### Sommaire d’études à l’appui de l’homologation du produit par l’USDA

<table>
<thead>
<tr>
<th>Nom d’établissement</th>
<th>Intervet Inc.</th>
</tr>
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<tbody>
<tr>
<td>Permis d'établissement de produits biologiques vétérinaires de l’USDA</td>
<td>165A</td>
</tr>
<tr>
<td>Code de produit</td>
<td>13D1.20</td>
</tr>
<tr>
<td>Nom attribué</td>
<td>Vaccin contre la maladie de Carré, l’adénovirus de type 2, le parainfluenza et le parvovirus canins, Virus vivants atténués</td>
</tr>
<tr>
<td>Noms commerciaux / Distributeur ou filiale (si différent du fabricant)</td>
<td>Merck Santé Animale Nobivac Canine 1-DAPPv – Merck Santé Animale Nobivac Canine DAPPv – Distributeur non-spécifié Quantum Dog DA2PPv – Distributeur non-spécifié</td>
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<tr>
<td>Date du Sommaire d’études</td>
<td>Le 14 mars 2019</td>
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</tbody>
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**Avertissement** : Ne pas utiliser les études qui suivent pour comparer un produit à un autre. Des légères différences dans la conception et l’exécution d’une étude peuvent rendre la comparaison dénuée de sens.
<table>
<thead>
<tr>
<th>Type d’étude</th>
<th>Efficacité</th>
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<tbody>
<tr>
<td>Étude portant sur</td>
<td>Adénovirus canin de type 2 (CAV-2)</td>
</tr>
<tr>
<td>Objectif de l’étude</td>
<td>Efficacité de la fraction CAV-1 du vaccin</td>
</tr>
<tr>
<td>Administration du produit</td>
<td>Deux doses ont été administrées par voie sous-cutanée à 21 jours d’écart.</td>
</tr>
<tr>
<td>Animaux expérimentaux</td>
<td>Chiens âgés de 7 à 8 semaines, séronégatifs à l’égard du CAV-1; 20 vaccinés, 5 témoins</td>
</tr>
<tr>
<td>Description de la provocation</td>
<td>Tous les chiens ont intentionnellement été infectés par le CAV-1 2 semaines après avoir reçu la deuxième dose de vaccin.</td>
</tr>
<tr>
<td>Intervalle observé après la provocation</td>
<td>Les chiens ont été examinés tous les jours à la recherche de signes cliniques, dont la fièvre, pendant les 14 jours qui ont suivi la provocation.</td>
</tr>
<tr>
<td>Résultats</td>
<td>Les températures rectales et les signes cliniques observés après la provocation sont compilés ci-dessous.</td>
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**Températures rectales et signes cliniques observés après la provocation :**

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<tr>
<th></th>
<th>Vaccinés</th>
<th>Témoins</th>
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<tbody>
<tr>
<td>Dépression modérée</td>
<td>0/20</td>
<td>4/5</td>
</tr>
<tr>
<td>Dépression grave</td>
<td>0/20</td>
<td>1/5</td>
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<tr>
<td>Hémorragie</td>
<td>0/20</td>
<td>4/5</td>
</tr>
<tr>
<td>Jaunisse</td>
<td>0/20</td>
<td>2/5</td>
</tr>
<tr>
<td>Fièvre (≥ 103,4 °F)</td>
<td>0/20</td>
<td>2/5</td>
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Voir les tableaux 1, 2, 3 et 4 pour prendre connaissance des données brutes.

Jour 0 est la date de la première vaccination
Jour 21 est la date de la deuxième vaccination
Jour 35 est la date de la provocation correspondant à deux semaines après la deuxième vaccination

| Date d’approbation par l’USDA | Le 1er avril 2010 |
Tableau 1. Titres obtenus à l’épreuve de séroneutralisation du virus CAV-1.

<table>
<thead>
<tr>
<th>Identifiant du chien</th>
<th>Groupe de traitement</th>
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<th>Jour 20 de l’étude</th>
<th>Jour 35 de l’étude</th>
<th>Jour 49 de l’étude</th>
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MGT = Moyenne géométrique des titres
S.O. = chien ne faisant plus partie de l’étude.
Afin de calculer la MGT, un titre supérieur à 4096 a été interprété comme étant 4096.
Tableau 2. Titres obtenus à l’épreuve de séroneutralisation du virus CAV-2.

