



# VACCINES LUMPY SKIN DISEASE

**Antoinette van Schalkwyk**

**Agricultural Research Council – Onderstepoort Veterinary Institute**

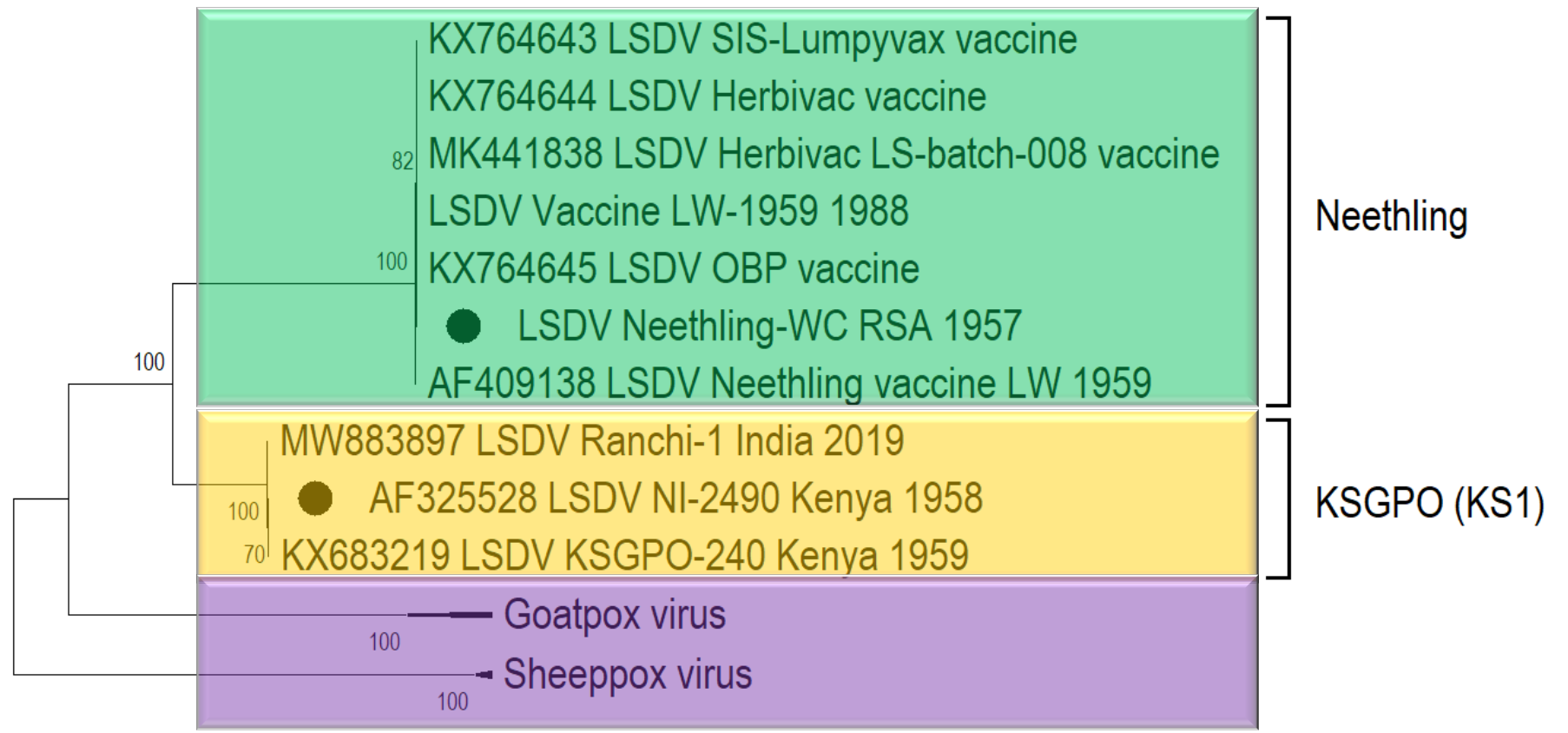
**NO DIVA**

**Homologous vaccines:**  
 Attenuated LSDV  
 (Neethling and KSGPO)

**Heterologous vaccines:**  
 Goatpox (Gorgan /  
 Uttarkashi)  
 Sheeppox (NISHKI)

Haegeman et al., 2023;  
 Hamdi et al., 2020;  
 Wolf et al., 2022

**DIVA**



Homologous inactivated vaccines: Safe, regular boosters; <1 year immunity

New vaccines: vector-, subunit, mRNA vaccines

# Lumpy skin disease: Available vaccines

Manufacturer	Product Name and Virus Strain	Target Species	Titre, Dose, Administration
Onderstepoort Biological Products (OBP) South Africa	Lumpy Skin Disease (LSD Neethling strain)	Vaccine for Cattle	$10^{3.5}$ TCID <sub>50</sub> /dose 2 ml SC
Intervet (Pty) South Africa/MSD Animal Health	Lumpyvax™ (LSD SIS Neethling strain)	Vaccine for Cattle	$10^{4.0}$ TCID <sub>50</sub> /dose 2 ml SC
MCI Santé Animale Morocco	Bovivax-LSD™ (LSD Kenya strain)	Vaccine for Cattle	$10^{3.5}$ TCID <sub>50</sub> /dose 2 ml SC
Jordan Bio-Industries Center (JOVAC) Jordan	LumpyShield-N™ (LSD Neethling strain)	Vaccine for Cattle	$10^{4.0}$ TCID <sub>50</sub> /dose 2 ml SC
Jordan Bio-Industries Center (JOVAC) Jordan	Caprivac™ (Gorgan GTP strain)	Vaccine for Cattle	
