

Semi-synthetic Artemisinin Project

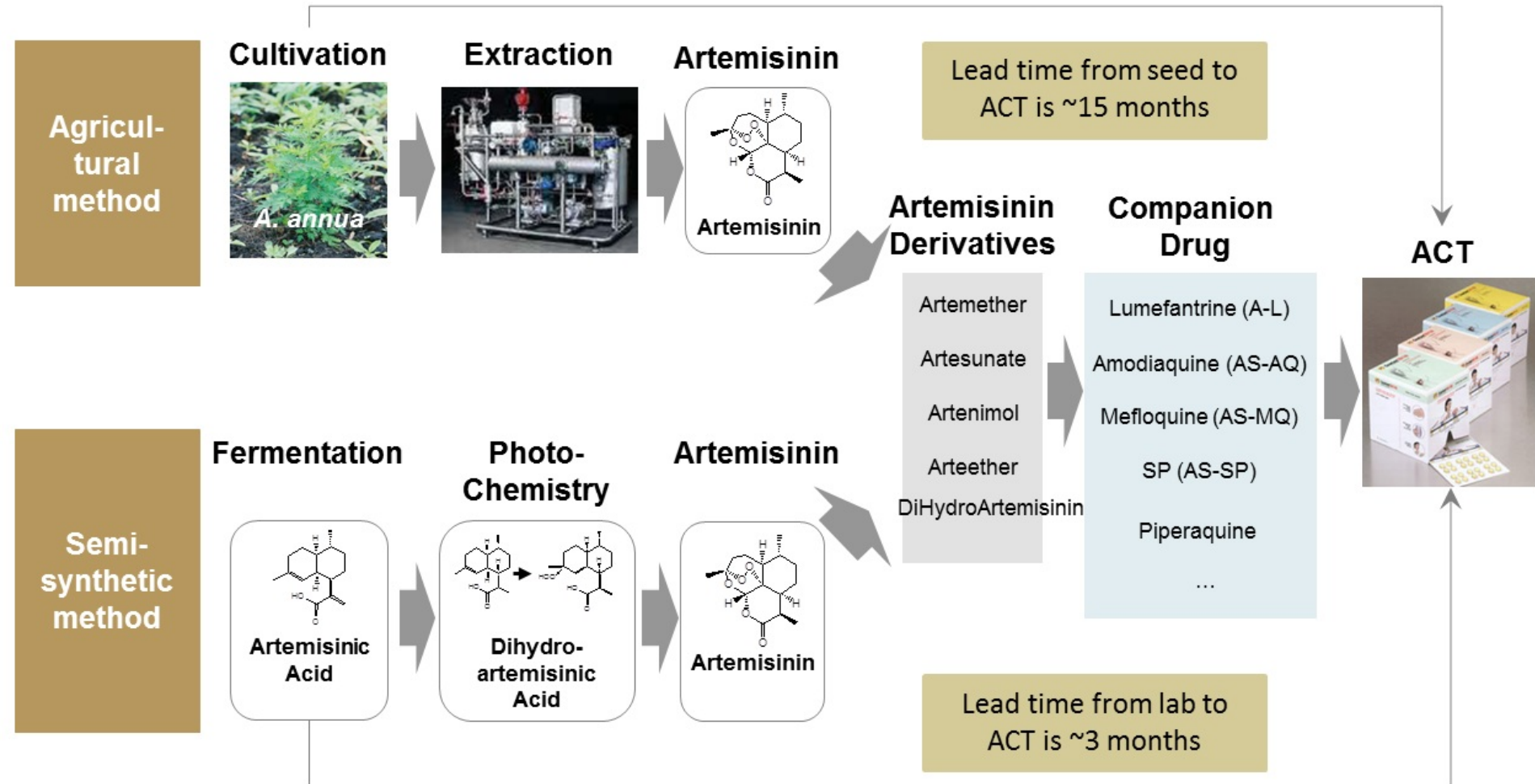
***RBM/UNITAID/WHO Artemisinin Conference
November 3, 2011 Ha Noi , Viet Nam***