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</tbody>
</table>

MGT = Moyenne géométrique des titres  
S.O. = chien ne faisant plus partie de l’étude.  
Afin de calculer la MGT, un titre supérieur à 4096 a été interprété comme étant 4096.
Tableau 3. Températures rectales après la provocation (°F)

<table>
<thead>
<tr>
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<th>J.É. 35*</th>
<th>J.É. 36</th>
<th>J.É. 37</th>
<th>J.É. 38</th>
<th>J.É. 39</th>
<th>J.É. 40</th>
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J.É. = Jour de l’étude
* Provocation

Les températures inscrites en caractères gras sont signe de fièvre (≥ 103,4 °F).
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J.É. = Jour de l’étude

* Provocation

Les températures inscrites en caractères **gras** sont signe de fièvre (**≥ 103,4 °F**).
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J.É. = Jour de l’étude; * Provocation
L1 = Dépression modérée; L2 = Dépression grave; H = Hémorragie; J = Jaunisse
Tableau 4. Observations cliniques après la provocation (suite)

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J.É. = Jour de l’étude; * Provocation  
L1 = Dépression modérée; L2 = Dépression grave; H = Hémorragie; J = Jaunisse
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<th>Type d’étude</th>
<th>Efficacité</th>
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<tbody>
<tr>
<td>Étude portant sur</td>
<td>Adénovirus canin de type 2</td>
</tr>
<tr>
<td>Objectif de l’étude</td>
<td>Démontrer l’efficacité du vaccin contre l’adénovirus canin de type 1 (hépatite) et l’adénovirus canin de type 2 (pneumopathie)</td>
</tr>
<tr>
<td>Administration du produit</td>
<td></td>
</tr>
<tr>
<td>Animaux expérimentaux</td>
<td>Chiens</td>
</tr>
<tr>
<td>Description de la provocation</td>
<td></td>
</tr>
<tr>
<td>Intervalle observé après la provocation</td>
<td></td>
</tr>
<tr>
<td>Résultats</td>
<td>Au terme de son évaluation des données issues de l’étude réalisée aux fins d’homologation du produit, l’USDA-APHIS a conclu que ce dernier satisfaisait aux normes réglementaires en vigueur au moment de la soumission de son dossier. Aucune donnée n’est publiée parce que cette étude a été soumise à l’USDA-APHIS avant le 1er janvier 2007 et que l’APHIS exige uniquement la publication des données soumises après cette date.</td>
</tr>
<tr>
<td>Date d’approbation par l’USDA</td>
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<td>Type d’étude</td>
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<td>Étude portant sur</td>
<td>Adénovirus canin de type 2 (CAV-2)</td>
</tr>
<tr>
<td>Objectif de l’étude</td>
<td>Démontrer que l’opacification de la cornée n’a aucun lien avec l’utilisation de ce vaccin.</td>
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</table>

**Administration du produit**

**Animaux expérimentaux**

**Description de la provocation**

**Intervalle observé après la provocation**

**Résultats**

Au terme de son évaluation des données issues de l’étude réalisée aux fins d’homologation du produit, l’USDA-APHIS a conclu que ce dernier satisfaisait aux normes réglementaires en vigueur au moment de la soumission de son dossier. Aucune donnée n’est publiée parce que cette étude a été soumise à l’USDA-APHIS avant le 1er janvier 2007 et que l’APHIS exige uniquement la publication des données soumises après cette date.

