Coarse Fraction RT and/or ONCEPT™ Melanoma Vaccine for Canine Oral Melanoma

Please attach all relevant cytology, histology, imaging and necropsy reports

Submitting Institution: ____________________________________ **Date of submission:** ________________________

Institution contact information: ____

Patient information

Patient I.D.: ____ **Breed:** ______________________________________

Age at time of treatment (yrs): ______ **Weight at beginning of treatment (kg):** ______ **Sex:** M MN F FS

Primary Tumor Description

Tumor location: ____ Rostral to 4th premolar / Caudal to 4th premolar

Lip: yes / no **Tongue:** yes / no **Ulcerated:** yes / no **Photo:** yes / no

Longest tumor dimension (cm) at beginning of treatment: ___________ / not applicable (microscopic disease)

Is this a recurrent tumor: yes / no

Date of tumor diagnosis: Histology _______________ Cytology ________________

Mitotic index if available (/10 hpf or specify if evaluated otherwise): _______________

History

Other relevant medical conditions at time of treatment: ____

____

____

____

Primary Tumor Imaging

Primary tumor imaging: None / Radiography / CT / MRI

Date of imaging: ________________________ (check if w/in 2 weeks of beginning RT and/or vaccine ☐)

Bony lysis: yes / no / not evaluated

Images available for review: yes / no

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Tumor Staging At Onset of Treatment

Right mandibular LN: **Palpation:** normal / abnormal **Date:** __________________

Size (long axis X short axis, cm): _________________

Cytology: yes / no **Date:** __________________

Histology: yes / no **Date:** __________________

Metastasis: yes / no / suspected but not confirmed

Extirpated: yes / no **Date:** __________________

Left mandibular LN: **Palpation:** normal / abnormal **Date:** __________________

Size (long axis X short axis, cm): _________________

Cytology: yes / no **Date:** __________________

Histology: yes / no **Date:** __________________

Metastasis: yes / no / suspected but not confirmed

Extirpated: yes / no **Date:** __________________

Tonsils: **Appearance:** normal / abnormal **Date:** __________________

Cytology: yes / no **Date:** __________________

Histology: yes / no **Date:** __________________

Metastasis: yes / no / suspected but not confirmed

Extirpated: yes / no **Date:** __________________

Right retropharyngeal LN: **Imaged:** yes / no CT / MRI **Date:** __________________

If imaged:

Appearance: normal / abnormal

Size (long axis X short axis, cm): _________________

Cytology: yes / no **Date:** __________________

Histology: yes / no **Date:** __________________

Metastasis: yes / no / suspected but not confirmed

Extirpated: yes / no **Date:** __________________

Left retropharyngeal LN: **Imaged:** yes / no CT / MRI **Date:** __________________

If imaged:

Appearance: normal / abnormal

Size (long axis X short axis, cm): _________________

Cytology: yes / no **Date:** __________________

Histology: yes / no **Date:** __________________

Metastasis: yes / no / suspected but not confirmed

Extirpated: yes / no **Date:** __________________

Thoracic radiographs: **Distant metastasis:** yes / no **Date:** __________________

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Surgery for primary tumor

Primary tumor surgically excised prior to RT and/or vaccine: yes / no

If not surgically excised, is the tumor considered excisable?: yes / no

Date of surgery: ________________________________

Margins of excision: complete / incomplete / not reported

If complete excision, histologic margin measurement (mm): __________________ / not reported

Clinical stage at initiation of RT and/or vaccine

Disease setting at time of treatment: macroscopic / microscopic

If macroscopic disease is present, specify at which site(s): primary tumor / lymph node

First-line treatment

Treatment protocol used: Concurrent radiotherapy and vaccine ☐ Radiotherapy only ☐ Vaccine only ☐

Radiation prescription and treatment planning (<u>if RT not used, continue to next section</u>)

Fractionation prescription: **8 Gy X 4 weekly fractions:** yes / no

If no, specify protocol: ____

RT treatment plan: manual / computer

If computer plan: 2D / 3D / IMRT

Beam type and energy: Co-60 / 4 MeV photons / 6 MeV photons / 10 MeV photons / electrons (___ MeV)

Lymph nodes: **Right mandibular LN irradiated:** yes / no / unknown

Same field as 1° tumor / Separate field

Same target dose as 1° tumor / Alternate dose: ___________

Left mandibular LN irradiated: yes / no / unknown

Same field as 1° tumor / Separate field

Same target dose as 1° tumor / Alternate dose: ___________

Tonsils irradiated: yes / no / unknown

Same field as 1° tumor / Separate field

Same target dose as 1° tumor / Alternate dose: ___________

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Radiation prescription and treatment planning continued (<u>if RT not used, continue to next section</u>)

