Modified Live African Swine Fever Virus Vaccine Candidate

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Description: Through a research collaboration between Consejo Superior de Investigaciones Científicas ("CSIC") in Spain and Kansas State University ("K-State"), a novel modified live African swine fever virus ("ASFV") vaccine candidate has been created and tested in swine safety and challenge studies.

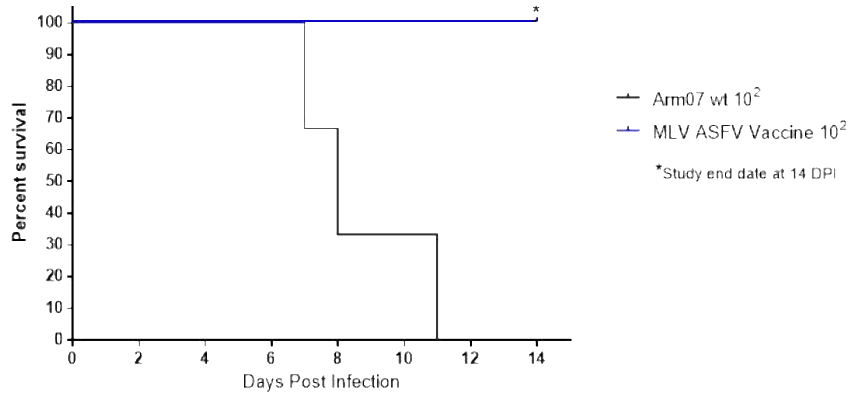
With modified live ASFV vaccine candidates, the main concern is safety. The researchers overcame this problem by deleting a novel gene from the virulent parental ASFV strain (Arm/07) to create a recombinant ASFV strain for vaccine development.

Swine Safety Study:

Experimental design: A total of 5 cross-bred piglets, 3-4 weeks of age and mixed sex, were enrolled in the safety study. Piglets were administered a 1 mL 10^2 plaque forming units (PFU) dose of the MLV ASFV vaccine candidate by intramuscular (IM) inoculation. Post inoculation, animals were observed for 14 days. Clinical symptoms and rectal temperatures were recorded daily. At the end of the observation period, at 14 days post inoculation (DPI), all animals were euthanized and necropsied.

Safety study results: All 5 piglets inoculated with the MLV ASFV vaccine candidate survived to the end of the observed period of 14 DPI, as compared to pigs inoculated with the same dose of wildtype Arm07 which did not survive past 10 DPI (Figure 1).

Figure 1.



The results from this safety study indicate that the recombinant MLV ASFV vaccine candidate is highly attenuated compared to the wildtype Arm07, and 100% survival is observed when administered IM at a dose of 10^2 PFU per animal.

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Swine Challenge Study with wildtype Arm07(Arm07wt)

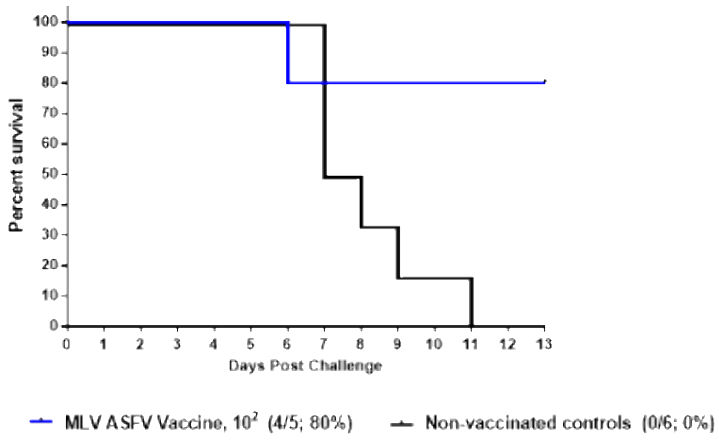
Experimental design. A total of 12 cross-bred piglets, 3-4 weeks of age and of mixed sex, were enrolled in the study. Piglets were divided into two groups. Piglets in Group 1 were administered a 1 mL dose of 10^2 PFU of the MLV ASFV vaccine candidate; and animals in Group 2 were held as unvaccinated controls for virulent ASFV challenge. Vaccination was intramuscular (IM). At 21 days post vaccination (DPV), all animals were challenged with 1 mL dose of $10^{2.2}$ hemadsorption units (HAU) of virulent wild type Arm07 virus, administered IM. Post challenge, animals were observed for 14 days and at the end of the observation period, all animals remaining in the study were necropsied. Clinical scores and rectal temperatures were recorded daily. Blood for qPCR was collected on days 0, 1, 3, 5, 10, 14 and 21 post vaccination and on days 0, 1, 3, 5, 7, and 10 post challenge (DPC) and prior to necropsy.

Challenge Study Results. Five out of six vaccinated piglets survived the 21 days post vaccination (DPV) period prior to virulent ASFV challenge; one piglet died at 13 DPV. All six non-vaccinated control pigs survived the observation period of 21 days prior to virulent ASFV challenge. All vaccinated pigs became viremic by 3 DPI based on ASFV DNA detected in their blood, with peak ASFV DNA detected at 5 DPI for most pigs; the DNA load subsequently gradually decreased. Overall, these results were consistent with the previous safety study.

At 21 DPV, the five remaining vaccinated pigs and the 6 non-vaccinated controls were challenged IM with virulent Arm07wt. Four of the five vaccinated piglets survived virulent ASFV challenge; one piglet was euthanized at 6 days post challenge. All six non-vaccinated control pigs died on 7 to 11 DPC. Average daily temperatures of non-vaccinated controls steadily increased from 5 to 10 DPC, while the average temperature of vaccinated pigs was maintained below 105ºF for the duration of the 13 DPC observation period.

In conclusion, the results from this vaccine efficacy study shows 80% survival of the vaccinated pigs following highly virulent ASFV challenge (Figure 2).

Figure 2.



Patent Status: Patent Pending

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