**Date d’approbation par l’USDA**

1980
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<th>Type d’étude</th>
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<td>Virus parainfluenza canin (CPIV)</td>
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<td>Objectif de l’étude</td>
<td>Démontrer l’efficacité du vaccin contre le virus parainfluenza canin</td>
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<tr>
<td>Administration du produit</td>
<td>Deux doses ont été administrées par voie sous-cutanée à 21 jours d’écart.</td>
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<td>Animaux expérimentaux</td>
<td>Chiens âgés de 8 semaines, séronégatifs à l’égard du CPIV; 20 vaccinés, 10 témoins</td>
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<tr>
<td>Description de la provocation</td>
<td>Tous les chiens ont intentionnellement été infectés par le CPIV 27 jours après avoir reçu la deuxième dose de vaccin.</td>
</tr>
<tr>
<td>Intervalle observé après la provocation</td>
<td>Les chiens ont été examinés tous les jours à la recherche de signes cliniques et leur température rectale a été prise pendant les 14 jours qui ont suivi la provocation. Des échantillons de sécrétions nasales ont été prélevés par écouvillonnage, aux fins de détection du CPIV, tous les jours pendant les 10 jours qui ont suivi la provocation.</td>
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<tr>
<td>Résultats</td>
<td><strong>Résultats sérologiques obtenus après la vaccination</strong></td>
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<td>(Voir les données brutes au tableau 1 ci-joint)</td>
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<tr>
<td></td>
<td><strong>Anticorps neutralisants dirigés contre le CPIV (positif si le titre ≥ 1:4)</strong></td>
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<tr>
<td></td>
<td>Vaccinés 19/20</td>
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<td>Témoins 0/10</td>
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<td>Tableau 2 est Températures corporelles. Les températures rectales ≥ 103,4 °F sont signe de fièvre.</td>
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<td><strong>Signes cliniques observés après la provocation</strong></td>
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<td>(Voir les données brutes au tableau 3 ci-joint)</td>
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<td><strong>Excréption du virus dans les sécrétions nasales après la provocation</strong></td>
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<td>(Voir les données brutes au tableau 4 ci-joint)</td>
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<td>Jour 0 est la date de la première vaccination</td>
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<td>Jour 21 est la date de la deuxième vaccination</td>
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<td>Jour 49 est la date de la provocation correspondant à 27 jours après la deuxième vaccination</td>
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<td>Date d’approbation par l’USDA</td>
<td>Le 14 janvier 2010</td>
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Tableau 1. Titres sériques d’anticorps neutralisants dirigés contre le CPIV

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</table>

S.O. : sans objet
MGT = Moyenne géométrique des titres
* Avant la provocation
** Le chien 0818004 a été retiré de l’étude parce que les chercheurs avaient seulement besoin de 20 des 21 chiens pour l’épreuve de provocation.
* Un résultat de 4 ou plus pour le titre sérique d’anticorps neutralisants dirigés contre le CPIV est considéré comme positif. Tous les témoins étaient séronégatifs avant la provocation.
Tableau 2. Températures corporelles (°F) suivant l’épreuve de provocation

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J.É. = Jour de l’étude  
* Provocation  
R = haut-le-coeur
Tableau 3. Observations cliniques après la provocation par le CPIV (suite)

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** 1 jour après la provocation
0 = aucun virus détecté
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<td>Démontrer l’efficacité du vaccin contre le virus de la maladie de Carré</td>
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<td>Administration du produit</td>
<td>Deux doses ont été administrées par voie sous-cutanée à 21 jours d’écart.</td>
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<td>Animaux expérimentaux</td>
<td>Vingt-cinq chiens âgés de 8 semaines, séronégatifs à l’égard du CDV; 20 vaccinés, 5 témoins</td>
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<td>Description de la provocation</td>
<td>Tous les chiens ont intentionnellement été infectés par le CDV 6 semaines après avoir reçu la deuxième dose de vaccin.</td>
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<td>Intervalle observé après la provocation</td>
<td>Les chiens ont été examinés à la recherche de signes cliniques tous les jours pendant les 21 jours qui ont suivi la provocation.</td>
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<td>Résultats</td>
<td>Le nombre de décès, les températures rectales et les signes cliniques observés après la provocation sont compilés ci-dessous; voir les tableaux 1 et 2 ci-joints pour prendre connaissance des données brutes.</td>
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**Décès après la provocation :**
Vaccinés : 0/20          Témoins : 5/5

**Températures rectales et signes cliniques observés après la provocation :**

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Jour 0 est la date de la première vaccination
Jour 21 est la date de la deuxième vaccination
Jour 63 est la date de la provocation correspondant à 6 semaines après la deuxième vaccination

| Date d’approbation par l’USDA     | Le 15 décembre 2009 |
Tableau 1. Titres obtenus à l’épreuve de séroneutralisation du virus CDV.