Right retropharyngeal LN irradiated: yes / no / unknown

Same field as 1° tumor / Separate field

Same target dose as 1° tumor / Alternate dose: ___________

Left retropharyngeal LN irradiated: yes / no / unknown

Same field as 1° tumor / Separate field

Same target dose as 1° tumor / Alternate dose: ___________

Number of treatment fields (i.e. if LN and 1° tumor treated in same field = 1; if LN and 1° tumor treated in 2 separate fields = 2)**:**

____

<u>For EACH treatment field:</u> *(for more than one field, please specify fields)*

How was the planning treatment volume (PTV) defined (for example, GTV (or incision) plus X cm of normal tissue margin)?**:**

____

____

Number of beams: ____

Beam arrangement: ____

Beam modifying devices (MLC, blocks, wedges, bolus etc.): ___________________________________

<u>If dosimetry data is available, specify the following for EACH treatment field</u>: *(for more than one field, please specify fields)*

Mean Dose in PTV: ____

Maximum Dose in PTV: ____

Minimum Dose in PTV: ____

Dose that covers 95% of PTV: ____

Percentage of PTV that received the prescribed dose: ____

Maximum Dose in treatment field: ____

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RT treatment dates (if RT not used, continue to next section)

RT fraction 1: ___________________________________

RT fraction 2: ___________________________________

RT fraction 3: ___________________________________

RT fraction 4: ___________________________________

Vaccination dates (if vaccine not used, continue to next section)

Vaccine no. 1: ____________________________________ **Vaccine no. 2:** ____________________________________

Vaccine no. 3: ____________________________________ **Vaccine no. 4:** ____________________________________

Booster no. 1: ____________________________________ **Booster no. 2:** ____________________________________

Booster no. 3: ____________________________________ **Booster no. 4:** ____________________________________

Protocol deviations

Please explain any deviations from the protocol schedule: ____

____

____

____

____

Medications

Concurrent medications during RT/vaccine: yes / no

If yes, list medications, date of prescription and reason for prescription:

____

____

____

____

____

____

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RT side effects (if RT not used, continue to next section)

Date	**List acute effects and VRTOG score for acute effects**	**List late effects and VRTOG score for late effects**	**Medication prescribed or other medical intervention**

(Use duplicate page or continue on back, if needed)

Vaccine complications (if vaccine not used, continue to next section)		
Date	**Description of complication related to vaccination**	**Medication prescribed or other medical intervention**

(Use duplicate page or continue on back, if needed)

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*Follow up summary (**list all visits**)*

THIS INFO WILL BE USED TO DETERMINE TIME TO TUMOR PROGRESSION

Date	**Tumor response*** **(CR/PR/SD/PD <u>or</u> NED <u>or</u> not reported)** Use criteria to describe each site separately		**Thoracic radiographs**	**Distant mets**	**Notes/Comments**
	1° tumor only	**LN only**			
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	

*** RECIST criteria for specified site based on the LONGEST dimension of the primary tumor and the SHORT AXIS of LNs**:
CR = disappearance of all detectable disease
PR = ≥30% decrease in disease measurement from baseline at specified site
PD = ≥20% increase in disease measurement at specified site, taking as reference the smallest measurement recorded at that site, or appearance of new lesions
SD = neither PR or PD criteria met
NED = no evidence of disease since beginning of treatment

(continue on next page, if needed)

*Follow up summary (**list all visits**) continued…*

THIS INFO WILL BE USED TO DETERMINE TIME TO TUMOR PROGRESSION

Date	**Tumor response*** **(CR/PR/SD/PD or NED or not reported)** Use criteria to describe each site separately		**Thoracic radiographs**	**Distant mets**	**Notes/Comments**
	1° tumor	**LN**			
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	
	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	CR ☐ PR ☐ SD ☐ PD ☐ NED ☐ Not reported ☐	Yes ☐ No ☐	Yes ☐ Lungs ☐ Other ☐ Specify:_______ No ☐	

* **RECIST criteria for specified site based on the LONGEST dimension of the primary tumor and the SHORT AXIS of LNs**:
CR = disappearance of all detectable disease
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PD = ≥20% increase in disease measurement at specified site, taking as reference the smallest measurement recorded at that site, or appearance of new lesions
SD = neither PR or PD criteria met
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(use duplicate page if needed for more entries)

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Other cancer therapies used after first-line protocol		
Date	**Other cancer therapy**	**Notes/comments**

(Use duplicate page or continue on back, if needed)

Survival data

Date of death: ___________________________________ Euthanasia / Unassisted death

Necropsy: yes / no

Death due to melanoma or treatment?:

yes / no / unknown

confirmed by necropsy / not confirmed by necropsy

Cause of death: ____
____
____

Please attach all relevant cytology, histology, imaging and necropsy reports

Please send completed data sheets:

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