

Supplementary Material S1. Search strategy, eligibility criteria, and products identified

S1.1 Record sets enumerated

Products for which a publicly accessible Center for Veterinary Biologics (CVB) record exists were identified primarily from records of the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) CVB. Products for which no public CVB record was located were identified from sponsor, regulatory-filing and secondary sources, as indicated for each entry in S1.4. Four record sets were enumerated, with the last search performed on 30 August 2026.

Record set	Content	Coverage enumerated
Veterinary Services Memoranda index	Complete index of CVB guidance documents (Nos. 800.50–800.301)	Full index
CVB Notices	Quarterly notices of licenses issued, reissued and terminated; product-specific licensing notices; historical license-transfer tables within issuance notices; and the appendix to Notice 17-08, which indexes retired notices by title	License-issuance notices posted from 2015 onward, through Notice 26-03, the most recent available on the final search date, covering licenses issued and terminated to 31 March 2026; product-specific notices, historical license-transfer tables and the Notice 17-08 index for each product identified, without date restriction
Veterinary biologics product summaries	Per-product <i>Summary of Studies Supporting USDA Product Licensure</i>	Retrieved individually by establishment and product code
Sponsor labeling and announcements	Product labels, availability announcements, regulatory filings	Corroborative use only

The issuance notices published in 2026 (Notices 26-01 and 26-03) record no further canine cancer immunotherapeutic biologic. The notice series cannot be enumerated indefinitely backwards. CVB Notice 17-08 sets a retention period of one year for quarterly issuance notices and for announcements of new conditional licenses, which is why notices of those kinds published in the earlier 2010s are no longer posted. Where a licensure event preceded the notices still available, it was recovered from later CVB documents that record it: the historical license-transfer tables in Notice 19-02 and the retired-notice index appended to Notice 17-08, as stated for each entry in S1.4. Korean provisions were obtained from the Korean Law Information Center (www.law.go.kr).

S1.2 Literature search

PubMed was searched for each product identified, combining the product name, its USDA true name, and the relevant tumor type, with reference-list snowballing from retrieved articles. No language or date restriction was applied. Last search 30 August 2026.

Product	Search string
Canine Melanoma Vaccine, DNA	(“Oncept” OR “Canine Melanoma Vaccine, DNA” OR “xenogeneic tyrosinase” OR “human tyrosinase DNA vaccine”) AND (dog OR dogs OR canine) AND (melanoma)
Canine Osteosarcoma Vaccine, Live <i>Listeria</i> Vector	(“AT-014” OR “ADXS31-164” OR “COV-LLV” OR “Listeria” AND “HER2”) AND (dog OR dogs OR canine) AND (osteosarcoma)
Gilvetmab	(“gilvetmab” OR “canine PD-1 monoclonal antibody” OR “anti-PD-1” AND caninized) AND (dog OR dogs OR canine) AND (melanoma OR “mast cell tumor” OR “mast cell tumour”)
Regulatory context	(“conditional license” OR “conditional licensure” OR “reasonable expectation of efficacy”) AND (veterinary OR “veterinary biologics”)

S1.3 Eligibility criteria

Definition. A product was treated as a canine cancer immunotherapeutic biologic if it holds or has held a United States Veterinary Biological Product License, is indicated for the treatment of neoplastic disease in dogs, and acts by an immunological mechanism.

Inclusion for detailed analysis. Licensure under 9 CFR 102.6; an indication for a solid tumor; and availability of the CVB record as a publicly accessible primary source.

Exclusion. Products indicated for hematopoietic malignancy; autologous therapeutic biologics, licensed under the pathway governed by Veterinary Services Memorandum 800.121 rather than under 9 CFR 102.6; autogenous biologics, which are not licensed as products; and chemically synthesized antineoplastic drugs, which fall under Food and Drug Administration Center for Veterinary Medicine jurisdiction.

S1.4 Products identified

Seven products met the definition. Three were analyzed in detail; four were excluded for the reasons given. The evidence source for each entry is stated.