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| 0815105             | B                   | < 2              | < 2               | < 2              | S.O.              |
| 0815204             | B                   | < 2              | < 2               | < 2              | < 2               |
| 0815207             | B                   | < 2              | < 2               | < 2              | S.O.              |
| 0815401             | B                   | < 2              | < 2               | < 2              | S.O.              |
| 0815503             | B                   | < 2              | < 2               | < 2              | S.O.              |
| 0815504             | B                   | < 2              | < 2               | < 2              | < 2               |
| 0815602             | B                   | < 2              | < 2               | < 2              | < 2               |
| 0883302             | B                   | < 2              | < 2               | < 2              | S.O.              |
| 0883402             | B                   | < 2              | < 2               | < 2              | S.O.              |

MGT = Moyenne géométrique des titres  
S.O. = chien ne faisant plus partie de l’étude.  
Séronégativité = MGT < 2
Tableau 2. Observations cliniques après la provocation par le CDV

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J.É. = Jour de l’étude; * Provocation
T = tics neuromusculaires; S = crises épileptiques/convulsions; L1 = dépression modérée;
L2 = dépression grave; I = Inappétence; H = déshydratation; D = diarrhée; B = diarrhée sanglante;
V = vomissement.
* Dans le corpus de données brutes, les observations cliniques consignées pour le chien 0815602 ont été attribuées au chien 0815601 par erreur.
Tableau 2. Observations cliniques après la provocation par le CDV (suite)

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| 0815103 | L1, I, D, V | L1, I, H, D, V | L1, I, H | T, L2, I, H, D | Mort |
| 0815204 | B           | I            | D        | S         | Mort |
| 0815504 | Témoin      | L1, I, V     | -        | H         | S    | Mort |
| 0815602 | I           | L1, I, H, B  | T         | S, L1, I, H | Mort |
| 0883304 | I           | I, H, D      | H        | H         | L1, I, H, V |

J.É. = Jour de l’étude
T = tics neuromusculaires; S = crises épileptiques/convulsions; L1 = dépression modérée;
L2 = dépression grave; I = Inappétence; H = déshydratation; D = diarrhée; B = diarrhée sanglante;
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* Dans le corpus de données brutes, les observations cliniques consignées pour le chien 0815602 ont été attribuées au chien 0815601 par erreur.
Tableau 2. Observations cliniques après la provocation par le CDV (suite)

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0815204               | B                    | Mort    | Mort    | Mort    | Mort    | Mort    | Mort    |
0815504               | Témoins              | Mort    | Mort    | Mort    | Mort    | Mort    | Mort    |
0815602               | Mort                 | Mort    | Mort    | Mort    | Mort    | Mort    | Mort    |
0883304               | S, L2, I, H, D, V   | Mort    | Mort    | Mort    | Mort    | Mort    | Mort    |

J.É. = Jour de l’étude
S = crises épileptiques/convulsions; L2 = dépression grave; I = Inappétence; H = Déshydratation;
D = diarrhée; V = vomissement
Tableau 2. Observations cliniques après la provocation par le CDV (suite)

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J.É. = Jour de l’étude suivant l’épreuve de provocation
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D = diarrhée; V = vomissement
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J.É. = Jour de l’étude

* Provocation
Tableau 3. Températures rectales (°F) prises après la provocation par le CDV (suite)

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J.É. = Jour de l’étude  
* Provocation
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<th>Type d’étude</th>
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<td>Objectif de l’étude</td>
<td>Efficacité de la fraction CPV du vaccin</td>
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<td>Administration du produit</td>
<td>Deux doses ont été administrées par voie sous-cutanée à 21 jours d’écart.</td>
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<td>Animaux expérimentaux</td>
<td>Chiens âgés de 8 semaines, séronégatifs à l’égard du CPV; 20 vaccinés, 5 témoins</td>
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<tr>
<td>Description de la provocation</td>
<td>Tous les chiens ont intentionnellement été infectés par le CPV de type 2b 75 jours après avoir reçu la deuxième dose de vaccin.</td>
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<td>Intervalle observé après la provocation</td>
<td>Les chiens ont été examinés tous les jours à la recherche de signes cliniques et leur température rectale a été prise pendant les 14 jours qui ont suivi la provocation. Des échantillons de sang et de fèces ont été recueillis chez les chiens 10 jours après la provocation.</td>
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<th>Résultats d’Efficacité du CPV</th>
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<th>Lymphopénie</th>
<th>Signes cliniques de la maladie</th>
<th>Excrétion du virus dans les fèces</th>
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Le tableau 1 résume les critères définissant l’infection consécutive à la provocation. Voir les tableaux 2 à 5 pour prendre connaissance des données brutes relatives respectivement à la température rectale, à la mortalité et aux signes cliniques, à l’excrétion du virus et à la lymphopénie.

