

**RAPID-RESPONSE VACCINES AGAINST EMERGING RNA VIRUSES
(RFT-539)**

Invention Summary:

Scientists at NDSU have developed a method to rapidly produce safe and efficacious vaccines against emerging RNA viruses. This is accomplished by damaging or destroying the RNA genome (so replication is diminished or eliminated) while maintaining the structural integrity of the capsid so antibodies recognize the native virus. Therefore, NDSU's method has the combined advantages of inactivated (safety) and attenuated (efficacy) vaccines. Note that viruses can be rapidly attenuated or completely inactivated, depending on how long the genome is exposed to RNase. It is also a rapid method, with vaccines being ready for cell-based production within approximately 3 - 4 weeks. The technology is broadly applicable to other human and animal RNA viruses such as PRRSV, Avian influenza, Ebola, West Nile, and Zika.

| Vaccine Development Approach | Time for development after first isolation and culture | Vaccine Efficacy | Vaccine Safety |
|---------------------------------|---|--|------------------|
| NDSU Rapid Response Method | Very Rapid, 3 to 4 weeks | Very effective | Very safe |
| Conventional Inactivated/Killed | Rapid, weeks to months | Usually inadequate | Very safe |
| Conventional Attenuated/Live | Long, months to years | More effective than inactivated | Inconsistent |
| mRNA/DNA | Rapid, weeks to months | Effective if one to few well validated protective antigens targets are sufficient for optimal efficacy. Knowledge of the targets may not be available for emerging viruses | Under evaluation |
| Protein Subunit | Variable depending on how amenable the target is to protein engineering | Effective if one to few well validated protective antigens targets are sufficient for optimal efficacy. Knowledge of the targets may not be available for emerging viruses | Very safe |

Table: Comparison of NDSU Rapid Response method with conventional vaccine production

The method has been demonstrated as effective against RNA viruses by using porcine epidemic diarrhea virus (PEDV) and a swine influenza virus that is also infections in humans as models. PEDV is a swine coronavirus with an RNA genome which emerged in the U.S in 2013 and spread extremely quickly to all the major swine production states. PEDV caused the death of a quarter of the U.S. swine population, and

an industry loss of \$540 million; making it an excellent example of an RNA virus where a rapid response vaccine with high efficacy and safety was needed. The NDSU rapid response vaccine technology was developed using PEDV as a first model system. Three-week-old pigs were administered the experimental vaccine produced using the NDSU method, and then challenged with virulent virus. The challenge virus was not detected in fecal matter of any of the vaccinated pigs and no microscopic or immunohistochemistry lesions were detected in intestinal, heart, spleen or lung tissues in vaccinated pigs, indicating 100% protection was elicited by vaccination. The vaccine virus was cleared in vaccinated pigs within 14 days of vaccination. The approach was also tested against a zoonotic swine influenza virus and found to be highly safe and effective. Thus, the NDSU vaccine development approach can have broad application to emerging RNA viruses.

Benefits:

1. Allows rapid preparation of a vaccine within weeks, in response to a new outbreak or re-emergence of a mutated strain of virus
2. Maintains integrity of the viral capsid so antibodies elicited from vaccination will be more effective against the native virus
3. Destroys genetic material of the virus, thereby greatly reducing its infectious capability, and providing a high safety margin
4. Oral and intranasal routes have been tested but would be amenable to any route of administration

Patents:

This technology is patent pending in the US ([US 2018/0245053](#)) and is available for licensing/partnering opportunities.

Phase of Development:

This technology has successfully completed laboratory testing with reproducible results.

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