



Challenges in creating novel vaccines against H1N1 influenza

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GSK is a global company committed to global health

- Pioneered tiered pricing for vaccines in the 1980s
- Almost 80% of the 1.1B doses of vaccine we produced in 2008 went to GAVI countries
- For many years, the only company developing drugs and vaccines for the “Big Three” killer diseases: AIDS, TB and malaria
- 1/3 of our vaccine R&D pipeline is dedicated to diseases that primarily or exclusively affect the developing world – repeatedly recognized as the richest vaccine pipeline in industry
- Work in partnership towards the goal of ensuring vaccines are available to all
- Ranked #1 by the Access to Medicines Index (2008)



GSK is a key company in the fight against influenza

GSK has developed and produces

Medicines

- Antivirals for treatment of influenza (Relenza)
- Antibiotics for complicating infections

Vaccines

- Seasonal influenza vaccines for prevention
- Pre-pandemic influenza vaccine for pre-pandemic preparedness and prevention before and early in a pandemic
- Pandemic vaccine for prevention during a pandemic
- Adjuvant technology
- Candidate monovalent H1N1 adjuvanted vaccine

Protective equipment

- Masks for reduction of transmission

GSK is committed to a global response against pandemic influenza – including the needs of the developing world

Medicines

- Increased production capacity of Relenza (50-60 m packs per year)
- Exploring alternate presentations
- Using technology transfer – including voluntary license to Simcere in China for China and other developing countries
- Using tiered pricing, including not-for-profit pricing for 50 LDCs
- Reserved production capacity for use in LDCs, through multilaterals or directly

Vaccines

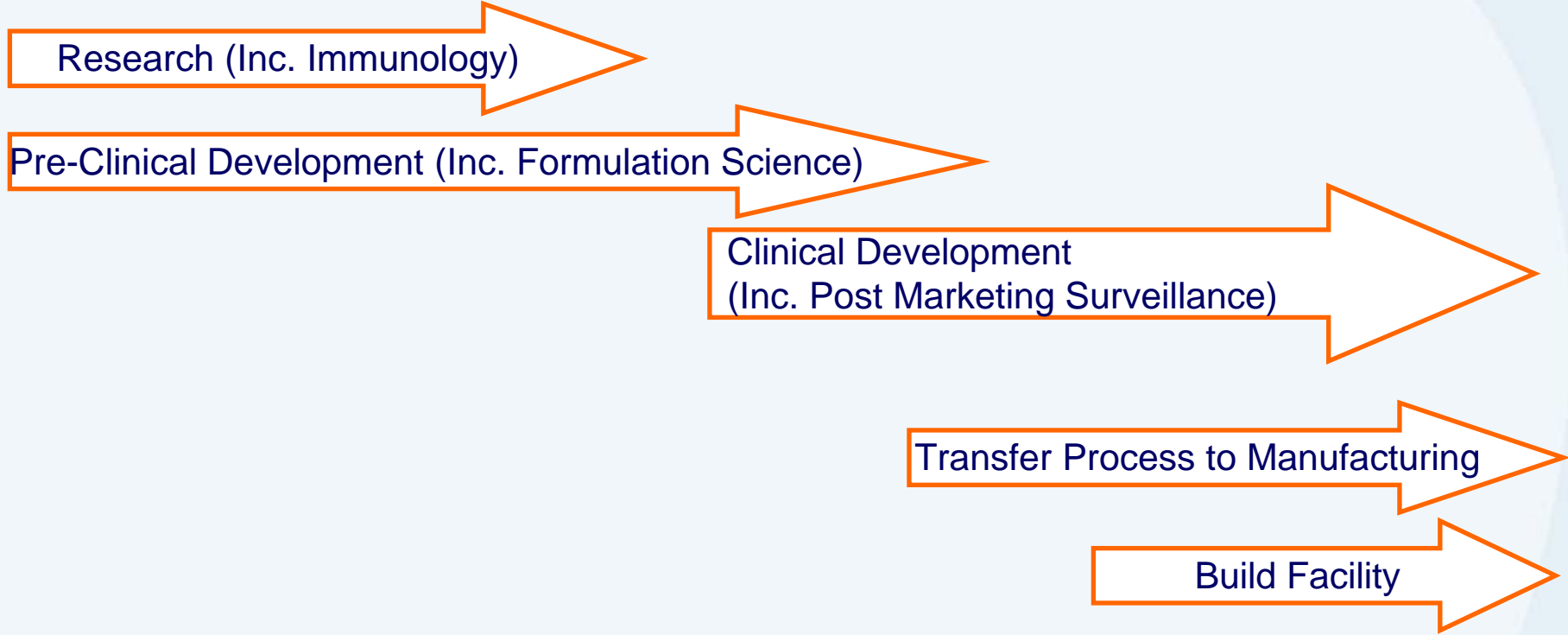
- Currently supplying seasonal influenza vaccine in the Southern hemisphere
- Standing ready to switch to H1N1 vaccine pending WHO and other public health authority recommendations
- Offering an H1N1 donation if WHO requests a conversion of our previous H5N1 commitment, pending Canadian regulatory approval
- Reserving available production capacity for supply to the developing world through tiered pricing

Adjuvants

- Offering to supply available AS03 adjuvant for use with other antigens, subject to regulatory approval and through tiered pricing