Jour 0 est la date de la première vaccination
Jour 21 est la date de la deuxième vaccination
Jour 96 est la date de la provocation correspondant à 75 jours après la deuxième vaccination

| Date d’approbation par l’USDA | Le 16 décembre 2009 |
Tableau 1. Critère définissant l’infection.

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<th>Signes cliniques de la maladie</th>
<th>Excrétion du virus dans les fèces</th>
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o = absent
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Tableau 2. Températures rectales (°F) prises après la provocation par le CPV

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J.É. = Jour de l’étude;
* La date de la provocation est le J.É. 96
Les températures rectales indiquées en caractères gras sont signe de fièvre (≥ 103,4 °F).
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J.É. = Jour de l’étude; La date de la provocation est le J.É. 96
Les températures rectales indiquées en caractères gras sont signe de fièvre (≥ 103,4 °F).
Tableau 3. Observations cliniques après la provocation par le CPV

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| 0882903              |                     | -      | -      | -       | -      | -      |
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J.É. = Jour de l’étude ; * La date de la provocation est le J.É. 96
V = Vomissement; M = Mucus ou sang dans les fèces; D = Diarrhée;
B = Diarrhée sanglante; H = Déshydratation; L1 = Dépression modérée;
L2 = Dépression grave; I = Inappétence
**Tableau 3. Observations cliniques après la provocation par le CPV (suite)**

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| 0815007              | Témoins             | Mort     | Mort     | Mort     | Mort     | Mort     | Mort     | Mort     |
| 0882903              |                     | Mort     | Mort     | Mort     | Mort     | Mort     | Mort     | Mort     |
| 0883002              |                     | Mort     | Mort     | Mort     | Mort     | Mort     | Mort     | Mort     |

J.É. = Jour de l’étude; * La date de la provocation est le J.É. 96
V = Vomissement; D = Diarrhée; B = Diarrhée sanglante; I = Inappétence
S.O. = sans objet (aucune observation consignée)
Tableau 4. Titres du CPV détectés par l’isolement du virus (UHA/1,0 mL)

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J.É. = Jour de l’étude
* La date de la provocation est le J.É. 96
Échantillons avec titre < 40 seront considérés comme virus négatifs et ceux de 40 ou plus seront considérés virus positifs
Tableau 4. Titres du CPV détectés par l’isolement du virus (UHA/1,0 mL) (suite)

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J.É. = Jour de l’étude;  
* La date de la provocation est le J.É. 96  
Échantillons avec titre < 40 seront considérés comme virus négatifs et ceux de 40 ou plus seront considérés virus positifs
Tableau 5.Nombre de lymphocytes après la provocation (x $10^3$ /µL)

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<td>5,8</td>
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<tr>
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</tr>
</tbody>
</table>

J.É. = Jour de l’étude
* La date de la provocation est le J.É. 96
Valeurs normales : de 1,3 à 4,1
Lymphopénie = réduction de 50 % ou plus par rapport au début de l’étude
Tableau 5. Nombre de lymphocytes après la provocation (x $10^3$/µL) (suite)

<table>
<thead>
<tr>
<th>Identifiant du chien</th>
<th>Groupe de traitement</th>
<th>J.É. 100</th>
<th>J.É. 101</th>
<th>J.É. 102</th>
<th>J.É. 103</th>
<th>J.É. 104</th>
<th>J.É. 105</th>
<th>J.É. 106</th>
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<td>7,9</td>
<td>7,3</td>
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<td>9,7</td>
<td>9,1</td>
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<td>5,5</td>
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<td>6,2</td>
</tr>
<tr>
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<td></td>
<td>5,3</td>
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<td>6,4</td>
<td>6,3</td>
<td>6,2</td>
<td>6,4</td>
</tr>
<tr>
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<td>6,4</td>
<td>7,1</td>
<td>6,5</td>
<td>6,9</td>
<td>6,6</td>
<td>6,8</td>
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<td>5,2</td>
<td>4,3</td>
<td>4,5</td>
<td>4,4</td>
<td>4,7</td>
<td>5,3</td>
</tr>
<tr>
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<td>4,5</td>
<td>3,9</td>
<td>3,9</td>
<td>4,4</td>
<td>3,7</td>
<td>4,8</td>
<td>3,7</td>
</tr>
<tr>
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<td></td>
<td>4,7</td>
<td>4,5</td>
<td>4,9</td>
<td>5,1</td>
<td>3,9</td>
<td>4,2</td>
<td>4,3</td>
</tr>
</tbody>
</table>