Product	Code · Est.	Mechanis m	Indication	License history	Evidence source	Analyzed
Canine Melanoma Vaccine, DNA (ONCEPT)	9240.D 0 · 124	Xenogene ic human tyrosinase plasmid DNA	Oral melanoma, stage II–III, locoregiona l control achieved	Conditiona l 22 March 2007; regular February 2010; currently licensed	CVB Notice 07-03; CVB Notice 19- 02, which records code 9240.D0 as first licensed 03/22/2007; CVB product summaries (est. 298 and 124)	Yes

Product	Code · Est.	Mechanis m	Indication	License history	Evidence source	Analyzed
Canine Osteosarcoma Vaccine, Live <i>Listeria</i> Vector (AT- 014 / COV- LLV)	— · 419	Live attenuated <i>Listeria</i> expressin g chimeric HER2	Appendicul ar osteosarco ma, dogs ≥1 year	Conditiona l December 2017; discontin ed by sponsor January 2020	CVB Notice 17-16; peer- reviewed report of discontinuati on	Yes
Gilvetmab	9790.02 (formerl y 9790.00) · 165A	Caninized anti-PD-1 monoclon al antibody	Mast cell tumor I–III; melanoma II–III	Conditiona l between December 2022 and October 2023; currently conditional	CVB product summary; CVB quarterly issuance notices; sponsor announceme nt	Yes
Canine Lymphoma Vaccine, DNA	9241.D 0 · 124	Xenogene ic murine CD20 plasmid DNA	B-cell lymphoma in remission	First conditional ly licensed 16 September 2015; terminated first quarter 2022	CVB Notice 19-02, which records code 9241.D0 as first licensed 09/16/2015; Notice 17-08 index, which identifies Notice 15- 11, “Issuance of a	No — hematopoie tic

Product	Code Est.	Mechanism	Indication	License history	Evidence source	Analyzed
					Conditional License for Canine Lymphoma Vaccine, DNA”; CVB quarterly issuance notices for the termination	
Anti-CD20 monoclonal antibody (AT-004)	—	Monoclonal antibody, CD20	B-cell lymphoma	Reported regular license January 2015	Sponsor regulatory filings; Notice 17-08 index records notices 12-23 and 14-03, “Issuance of a Conditional License for Canine Lymphoma Monoclonal Antibody,” which do not identify the	No — hematopoietic

Product	Code Est.	Mechanism	Indication	License history	Evidence source	Analyzed
					target antigen	
Anti-CD52 monoclonal antibody (AT-005)	—	Monoclonal antibody, CD52	T-cell lymphoma	Reported conditional license January 2014	Sponsor regulatory filings; Notice 17-08 index as above	No — hematopoietic
Autologous cellular immunotherapy	—	Autologous tumor vaccine with activated autologous T cells	Osteosarcoma	Reported Autologous Prescriptions Product license	Sponsor announcement; published review (VSM 800.121)	No — separate licensure pathway

For the three products analyzed and for the canine lymphoma vaccine, a CVB record is available as a primary source. For the two monoclonal antibodies, USDA records confirm that conditional licenses were issued for a canine lymphoma monoclonal antibody but do not identify the target antigen, so the product identity and licensure dates rest on sponsor sources. For the autologous cellular immunotherapy, identification rests wholly on secondary sources. No argument in the review depends on the excluded products.

S1.5 CVB guidance applicable to this product class

Identified by enumerating the complete Veterinary Services Memoranda index.

Memorandum	Title	Issue date	Relevance
800.126	Efficacy and Safety Studies for Cancer Immunotherapeutics	2 September 2020	Product-class specific; study design, licensure

Memorandum	Title	Issue date	Relevance
			pathway, re-evaluation intervals
800.75	Reissuance of Product Licenses for Products Under Conditional Licenses	14 July 2022	Section 5 addresses conditional licenses for cancer immunotherapies
800.121	Autologous Therapeutic Biologics	21 June 2017	Governs the pathway used by one excluded product
800.125	Preparation and Submission of Adverse Event Reports by Licensees and Permittees	17 August 2020	Post-licensure adverse event reporting
800.202	General Licensing Considerations: Efficacy Studies	26 October 2016	Baseline efficacy study guidance
800.204	General Licensing Considerations: Field Safety Studies	25 January 2018	Field safety studies
800.207	General Licensing Considerations: Target Animal Safety Studies	6 July 2010	Target animal safety
800.200	General Licensing Considerations: Study Practices and Documentation	12 June 2014	Study conduct
800.301	Good Clinical Practices	26 July 2001	Clinical study conduct
800.54	Guidelines for the Preparation and Review of Labeling Materials	17 September 2018	Conditional-license label statements
800.57	Market Suspensions and Post Marketing Temperature Deviations	11 June 2018	Post-marketing market suspension

Memorandum	Title	Issue date	Relevance
800.69, 800.103	Guidelines for Autogenous Biologics; Reissuance of Product Licenses for Autogenous Products	22 November 2021; 18 July 2018	Define autogenous products, excluded from this review