

Supplementary Table 1. Included Malignancy Site Groupings and Associated MedDRA Preferred Terms for the GEMINI LTS Study

Grouping	MedDRA preferred terms
Breast	Breast cancer
Central nervous system	Glioblastoma, spinal cord neoplasm
Gynecologic	Ovarian cancer
Liver	Hepatic neoplasm malignant
Lower gastrointestinal	Colon cancer, colon cancer metastatic, rectal cancer
Lymphoma	B-cell lymphoma
Metastases	Metastases to peritoneum
Mouth and throat	Tongue neoplasm
Multiple myeloma	Multiple myeloma
Prostate	Prostate cancer
Renal and bladder	Bladder neoplasm, renal cancer, renal cell carcinoma, renal neoplasm, transitional cell carcinoma
Respiratory	Lung neoplasm, lung neoplasm malignant
Soft tissue sarcomas	Leiomyosarcoma
Thyroid	Thyroid cancer, thyroid neoplasm

LTS, Long-Term Safety; MedDRA, Medical Dictionary for Regulatory Activities

Supplementary Table 2. Included Malignancy Site Groupings and Associated MedDRA Preferred Terms for the Post-Marketing Data

Grouping	MedDRA preferred terms
Bone	Bone cancer metastatic
Breast	Breast cancer, breast cancer female, breast cancer metastatic, breast cancer recurrent, breast neoplasm, intraductal proliferative breast lesion, lobular breast carcinoma in situ
Central nervous system	Brain neoplasm, malignant neoplasm of spinal cord, metastases to nervous system, spinal cord neoplasm
Ear, nose, and throat	Ear neoplasm, lip neoplasm malignant stage unspecified, mucoepidermoid carcinoma of salivary gland, salivary gland cancer recurrent, squamous cell carcinoma (jaw), squamous cell carcinoma of the tongue, throat cancer, tonsil cancer, tongue neoplasm malignant stage unspecified
Esophageal and gastric	Adenocarcinoma gastric, esophageal squamous cell carcinoma, gastric cancer, gastric cancer recurrent
Gallbladder, bile duct, and pancreatic	Adenocarcinoma of pancreas, bile duct cancer, cholangiocarcinoma, gallbladder cancer, pancreatic carcinoma, pancreatic carcinoma metastatic
Gynecologic	Endometrial cancer, ovarian germ cell teratoma, uterine cancer, vaginal cancer
Hematologic	Acute myeloid leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, leukemia, myelodysplastic syndrome, myelofibrosis, plasma cell myeloma
Liver	Hepatic cancer, hepatic cancer stage IV, hepatocellular carcinoma
Lower gastrointestinal	Anal squamous cell carcinoma, appendix cancer, colon adenocarcinoma, colon cancer, colon cancer metastatic, colon neoplasm, colorectal adenocarcinoma, colorectal cancer, gastrointestinal carcinoma, gastrointestinal neoplasm, intestinal adenocarcinoma, malignant polyp, metastatic squamous cell carcinoma, mucinous adenocarcinoma of appendix, neoplasm malignant, rectal adenocarcinoma, rectal

Grouping	MedDRA preferred terms
	cancer, rectal cancer metastatic, rectal neoplasm, small intestine adenocarcinoma, small intestine carcinoma metastatic, small intestine carcinoma stage IV
Lymphoma	B-cell small lymphocytic lymphoma, B-cell lymphoma, B-cell unclassifiable lymphoma high grade, Burkitt's lymphoma, central nervous system lymphoma, diffuse large B-cell lymphoma, EBV-associated lymphoma, GI lymphoma, hepatosplenic T-cell lymphoma, lymphoma, non-Hodgkin's lymphoma, post-transplant lymphoproliferative disorder, T-cell lymphoma stage IV
Neuroendocrine	Adrenal neoplasm, carcinoid tumor of the appendix (neuroendocrine), carcinoid tumor pulmonary (neuroendocrine), neoplasm of appendix (neuroendocrine), neuroendocrine carcinoma, neuroendocrine carcinoma of the skin
Prostate	Prostate cancer, prostate cancer stage IV
Renal and bladder	Bladder cancer, bladder neoplasm, bladder transitional cell carcinoma, metastatic renal cell carcinoma, renal cancer, renal cancer metastatic, renal cell carcinoma, renal neoplasm
Respiratory	Adenocarcinoma (lung), laryngeal neoplasm, lung cancer metastatic, lung carcinoma cell type unspecified recurrent, lung carcinoma cell type unspecified stage IV, lung neoplasm, lung neoplasm malignant, non-small cell lung cancer metastatic, pleural mesothelioma, small cell lung cancer, squamous cell carcinoma of lung
Skin (melanoma)	Malignant melanoma, superficial spreading melanoma stage unspecified
Skin (unspecified/other)	Kaposi's sarcoma, neoplasm, neoplasm malignant, neoplasm skin, recurrent cancer, skin cancer
Thyroid	Papillary thyroid cancer, parathyroid tumour, thyroid cancer, thyroid cancer metastatic

Grouping	MedDRA preferred terms
Unspecified malignant neoplasm	Adenocarcinoma, neoplasm malignant, recurrent cancer
Unspecified gastrointestinal neoplasm	Gastrointestinal neoplasm
EBV, Epstein–Barr virus; MedDRA, Medical Dictionary for Regulatory Activities	