

SANOFI PASTEUR 

Sanofi Pasteur COVID-19 Recombinant  
Project Team French Scientific Committee July 15th, 2020

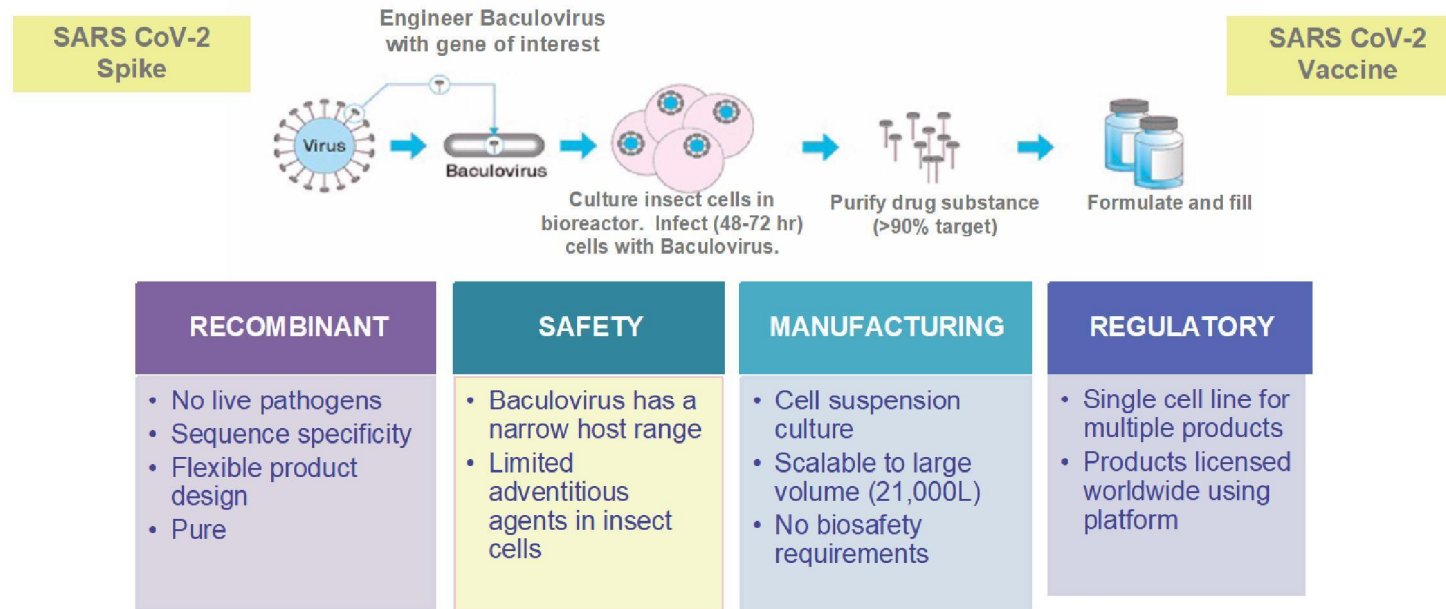
# COVID-19 Project Review

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AGENDA 15 Jul 2020

1. Introduction
2. Non-clinical
3. Clinical
4. Regulatory
5. CMC / Manufacturing

# Baculovirus Expression System Technology (BEST) Platform



\*severe acute respiratory syndrome coronavirus 2, (SARS-CoV-2)