Middle East for Vaccines (MEVAC) Egypt	MEVAC LSD (LSD Neethling strain)	Vaccine for Cattle	$10^{3.5}$ TCID <sub>50</sub> /dose 2 ml SC
National Veterinary Institute (NVI) Ethiopia	Lumpy Skin Disease vaccine (LSD Neethling strain)	Vaccine for Cattle	$10^{3.0}$ TCID <sub>50</sub> /dose 2 ml SC
Kenya Veterinary Vaccines Production Institute (KEVEVAPI)	Lumpivax™ (LSD Neethling strain)	Vaccine for Cattle	Not known TCID <sub>50</sub> /dose 2 ml SC
Pendik Veterinary Control Institute/ Ministry of Agriculture, Turkey	Penpox-M™ Live SPPV (Bakirköy SPPV strain)	Vaccine for Cattle	$10^{2.5}$ TCID <sub>50</sub> /dose 2 ml SC
Vetal Company Turkey	Poxvac™ (Bakirköy SPPV strain)	Vaccine for Sheep and Cattle	$10^{2.5}$ TCID <sub>50</sub> /dose 2 ml SC
	Lumpyvac™ (LSD Neethling strain)	Vaccine for Cattle	$10^{3.5}$ TCID <sub>50</sub> /dose 2 ml SC
Dollvet Turkey	Poxdoll™ (Bakirköy SPPV strain)	Vaccine for Sheep, goats and Cattle	$10^{2.5}$ TCID <sub>50</sub> /dose 2 ml SC
	LSD-NDOLL (LSD Neethling strain)	Vaccine for Cattle	$10^{3.5}$ TCID <sub>50</sub> /dose 2 ml SC
FGBI-Federal Centre for Animal Health Russia	Sheep Pox Cultyral Dry™(Arriah (NISHKI) SPPV strain)	Vaccine for Sheep and Cattle	Not known TCID <sub>50</sub> /dose
ABIC, Israel	RM 65 Sheeppox (Yugoslavia RM65)	Vaccine for Sheep and Cattle	

