A rigorous clinical development process established and monitored by the FDA helps to ensure that safe and effective medicines are available to the US population.¹

Companies that make medicines and vaccines are required to follow certain steps in order to get permission from the FDA to market that product within the United States. This process of drug development ensures that the companies prove they have succeeded one step at a time before moving on to test the product in a greater number of people. The entire process is designed to help ensure that any new product is both safe and effective for the group of patients who will ultimately use it. This process typically takes many years.¹

Novavax is following a development process that has been discussed with the FDA to study its RSV F vaccine for pregnant women.

It is of the highest importance to ensure that any maternal vaccine will be safe and effective for both the mother and the baby. The drug development process for the RSV F vaccine has revealed key findings:

- Safe dose of the vaccine identified for pregnant mothers in their third trimester.
- Vaccine shown to trigger the mother’s immune system to create antibodies that are shared with the baby in her womb.
- Antibodies shown in animal studies to protect against RSV infection.
- To date, the vaccine has been well tolerated.
  - Some women have reported mild to moderate and temporary pain where the vaccine was injected, which may be similar to what you may experience with other vaccinations
  - The vaccine has not been shown to have any adverse effects on infant safety

The vaccine is now in phase 3 of clinical research.
Facts and Figures About the Phase 3 Trial of RSV Vaccine for Maternal Immunization

- First pregnant mother vaccinated in this study: December 2015
- A global trial is ongoing: USA, United Kingdom, South Africa, Australia, New Zealand, Chile, Argentina, Spain, Mexico, Philippines, and potentially other countries
- Plan to vaccinate up to 8600 pregnant women worldwide in this study

Safety for Mother and Baby is of the Highest Importance

A special committee of pediatricians, OB/GYNs, and other experts was established to ensure safety of the vaccine throughout this study. This committee, the Data Safety Monitoring Board (DSMB), has the important job of reviewing all of the data as the study goes along (rather than waiting to the end) to make sure there is no undue risk to pregnant mothers or their babies in this study. The DSMB meets on a set schedule, and met as recently as April 2017.

If the DSMB felt it was necessary, they could recommend to stop this study at any time due to safety concerns. However, so far, the formal recommendations made by this board after review of data at each meeting has been to continue this RSV vaccine study without any changes.

The Prepare TM Trial of the RSV F vaccine to protect babies continues to progress without being impacted by any observed safety concerns.

For additional information please visit www.Prepare4RSV.com

References