia. **13.** Armstrong AW, et al. *J Am Acad Dermatol*. 2023;88(1):29-39. **14.** Strober B, Thaçi D, Sofen H, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: Efficacy and safety results from the 52-week, randomized, double-blinded, phase 3 program for evaluation of TYK2 inhibitor psoriasis second trial. *J Am Acad Dermatol*. 2023;88(1):40-51. **15.** Data on file. BMS-REF-DEU-0020. Princeton, NJ: Bristol-Myers Squibb Company; 2022. **16.** Data on file. BMS-REF-DEU-0021. Princeton, NJ: Bristol-Myers Squibb Company; 2022.

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