Tuppurainen et al., 2021

# Lumpy skin disease: Vaccine testing (literature study by Pravesh Kara)

Breed Age Gender	Construct / Vaccine Dose Route & Volume	Number of animals	Fever (%)	Start of fever (Ave Days)	Inoculation site reaction (%)	>1 nodule (%)	Clinical reaction [other than fever] (%)	Shedding (PCR) (%)	Nodule (PCR) (%)	Viremia (PCR / VI) (%)	VNT 1 (%)	VNT 2 (%)	ELISA (%)	IPMA (%)	iFIT / IFAT (%)	Reference
Holstein - Friesen 6 months Male	LSD Neethling OBP [1.4x10 <sup>7</sup> TCID <sub>50</sub> ] SC Route: 2ml	5	0/5 (0%)	N/A	1/5 (20%)	0/5 (0%)	1/5 (20%)	Nd	0/1 (0%)	PCR 0/5 VI 0/5	0/5 (0%)	nd	nd	nd	nd	Kara et al., 2018
Holstein 6 months Male	LSD Neethling OBP [1x10 <sup>3.5</sup> TCID <sub>50</sub> ] SC Route: 2ml	7	6/7 (86%)	1 dpv (4.2 days)	0/7 (0%)	0/7 (0%)	0/7 (0%)	Nd	0/7 (0%)	0/7 (0%)	1/7 (14%)	3/7 (43%)	nd	7/7 (100%)	nd	Haegeman et al., 2021a
	LSD Neethling Lumpyvax [1x10 <sup>4</sup> TCID <sub>50</sub> ] SC Route	7	7/7 (100%)	1 dpv (10.3 days)	0/7 (0%)	0/7 (0%)	0/7 (0%)	Nd	0/7 (0%)	0/7 (0%)	1/7 (14%)	4/7 (57%)	nd	5/7 (72%)	nd	
	LSD Neethling HerbivacLS [1x10 <sup>2.5</sup> TCID <sub>50</sub> ] SC Route	7	4/7 (57%)	1 dpv (3 days)	0/7 (0%)	3/7 (43%)	3/7 (43%)	nd	3/7 (43%)	4/7 (57%)	3/7 (43%)	5/7 (71%)	nd	6/7 (86%)	nd	
	LSD Neethling (O variant) MCI [1x10 <sup>3</sup> TCID <sub>50</sub> ] SC Route	7	4/7 (57%)	1 dpv (3.8 days)	3/7 (43%)	2/7 (29%)	3/7 (43%)	nd	2/7 (29%)	2/7 (29%)	4/7 (57%)	3/7 (43%)	nd	7/7 (100%)	nd	
Holstein-cross 4-6 months	LSD KSGP Kenyavac [1x10 <sup>2.5</sup> TCID <sub>50</sub> ] SC Route	7	5/7 (71%)	1 dpv (6.8 days)	0/7 (0%)	0/7 (0%)	0/7 (0%)	nd	0/7 (0%)	0/7 (0%)	0/7 (0%)	2/7 (29%)	nd	5/7 (72%)	nd	Bamouh et al., 2021
	LSD Neethling (LSD_Nt) [1x10 <sup>4</sup> TCID <sub>50</sub> ] SC Route: 2ml	15	7/15 (47%)	2 dpv (2 days)	0/15 (0%)	1/15 (7%)	1/15 (7%)	1/15 (7%)	1/15 (7%)	nd	7/15 (47%)	nd	nd	nd	nd	
	LSD Neethling (LSD_Nt) [1x10 <sup>5</sup> TCID <sub>50</sub> ] SC Route: 2ml	30	13/30 (43%)	NI (4.3 days)	2/30 (7%)	2/30 (7%)	2/30 (7%)	2/30 (7%)	2/30 (7%)	nd	23/30 (73%)	nd	nd	nd	nd	
	LSD KSGP O-240 [1x10 <sup>4</sup> TCID <sub>50</sub> ] SC Route: 2ml	12	5/12 (42%)	NI (5.6 days)	0/12 (0%)	0/12 (0%)	0/12 (0%)	0/12 (0%)	0/12 (0%)	nd	12/12 (100%)	nd	nd	nd	nd	
