ZOETIS' APPROACH TO AFRICAN SWINE FEVER



In its Center for Transboundary and Emerging Diseases (CTED), Zoetis has a virtual hub that brings together the company's capabilities in surveillance, alliances with animal health centers of excellence worldwide, along with expertise in vaccine development, regulatory affairs and flexible manufacturing capacity to effectively prevent and control infectious disease outbreaks.

NEXT STEPS FOR VACCINE DEVELOPMENT

In September 2019, Zoetis reached a non-exclusive license agreement with the United States Department of Agriculture (USDA) Agricultural Research Service (ARS) for the development and commercial production of African Swine Fever vaccines.

- The agreement with USDA ARS gives Zoetis access to three patents related to ASF live attenuated vaccine strains.
- USDA-ARS has conducted proof of concept studies that have demonstrated both safety and efficacy at various dose levels. ^{1, 2, 3,}

A critical step in delivering a commercial vaccine is establishing a scalable, stable cell line for vaccine virus production. Published vaccine efficacy studies have utilized primary cells to propagate the virus; however, transition to a manufacturing friendly cell line is challenging as it has been demonstrated that prolonged passage may lead to further attenuation⁴.

Because development of a live-attenuated virus vaccine is a complex process depending on a variety of factors, it could take several years to develop and license a vaccine for African Swine Fever.

"Our agreement with the USDA is important progress to accelerate our research and development of an African Swine Fever vaccine," said Dr. John Hardham, Research Director, Global Biologics Research at Zoetis.

"Led through our Center for Transboundary and Emerging Diseases, we now can get to work creating a manufacturing-friendly process that could lead us to ultimately develop the right solution to help control

African Swine Fever."

"At Zoetis, we strive to be first to know and fast to market in helping to combat transboundary and emerging diseases that threaten livestock and companion animals as well as those zoonotic diseases that can also transmit between animals and people," said Dr. Catherine Knupp, Executive Vice President and President, Research and Development at Zoetis. "The effects of African Swine Fever have been devastating to pigs, as well as the farmers and veterinarians who care for them, in a growing number of countries, and we are committed to supporting our customers to develop a vaccine."

ABOUT AFRICAN SWINE FEVER

African Swine Fever (ASF) is a highly contagious, infectious animal disease. As a viral disease impacting only pigs and not people, it is not a public health threat or a food safety concern.

ASF has been widespread in sub-Saharan Africa, Eastern Europe and Russia, and the Italian island of Sardinia. Since its emergence in China in August 2018 and its subsequent spread to every Chinese province, ASF has been detected in the Philippines, Mongolia, Vietnam, Laos, Cambodia, Myanmar, North Korea, South Korea, and East Timor/Leste. With some reports indicating ASF has resulted in the loss of over half of China's domestic pig herd, ASF is having a significant impact on the global pork supply.

¹O'Donnell, V., Holinka, L.G., et. al. (2016) "African swine fever virus Georgia isolate harboring deletions of 9GL and MGF360/505 genes is highly attenuated in swine but does not confer protection against parental virus challenge." Virus Research, 221(2016), 8-14.

²O'Donnell, V., Holinka, L.G., et. al. (2015). "African Swine Fever Virus Georgia 2007 with a Deletion of Virulence – Associated Gene 9GL (B119L), when Administered at Low Doses, Leads to Virus Attenuation in Swine and Induces an Effective Protection against Homologous Challenge." Journal of Virology, 89(16), 8556-8566.

3 O'Donnell, V., Holinka, L.G., et. al. (2015). "African Swine Fever Virus Georgia Isolate Harboring Deletions of MGF360 and MGF505 Is Attenuated in Swine and Confers Protection against Challenge with Virulent Parental Virus." Journal of Virology, 89(1), 6048-6056.

⁴ Krug, P.W., Holinka, L.G., et. al. (2014). "The Progressive Adaptation of a Georgian Isolate of African Swine Fever Virus to Vero Cells Leads to a Gradual Attenuation of Virulence in Swine Corresponding to Major Modifications of the Viral Genome." Journal of Virology, 89(4), 2524-2532.

