#jamies privates 2# FDAapprovescemiplimab rwlc for adjuvanttreatmentof Libtayo cemiplimab rwlc Approvedin the U.S. as.

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Oct 8 2025 On October 8 2025 the Food andDrugAdministrationapprovedcemiplimab rwlc Libtayo Regeneron Pharmaceuticals Inc

for the adjuvanttreatmentof adults with cutaneous squamous cell carcinoma Oct 8 2025 TheFDAevaluatedLibtayounder Priority Review which is reserved for medicines that represent potentially significant improvements in efficacy or safety in thetreatmentof serious conditions

An additional regulatory application is also under review in the European Union with a decision expected by the first half of 2026 Oct 9 2025 FDA approval historyforLibtayo cemiplimab rwlc used totreatSquamous Cell Carcinoma Basal Cell Carcinoma Non Small Cell Lung Cancer

Supplied by Sanofi Oct 8 2025 The USFDAhasapprovedthe supplemental biologics license application sBLA forcemiplimab rwlc Libtayo as adjuvanttreatmentin adults with high risk cutaneous squamous cell carcinoma CSCC

1 The sBLAapprovalwas based on an extensive review of data from the pivotal phase 3 C POST study NCT03969004 which demonstrated a statistically significant and clinically meaningful improvement Oct 20 2025 Findings showedcemiplimabreduced the risk of disease recurrence or death by 68% compared with placebo

The Food andDrugAdministration FDA hasapprovedLibtayo cemiplimab rwlc for the adjuvanttreatmentof adult patients with cutaneous squamous cell carcinoma CSCC at high risk of recurrence after surgery and radiation Oct 8 2025 Cemiplimab sapprovalis supported by findings from the C POST clinical trial

TheFDAapprovedcemiplimab rwlc Libtayo Regeneron Pharmaceuticals for the adjuvanttreatmentof adults with cutaneous squamous cell carcinoma CSCC who are at a high risk of recurrence following surgery and radiation Learn aboutLIBTAYO cemiplimab rwlc in thetreatmentof advanced NSCLC BCC CSCC as an adjuvanttreatmentfor high risk CSCC

Review Important Safety Info Full Prescribing Information including Med Guide Oct 10 2025 On October 8 2025 Regeneron Pharmaceuticals announced that the U.S

Food andDrugAdministration FDA approvedLibtayo cemiplimab rwlc a PD 1 inhibitor as the first and only immunotherapy for adjuvanttreatmentof adult patients with cutaneous squamous cell carcinoma CSCC at high risk of recurrence following surgery and radiation

Thisapproval evaluated under Priority Review is Oct 28 2025 In a significant step forward for skin cancer management the U.S

Food andDrugAdministration FDA hasapprovedcemiplimab rwlc Libtayo as an

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