BIMZELX® (bimekizumab-bkzx): A CONSISTENT SAFETY PROFILE WITH 4 YEARS OF DATA[2]

Bimzelx® (bimekizumab-bkzx)

The chronic nature of psoriasis requires persistent management, making long-term safety assessment of treatment a cornerstone for clinical decision-making. BIMZELX demonstrated a consistent safety profile over 4 years with low incidences of adverse events across the pooled analysis of short-term and long-term safety data.[2]

ROBUST SAFETY DATA ACROSS 5 PHASE 3/3B CLINICAL TRIALS[2]

	SHORT TERM (PHASE 3)* Weeks 0-16 % (n)		LONGER TERM (PHASE 3/3b)† Year 4 EAIR/100PY (95% CI)
	BIMZELX 320 MG (n=989)	PLACEBO (n=169)	BIMZELX ALL DOSES (n=2,186)
Candida infections	9.1% (90)	0%	10.4 (9.5, 11.3)
Oral candidiasis	7.6% (75)	0%	8.9 (8.1, 9.7)
Injection site reactions	2.7% (27)	1.2% (2)	1.7 (1.4, 2.0)
ALT or AST elevations			
>3x ULN	1.3% (13)	1.2% (2)	1.9 (1.6, 2.3)
>5x ULN‡	0.3% (3)	0%	0.5 (0.4, 0.7)
Malignancies (inc. NMSC)	0.4% (4)	0.6% (1)	0.9 (0.6, 1.1)
Serious infections	0.3% (3)	0%	1.3 (1.0, 1.6)
Adjudicated MACE	0.1% (1)	0%	0.6 (0.4, 0.8)
Adjudicated inflammatory bowel disease§	0.1% (1)	0%	0.2 (0.1, 0.3)
Adjudicated suicidal ideation and behavior	0%	0%	0.1 (0.1, 0.2)
Serious hypersensitivity reactions‖	0%	0%	0.1 (0.0, 0.2)

*Pooled short-term data from Weeks 0-16 of 3 Phase 3 trials (BE SURE, BE VIVID, and BE READY).[2]
†Longer-term data from 5 Phase 3/3b trials (Phase 3: BE SURE, BE VIVID, BE READY, and their OLE BE BRIGHT; Phase 3b: BE RADIANT). BE RADIANT ran for 3 years; therefore, the total pooled exposure only includes BE RADIANT data to Year 3 (cut-off May 6, 2022) in addition to BE BRIGHT data to Year 4 (cut-off Nov. 14, 2022).[2]
‡Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN.
§Includes any TEAE adjudicated as definite or probable IBD.[2] Long-term data included in the BIMZELX Prescribing Information includes seven cases of new onset IBD (including ulcerative colitis, Crohn's disease, and IBD-undetermined) in subjects exposed to BIMZELX (0.12 per 100 PY).[1]
‖No anaphylactic reactions associated with BIMZELX were reported.[2]

ALT=alanine aminotransferase. AST=aspartate aminotransferase. CI=confidence interval. EAIR=exposure-adjusted incidence rate. IBD=inflammatory bowel disease. MACE=major adverse cardiovascular event. NMSC=non-melanoma skin cancer. PY=patient-year. TEAE=treatment-emergent adverse event. ULN=upper limit of normal.

INDICATION

BIMZELX is a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

Suicidal Ideation and Behavior
BIMZELX® (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections
BIMZELX may increase the risk of infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities
Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase and bilirubin at baseline, periodically during treatment with BIMZELX and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease
Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations
Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

MOST COMMON ADVERSE REACTIONS
Most common adverse reactions (≥ 1%) are upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

References
1. BIMZELX [prescribing information]. Smyrna, GA: UCB, Inc. **2**. Data on file. UCB, Inc., Smyrna, GA.

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Please see full Prescribing Information at BIMZELXhcp.com.

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