



## National Influenza Vaccine Summit

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## Objectives

- Last year's delivery performance
- This year's projections and offerings
- Influenza vaccines in near term development



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## Novartis Supply Performance

- In 2011, Novartis completed the shipping of >27 million FLUVIRIN® doses
  - Delivered to all our customers in the full quantities ordered
  - Delivered ahead of contracted delivery schedules, allowing for early administration
  - ~70% of supply in market by end Aug. ~100% by end Sept.
  
- In 2012, Novartis plans to bring sufficient supply to market to meet all pre-booked demand
  - Shipping expected to begin early-mid August and continue thru early October
  - Manufacturing proceeding well, no issues foreseen at this point

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## Formulations Available in 2012

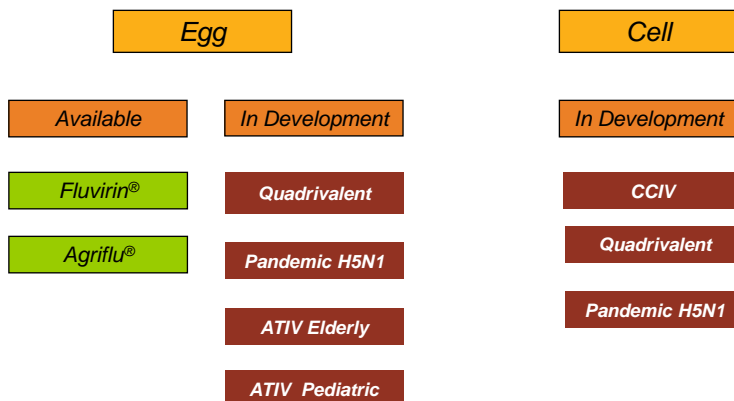
| Product                                       | Age         | Presentation       | Administration |
|---|-------------|--------------------|----------------|
| <b>Fluvirin®</b><br>(Influenza Virus Vaccine) | <b>4y+</b>  | <b>PFS, MDV</b>    | <b>IM</b>      |
| <b>Agriflu®</b><br>(Influenza Virus Vaccine)  | <b>18y+</b> | <b>PFS, T-free</b> | <b>IM</b>      |

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# Novartis Influenza Vaccine Products

Including US Development Portfolio



■ US Approved  
■ Planned / Not yet approved for license in the US

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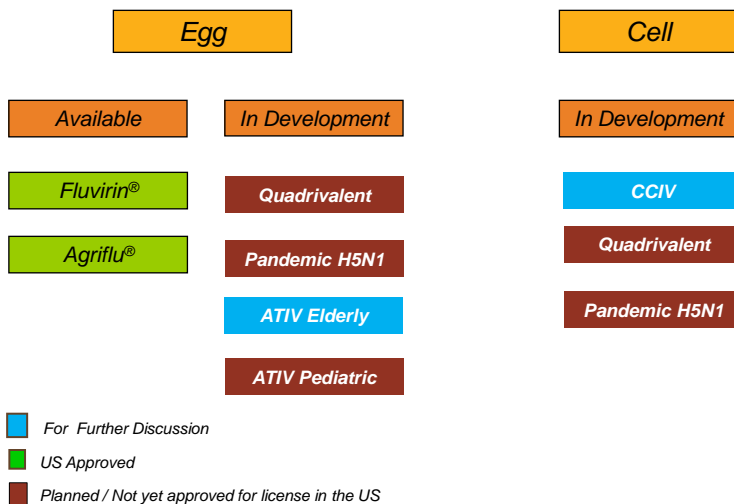
## Novartis Pipeline Focused on Insuring Supply Reliability and Improving Protection for Infants and Seniors



- Two manufacturing platforms: cell culture, egg
- Redundant sites: UK, Italy (egg) and Germany, US (cell culture) to ensure reliable supply
- Using proprietary MF59 adjuvant platform for infants and seniors as adjuvanted technology may offer significant benefit for vaccine response
- Also improving current products by adding second B strain and expanding age indication



## Novartis Influenza Vaccine Products Including US Development Portfolio



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## Novartis Cell Culture Influenza Vaccine

Marburg, Germany



- BLA submitted Nov. 2011 for adults  $\geq 18$

Holly Springs, North Carolina



- sBLA planned later with Holly Springs produced material
- Holly Springs facility declared pandemic ready December 2011

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## Cell Culture Vaccine\* : Overall Summary

- Two sites have cell culture lines in operation
- New technology at scale and ready for production
- Cell culture based influenza vaccine free of egg proteins and antibiotics

\*BLA filed in the US for use of CCIV in individuals  $\geq 18$  years of age

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## ATIV: Development Plans (US)



*MF59 prepared for influenza vaccines*

Marketing applications will be submitted for those  $\geq 65$  years of age and for use in children 6-72 months

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## ATIV: Product Profile

- Initial European approval (Italy) in 1997 for persons  $\geq 65$  years of age under the trade name Fludax®
  - » Licensed in over 30 countries ; >50 million doses distributed
- Egg-derived, surface-antigen (subunit), inactivated influenza vaccine adjuvanted with MF59
- Presented as a 0.5 mL sterile suspension for injection in a prefilled syringe

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## Summary

- Seasonal Vaccine Production On Time, Volume Sufficient
- Cell Culture-based Vaccine: Application Pending
- Adjuvanted TIV for Seniors and Children to Follow



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