Tue H. Nguyen, PhD – OWH & Laurence Goldenberg, PharmD - Sanofi

The Artemisinin Enterprise

- The Artemisinin Enterprise consists of 3 complementary projects funded by BMGF to improve artemisinin production technologies
- The semi-synthetic artemisinin project is one of the currently active initiatives to ensure global demand for ACTs can be met

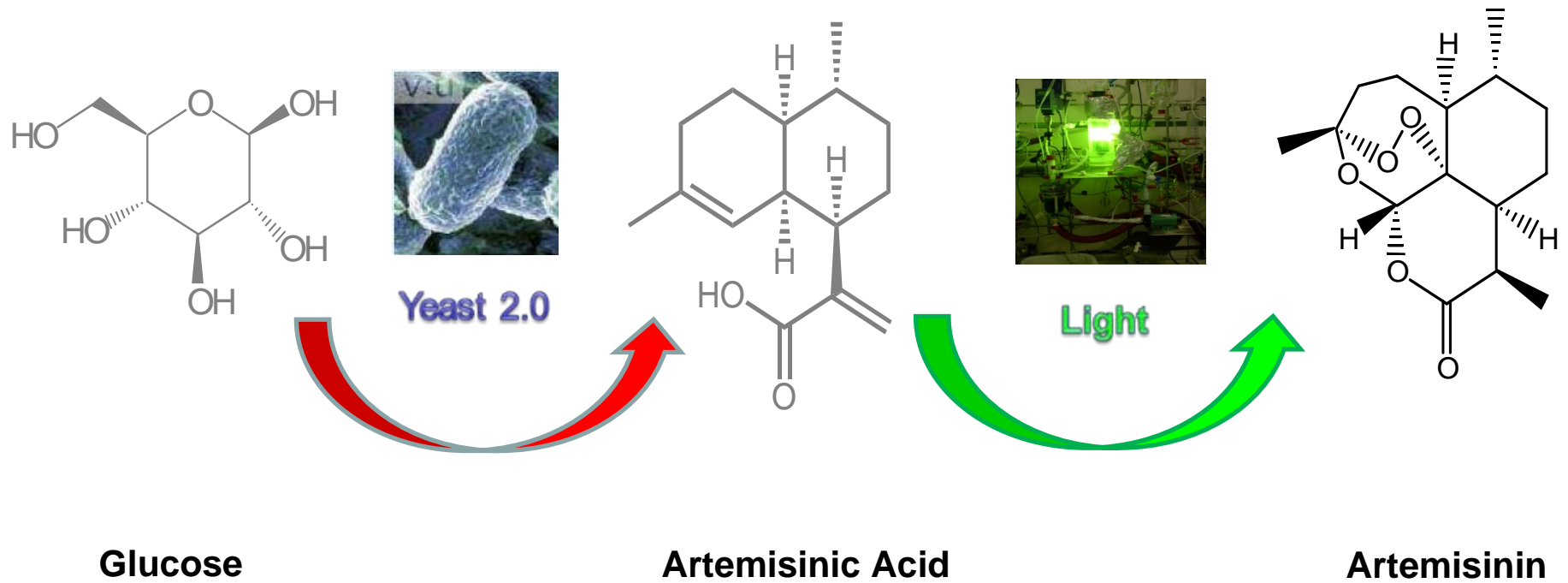
A 2nd Source to Stabilize the Supply Chain & Price