Challenges: Vaccine development is a long and costly process

Identify Antigens → Produce Antigens → Pre-Clinical Testing → Proof of Concept → Phase I → Phase II → Phase III → File → Registration/Post Marketing



Challenges: Development of a safe and effective novel H1N1 vaccine

GSK has developed pre-pandemic and pandemic vaccines

- Based on H5N1 data
- Demonstrated broad and sustained immunity against different H5N1 clades
- An acceptable safety profile in all age groups
- Approved in the EU and several other countries, further submissions in progress
- This data now needs to be validated for H1N1 California – regulatory variations submitted where regulatory pathways are clear – elsewhere regulatory pathways need to be clarified



Antigen - SSW Dresden
(Germany)

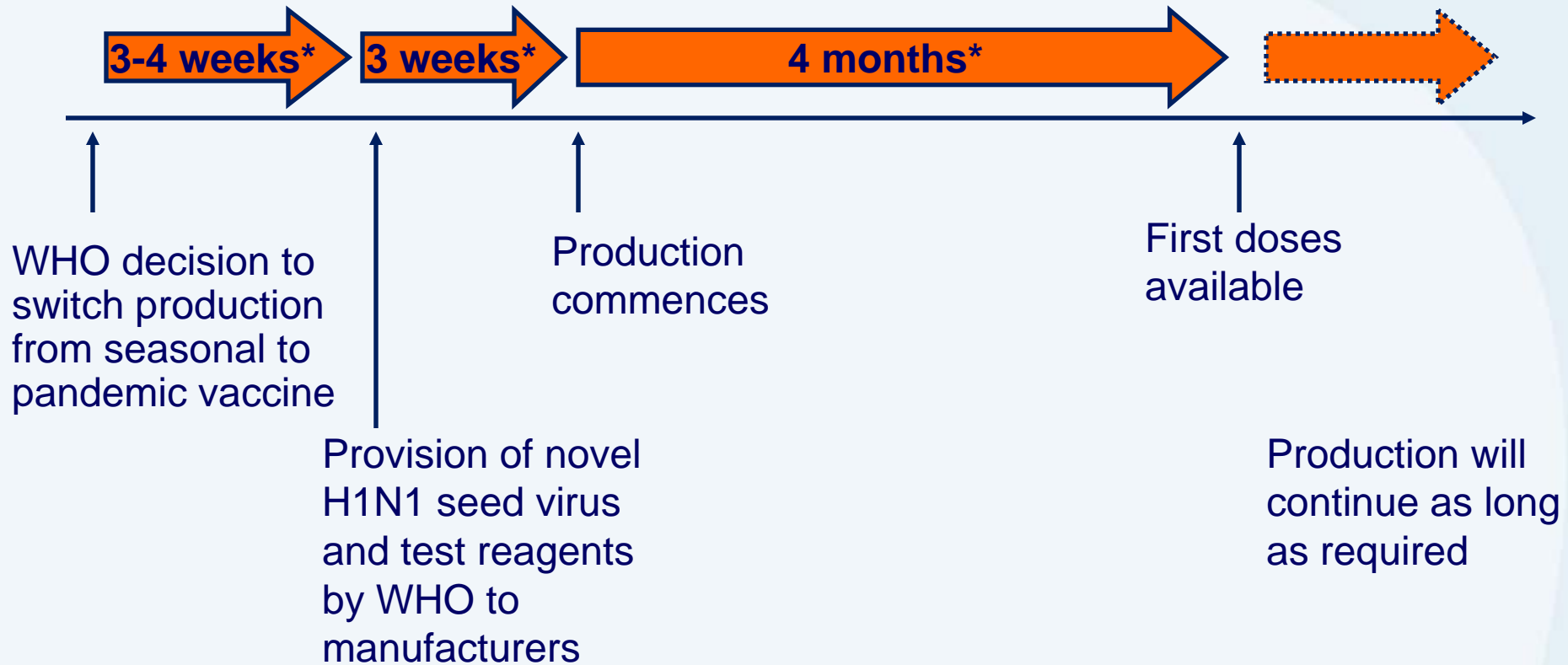


AS03 – Rixensart
(Belgium)



Antigen - Quebec
St. Foy (Canada)

Challenges: Move to large scale manufacture



If WHO does not declare an H1N1 pandemic, some countries may request manufacturers to produce an H1N1 vaccine for stockpiling





* Approximate timings

Challenges: Managing timing

- The initial lead time involved in influenza manufacture is independent of the capacity or location of manufacturing
- It is due to the time taken for antigen production, downstream processing, filling, quality control and distribution
- Whatever technology is used, it will take many months to deliver billions of doses of pandemic influenza vaccines
- The only way to have vaccine available in advance of the first pandemic wave is via the use of pre-vaccination or pre-pandemic stockpiling strategies.

To realize the full potential of vaccines and other innovations, many need to be involved

Critical success factors

- Include critical diseases in R&D pipelines 
- Plan development for licensure in countries of need 
- Deliver timely planning for manufacturing capacity 
- Build adequate distribution and delivery systems 
- Create sustained financing mechanisms
- Build awareness to increase acceptability and uptake

And we need to ensure long term planning to respond to today's "innovation pile up"

Together we need to think globally – and act!

***“A vaccine that sits
on the shelf
is useless”***

- Albert Sabin