| 0814701              |                     | 3,6     | 1,4     | 2,5     | 2,3     | 5,0     | 5,6     | 5,3     |
| 0814903              |                     | 1,7     | 1,7     | 1,0     | Mort    | Mort    | Mort    | Mort    |
| 0815007              | Témoins             | 1,6     | 2,1     | 2,0     | Mort    | Mort    | Mort    | Mort    |
| 0882903              |                     | 2,4     | 1,5     | 1,8     | Mort    | Mort    | Mort    | Mort    |
| 0883002              |                     | 6,1     | 3,5     | 2,7     | Mort    | Mort    | Mort    | Mort    |

J.É. = Jour de l’étude
* La date de la provocation est le J.É. 96
Valeurs normales : de 1,3 à 4,1
Lymphopénie = réduction de 50 % ou plus par rapport au début de l’étude
<table>
<thead>
<tr>
<th>Type d’étude</th>
<th>Innocuité</th>
</tr>
</thead>
<tbody>
<tr>
<td>Étude portant sur</td>
<td>TOUS</td>
</tr>
<tr>
<td>Objectif de l’étude</td>
<td>Faire la preuve de l’innocuité du produit administré dans des conditions d’utilisation normales.</td>
</tr>
<tr>
<td>Administration du produit</td>
<td>2 doses administrées par voie sous-cutanée à 3 semaines d’écart</td>
</tr>
<tr>
<td>Animaux expérimentaux</td>
<td>346 chiens de 4 états; 116 avaient 8 semaines, soit l’âge minimal recommandé; les 230 autres avaient 9 semaines ou plus.</td>
</tr>
<tr>
<td>Description de la provocation</td>
<td>Sans objet</td>
</tr>
<tr>
<td>Intervalle observé après la provocation</td>
<td>Les cliniciens-chercheurs ont communiqué avec les propriétaires des chiens 14 jours après chaque vaccination pour vérifier l’état de santé de leur animal. De plus, tous les chiens ont été examinés à la clinique juste avant l’administration de la deuxième dose de vaccin. Pendant les 14 jours ayant suivi chaque vaccination, les chercheurs ont examiné les chiens élevés à des fins de recherche afin de déceler le moindre évènement indésirable ou la moindre réaction au point d’injection.</td>
</tr>
<tr>
<td>Résultats</td>
<td>Veuillez consulter le tableau 1 ci-joint pour prendre connaissance des évènements indésirables.</td>
</tr>
<tr>
<td>Date d’approbation par l’USDA</td>
<td>Le 14 juin 2017</td>
</tr>
</tbody>
</table>
Tableau 1 : Fréquence des événements indésirables

<table>
<thead>
<tr>
<th>Événements indésirables*</th>
<th>Âge min. (8 semaines)</th>
<th>Autres (9 semaines ou plus)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enflure au point d'injection (passagère, moins de 2,5 po de diamètre)#</td>
<td>0</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Moins de 1,0 po</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>De 1,0 à 1,5 po</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>De 1,5 à 2,5 po</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Douleur au point d’injection</td>
<td>0</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Anorexie</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Trouble anxieux</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Infection cutanée d'origine bactérienne</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Trouble du comportement, sans plus de précision</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Blépharite</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Insuffisance cardiaque</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dermatite et eczéma</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Diarrhée</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Otite, sans plus de précision</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Vomissement</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Épistaxis</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Douleur généralisée</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Réaction d’hypersensibilité</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Léthargie</td>
<td>1</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Troubles locomoteurs, sans plus de précision</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Masse palpable ailleurs qu’au point d’injection, sans plus de précision</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Prurit</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Troubles cutanés, sans plus de précision</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Éternuements</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Trouble général, sans plus de précision</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Aucun événement indésirable</td>
<td>114</td>
<td>192</td>
<td>306</td>
</tr>
</tbody>
</table>

* Comprennent les événements indésirables que le clinicien-chercheur a considérés comme liés au vaccin expérimental ou dont l’éventuel lien de cause à effet avec ce vaccin était inconnu.