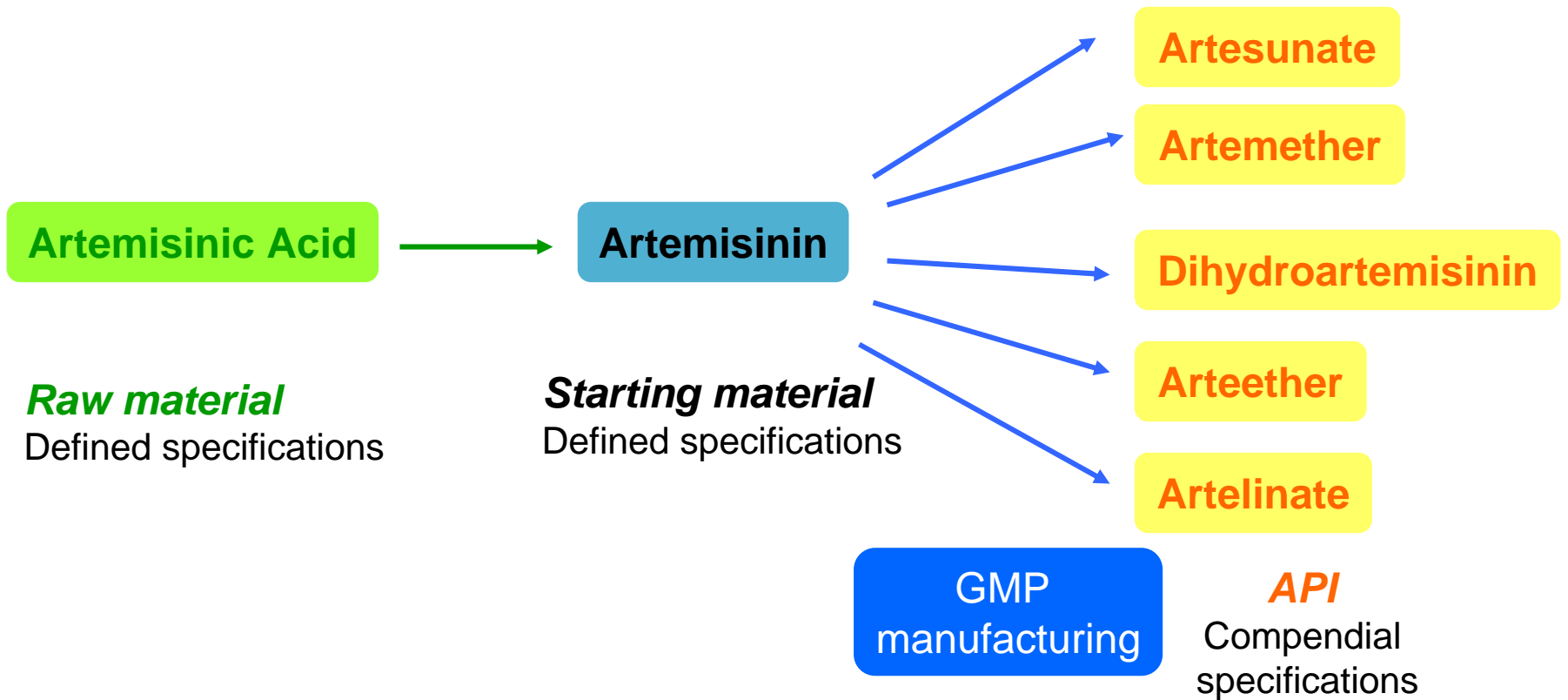
Semi-Synthetic Artemisinin Project Goals

- Create a complementary source of non-seasonal, high-quality and affordable artemisinin to supplement the current plant-derived supply
- Ensure semi-synthetic artemisinin is available to all qualified derivative manufacturers
- Contribute to stabilizing the price of ACTs to benefit patients and payers

