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NCCN Guidelines Panel: Primary Cutaneous Lymphoma

NCCN Primary Cutaneous Lymphoma Panel: On behalf of Merck & Co., Inc., I respectfully request the NCCN Primary Cutaneous Lymphoma panel to review the enclosed information for KEYTRUDA, in reference to Mycosis Fungoides (MF) and Sézary Syndrome (SS).

Specific Changes: We respectfully request that the NCCN Primary Cutaneous Lymphoma panel to consider the inclusion of pembrolizumab as a treatment option for Mycosis Fungoides and Sézary Syndrome under category 2A recommendation.

FDA Clearance: KEYTRUDA (pembrolizumab) is not indicated for the treatment of patients with Mycosis Fungoides and Sézary Syndrome.

Rationale: Based on the clinically meaningful results, durable responses and unmet medical needs for these rare cancers, the totality of data in the phase 2 study published in *J Clin Oncol.* 2019 supports our request for category 2A recommendation for pembrolizumab.

The following resources are submitted to assist the committee with their review.

1. Khodadoust M, Rook A, Porcu P, et al. Pembrolizumab in Relapsed and Refractory Mycosis Fungoides and Sézary Syndrome: A Multicenter Phase II Study. *J Clin Oncol.* 2019: JCO1901056. doi: 10.1200/JCO.19.01056. [Epub ahead of print]
2. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.

Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,



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