# L’enflure au point d'injection s’est résorbée d'elle-même en 6 jours ou moins.
<table>
<thead>
<tr>
<th>Type d’étude</th>
<th>Innocuité</th>
</tr>
</thead>
<tbody>
<tr>
<td>Étude portant sur</td>
<td>TOUS</td>
</tr>
<tr>
<td>Objectif de l’étude</td>
<td>Prouver l’innocuité du vaccin sur le terrain</td>
</tr>
<tr>
<td>Administration du produit</td>
<td>Deux doses espacées de 19 à 28 jours, administrées par voie sous-cutanée</td>
</tr>
<tr>
<td>Animaux expérimentaux</td>
<td>L’étude a été menée dans quatre états, chez 609 chiens d’âge (de 7 semaines à 14 ans), de race et de sexe différents. Au moment de leur vaccination, 231 de ces chiens avaient 8 semaines ou moins; les 378 autres étaient plus âgés.</td>
</tr>
<tr>
<td>Description de la provocation</td>
<td>Sans objet</td>
</tr>
<tr>
<td>Intervalle observé après la provocation</td>
<td>Les chercheurs ont mis les chiens en observation immédiatement après leur vaccination afin de déceler le moindre événement indésirable. Les chiens appartenant à des clients ont été surveillés par ces derniers pendant 19 ± 8 jours après chaque vaccination. Les chiens élevés aux fins de recherche ont été observés pendant les 2 à 6 heures ayant suivi leur vaccination, puis une fois par jour pendant 14 jours.</td>
</tr>
<tr>
<td>Résultats</td>
<td>Fréquence des événements indésirables</td>
</tr>
<tr>
<td><strong>Nbre de chiens recrutés</strong></td>
<td><strong>Nbre de doses administrées</strong>*</td>
</tr>
<tr>
<td>609</td>
<td>1217**</td>
</tr>
</tbody>
</table>

* 2 doses par chien; ** Un chien n’a pas reçu la 2e dose.

Voir le tableau des événements indésirables à la page suivante.

| Date d’approbation par l’USDA | 15 mars 2010 |
Tableau des événements indésirables

<table>
<thead>
<tr>
<th>Description des événements indésirables</th>
<th>Nombre d’occurrences*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grattage de l’endroit où a été injecté le vaccin</td>
<td>8</td>
</tr>
<tr>
<td>Apathie et halètement</td>
<td>1</td>
</tr>
<tr>
<td>Petite bosse au point d’injection</td>
<td>5</td>
</tr>
<tr>
<td>Apathie</td>
<td>9</td>
</tr>
<tr>
<td>Petite bosse au point d’injection découverte le lendemain de la vaccination</td>
<td>3</td>
</tr>
<tr>
<td>Apathie et salivation</td>
<td>1</td>
</tr>
<tr>
<td>Sensibilité au point d’injection</td>
<td>2</td>
</tr>
<tr>
<td>Douleur et malaise</td>
<td>1</td>
</tr>
<tr>
<td>Apathie, tremblements et petite bosse au point d’injection</td>
<td>1</td>
</tr>
<tr>
<td>Apathie et sensibilité au point d’injection immédiatement après la vaccination</td>
<td>1</td>
</tr>
<tr>
<td>Grattage de l’endroit où a été injecté le vaccin et pleurs après la vaccination</td>
<td>2</td>
</tr>
<tr>
<td>Apathie, fièvre et vomissements le jour de la vaccination</td>
<td>1</td>
</tr>
<tr>
<td>Apathie et fièvre le jour de la vaccination</td>
<td>1</td>
</tr>
<tr>
<td>Œdème de Quincke modéré</td>
<td>1</td>
</tr>
</tbody>
</table>

* Certains chiens ont présenté plusieurs événements indésirables après avoir été vaccinés.

Tous les événements indésirables observés se sont résorbés sans traitement peu de temps après la vaccination (4 jours au maximum).