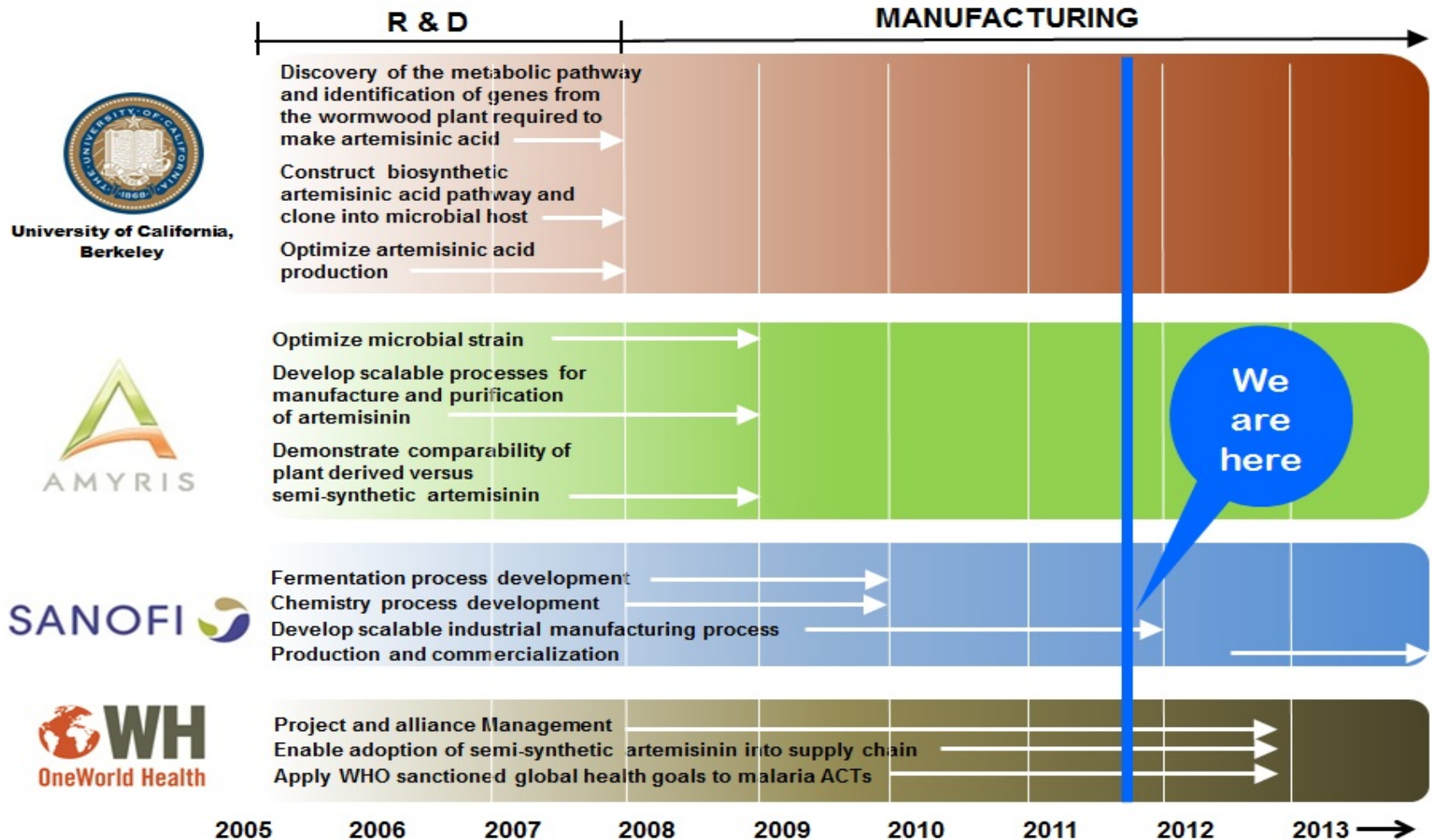
A Novel Semi-synthetic Route



Artemisinin as a Starting Material



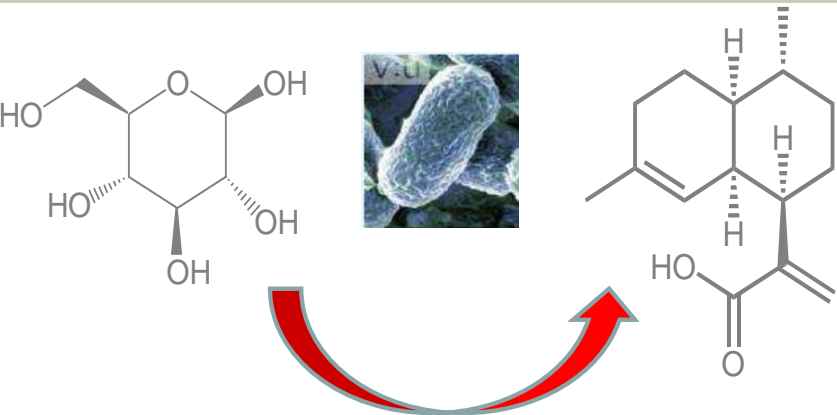
Semi-synthetic Artemisinin - The Partnership



SANOFI

- Achievements
 - Fermentation
 - Chemistry
- Timeline to Market
- Analytical data
- Commercial Planning

Fermentation - From Pilot to Industrial Scale

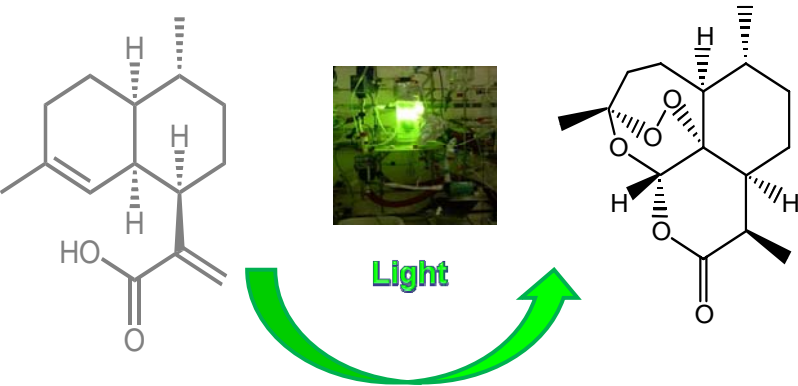


Glucose

Artemisinic Acid

- Process development and Industrial scale-up completed 😊