## Previous experience on SARS vaccine

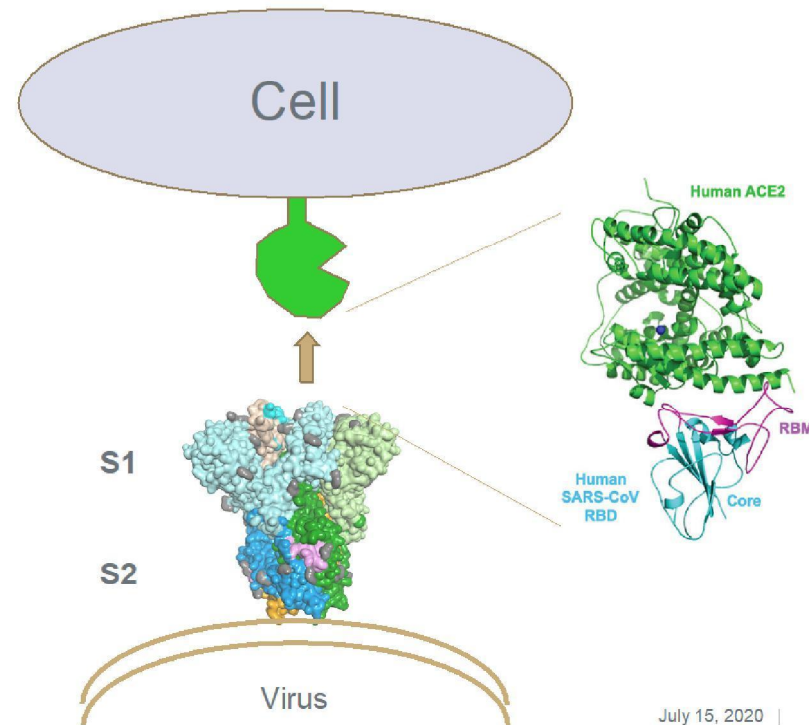
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### Non-clinical SARS data

- **Protein Sciences produced a truncated version of the SARS CoV spike protein for the US NIH**
  - The transmembrane and adjacent cytoplasmic domains of the SARS CoV spike protein were deleted (S dTM)
- **Nonclinical studies confirmed immunogenicity, and afforded partial protection in ferrets\***
- **Clinical testing was not performed on this candidate**
- **This work is now being leveraged to develop a COVID-19 vaccine, using the existing seasonal recombinant influenza vaccine infrastructure**

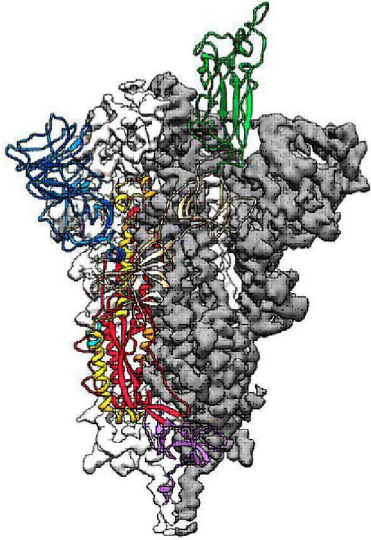
## The Spike protein is the antigen targeted by Neut Abs

- **S** is the major surface glycoprotein
- Cleaved in **S1** and **S2**
- **S1** binds to the human receptor **ACE2**
- **S2** promotes the fusion and cell entry