Morocco (Zebu) 6-8 months	LSD KSGP O-240 [1x10 <sup>5</sup> TCID <sub>50</sub> ] SC Route: 2ml	12	9/12 (75%)	NI (3.8 days)	1/12 (8%)	3/12 (25%)	3/12 (25%)	3/12 (25%)	3/12 (25%)	nd	12/12 (100%)	nd	nd	nd	nd	Hamdi et al., 2020
	LSD Neethling OBP [1x10 <sup>4</sup> TCID <sub>50</sub> ] SC Route	15	1/15 (7%)	1 dpv (1 day only)	0/15 (0%)	0/15 (0%)	0/15 (0%)	0/15 (0%)	0/15 (0%)	nd	7/15 (47%)	nd	nd	nd	nd	
Holstein-Friesen 9-10 months	LSD Neethling (Nt_hd) [1x10 <sup>7</sup> TCID <sub>50</sub> ] IV Route: 3ml & SC Route: 1ml	6	0/6 (0%)	N/A	2/6 (33%)	0/6 (0%)	0/6 (0%)	2/6 (33%)	0/6 (0%)	4/6 (67%)	4/6 (67%)	nd	5/6 (83%)	nd	6/6 (100%)	Moller et al., 2019
Holstein-Friesen 4-6 months	LSD Neethling HerbivacLS [1x10 <sup>2.5</sup> TCID <sub>50</sub> ] SC Route: 2ml	6	3/6 (50%)	5-6 dpv. (4-6 days)	5/6 (83%)	0/6 (0%)	5/6 (83%)	0/6 (0%)	nd	4/6 (67%)	5/6 (83%)	nd	5/6 (83%)	nd	nd	Wolff et al., 2020
Borana (Zebu) 12-24 months	LSD Neethling (NVI, Ethiopia) [1x10 <sup>4.5</sup> TCID <sub>50</sub> ] SC Route	5	0/5 (0%)	N/A	0/5 (0%)	0/5 (0%)	0/5 (0%)	nd	nd	nd	nd	nd	nd	nd	0/5 (0%)	Gari et al., 2015
	LSD Neethling (NVI, Ethiopia) [1x10 <sup>3.5</sup> TCID <sub>50</sub> ] SC Route	5	0/5 (0%)	N/A	0/5 (0%)	0/5 (0%)	0/5 (0%)	nd	nd	nd	nd	nd	nd	nd	0/5 (0%)	
	LSD KSGP O-180 [1x10 <sup>4.5</sup> TCID <sub>50</sub> ] SC Route	5	0/5 (0%)	N/A	0/5 (0%)	0/5 (0%)	0/5 (0%)	nd	nd	nd	nd	nd	nd	nd	0/5 (0%)	
	LSD KSGP O-180 [1x10 <sup>3.5</sup> TCID <sub>50</sub> ] SC Route	5	0/5 (0%)	N/A	0/5 (0%)	0/5 (0%)	0/5 (0%)	nd	nd	nd	nd	nd	nd	nd	0/5 (0%)	
Dexter 11-16 months Male	LSD Neethling OBP [1x10 <sup>3.5</sup> TCID <sub>50</sub> ] SC Route: Vaccination 1	6	0/6 (0%)	N/A	0/6 (0%)	0/6 (0%)	0/6 (0%)	nd	nd	0/6 (0%)	0/6 (0%)	nd	nd	nd	nd	Osuagwuh et al., 2007
	LSD Neethling OBP [1x10 <sup>3.5</sup> TCID <sub>50</sub> ] SC Route: Repeat Vaccination 21 dpv	6	0/6 (0%)	N/A	0/6 (0%)	0/6 (0%)	0/6 (0%)	nd	nd	0/6 (0%)	4/6 (67%)	nd	nd	nd	nd	
Holstein 6 months Male	LSD Lumpivax (KEVEVAPI, Kenya) [Dose: NI] SC Route: 2ml	7	7/7 (100%)	NI	7/7 (100%)	2/7 (29%)	7/7 (100%)	nd	3/3 (100%)	1/7 (14%)	nd	nd	1/7 (14%)	7/7 (100%)	nd	Haegeman et al., 2021b
Breed: NI 6-9 months Male	LSD Lumpi-ProVac Ind [1x10 <sup>3.5</sup> TCID <sub>50</sub> ] Route: NI	8	3/8 (37.5%)	NI	0/8 (0%)	0/8 (0%)	Viremia 5/8 (62.5%) 3dpv only	0/8 (0%)	0/8 (0%)	PCR 5/8 (62.5%) 3dpv only	7/8 (87.5%)	nd	nd	nd	nd	Kumar et al., 2022