- Facility and equipment are in place 😊
- Tech transfer to manufacturing site completed 😊
- Validation begins Nov. 2011 😊

Chemistry - From Pilot to Industrial Scale

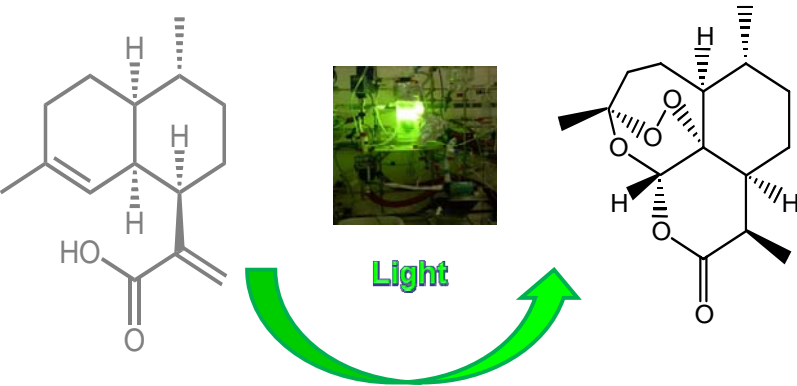


Artemisinic Acid

Artemisinin

- Process development and Industrial scale-up completed using current capabilities 😊
- Construction and Installation of final facility on going 😊
- Tech transfer to final manufacturing site on going 😊