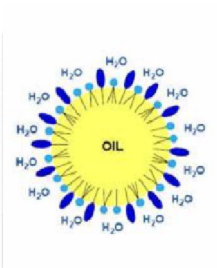


# SP COVID-19 vaccine candidate

Prefusion Spike protein



Squalene-based adjuvant



AF03 / SP  
AS03 / GSK

Neutralizing Ab  
Th1/Th2 CD4 T cells

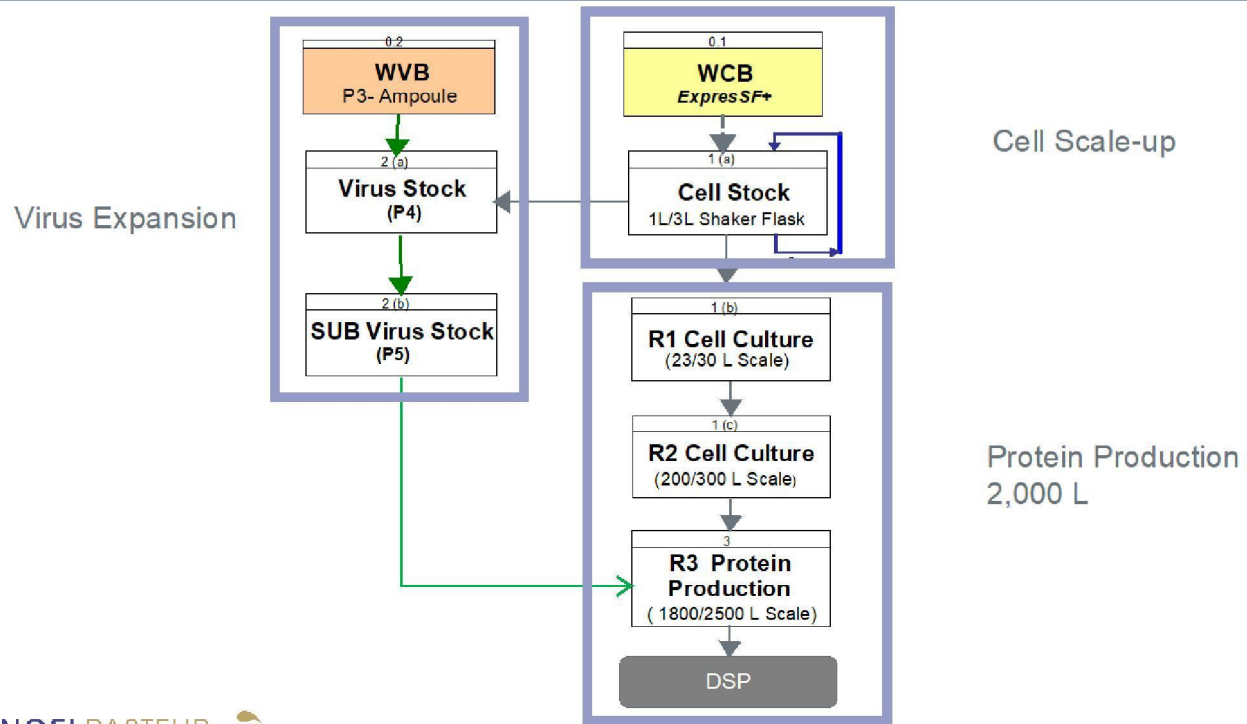
## Advantages of the platform

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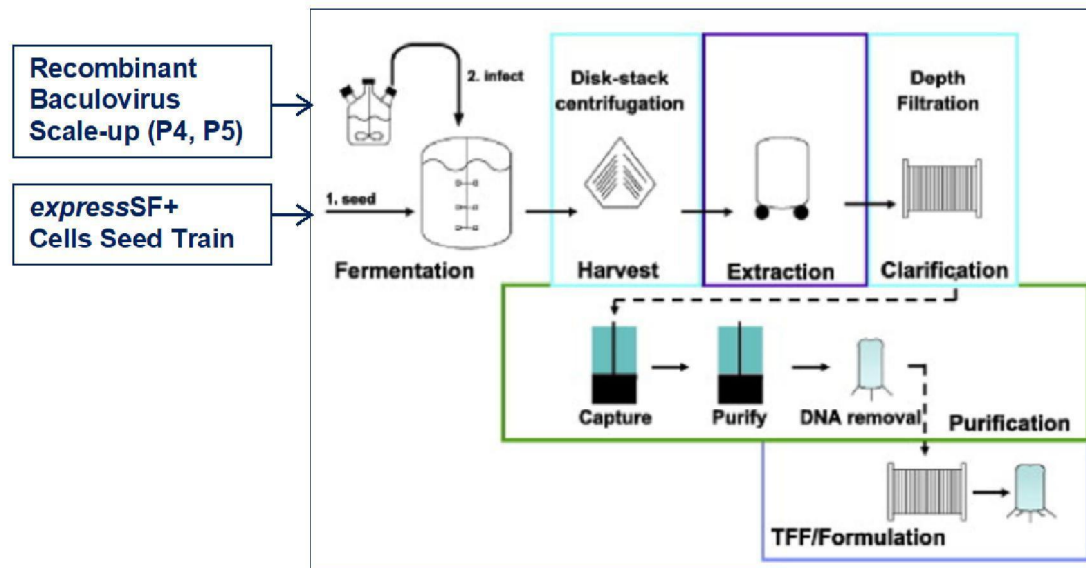
Provides a rapid / low risk path to large scale supply

- **SARS CoV2 Research and Clinical material are being produced**
  - Assuming a similar purification process, the CoV-2 prefusion stabilized S vaccine candidate is being produced
- **The manufacturing platform is well understood by the FDA and under consideration of other global regulatory authorities**
  - Should facilitate licensure or use under Emergency Use Authorization (EUA)
- **Existing infrastructure to facilitate production of large quantities of vaccine**
  - Can be produced at existing facilities (Pearl River)