**Not all animals** naturally infected or vaccinated develop neutralizing antibodies against LSDV or they develop low levels of antibodies undetectable by current serological assays

# Lumpy skin disease: Outline of production of LSD vaccines

Part of dossier  
submitted to  
regulatory approval

- Production of vaccine:

- Quality
- Safety
- Efficacy

- Quality assurance:

- Manufactures – GLP and GMP
- Quality risk management plan – Quality control
- A complete outline of production

- Process validation:

- A complete outline of production
- Written record of process must be kept for each batch

Part of dossier  
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- Characteristics of the seed / cells
  - Identification of the master seed virus and quantity of virus
  - Quality: Sterility, purity and freedom from extraneous agents
- Historical record: geographical origin, animal species from which the virus was recovered, isolation procedure, tissue culture or animal passage history
- Identity: species and strain identification using DNA sequencing
- Purity: the absence of bacteria, fungi, mycoplasma, and other viruses (including other capripoxviruses)
- Safety (overdose, one /repeated dose tests, and reversion to virulence tests)
- Efficacy data, linked to a specified (protective) dose
- Stability

# Lumpy skin disease: Requirements for LSDV vaccine candidates and batch production

Part of dossier  
submitted to  
regulatory approval

- Vaccine safety

- Target animal that the vaccine is intended for (species and age)
- Localized reaction, fever, effect on milk production
- Overdose test
  - 10 x the recommended dose
- Repeat dose test
  - Safety of the vaccine dose recommendation
  - Administered in 14 days interval
- Increase in virulence
  - Repeat passage in animals
- Environmental considerations
  - Vaccine should not be shedded, spread or infect in contact animals

Part of dossier  
submitted to  
regulatory approval

- Vaccine efficacy

- Onset and duration of immunity
- Vaccination – challenge studies
  - 21 days post vaccination
  - Known virulent strain ( $10^4$  to  $10^{6.5}$  TCID<sub>50</sub>)
  - Should produce clinical disease in >50% of the susceptible animals
  - Examine sero-conversion over different time points



# Lumpy skin disease: Requirements for LSDV vaccine candidates and batch production

After a vaccine has been approved

National regulatory authorities might also require official control authority re-testing (check testing) of final products and batches in government laboratories or an independent batch quality control by a third party.

- Batch / serial test before release
- Purity (absence of different contaminants)
  - Culture / molecular techniques
- Identity (The specified Capripoxvirus)
  - PCRs, Sanger sequencing, NGS
- Potency ( $10^3 - 10^4$  / dose)
  - Virus titration
- Safety / efficacy
  - Normal field conditions
- Duration of immunity

An independent batch quality control may be warranted or asked by national or international regulatory authorities.

**Questions?**

**Antoinette van Schalkwyk**

**Agricultural Research Council – Onderstepoort Veterinary Institute**

**[vanschalkwyka1@arc.agric.za](mailto:vanschalkwyka1@arc.agric.za)**