# Universal Upstream Process



# Universal HA Protein Downstream Process



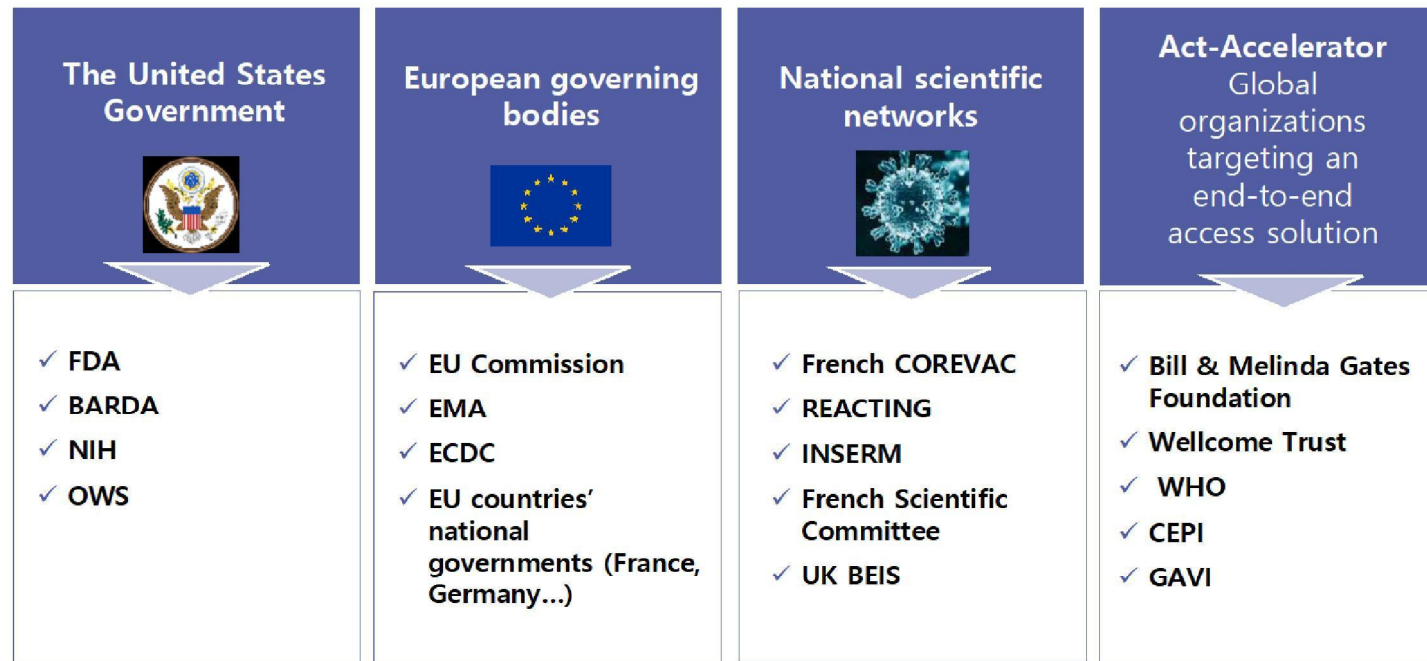
- Scale down model at 1L, 4L, 10L and 40L scales
- Technology transfer to 459L, 1,800L and 18,000L scales
- Less than one week for production of one HA lot
- rHA protein is highly purified recombinant protein

# Sanofi COVID-19 Vaccine Program

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- **Work has promptly started on production of vaccine candidate**
  - Viral bank
  - Development material produced for non-clinical studies
  - Non-clinical testing plan defined
  - Planning for clinical activities are well under way
- **Interactions with regulatory authorities to determine fastest path to availability**
- **Discussions with external groups (WRAIR, NIH...) to expedite development**
- **Continued partnership with BARDA on advancing the program**
- **Leveraging all capabilities and resources (Research, Clinical, Regulatory teams, Industrial Affairs...) to accelerate licensure and implementation**

## COVID-19 : partnerships will be essential to success



# SPEED: 1<sup>st</sup> doses by end 2020, license by June 2021