Chemistry - From Pilot to Industrial Scale

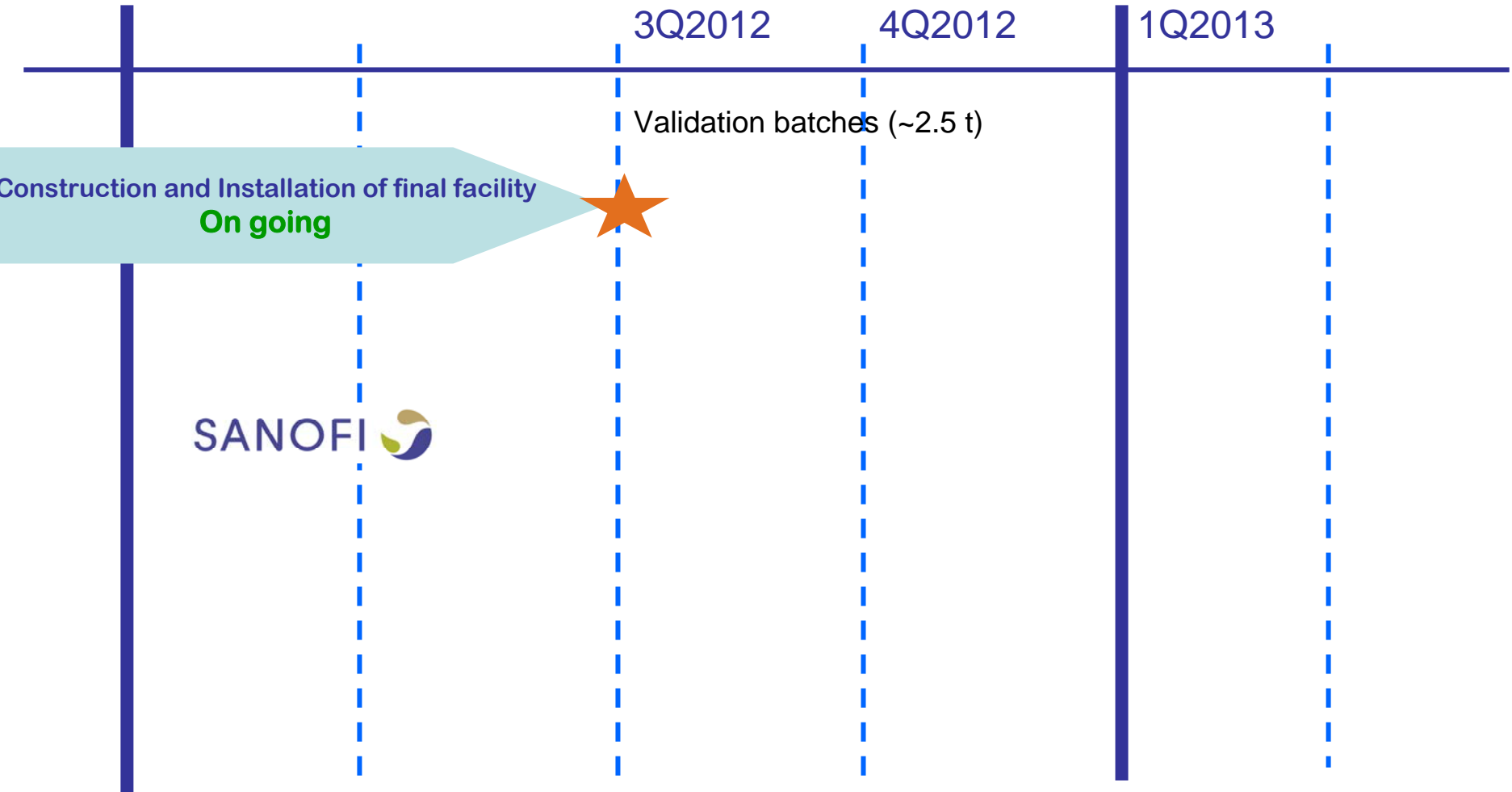


Artemisinic Acid

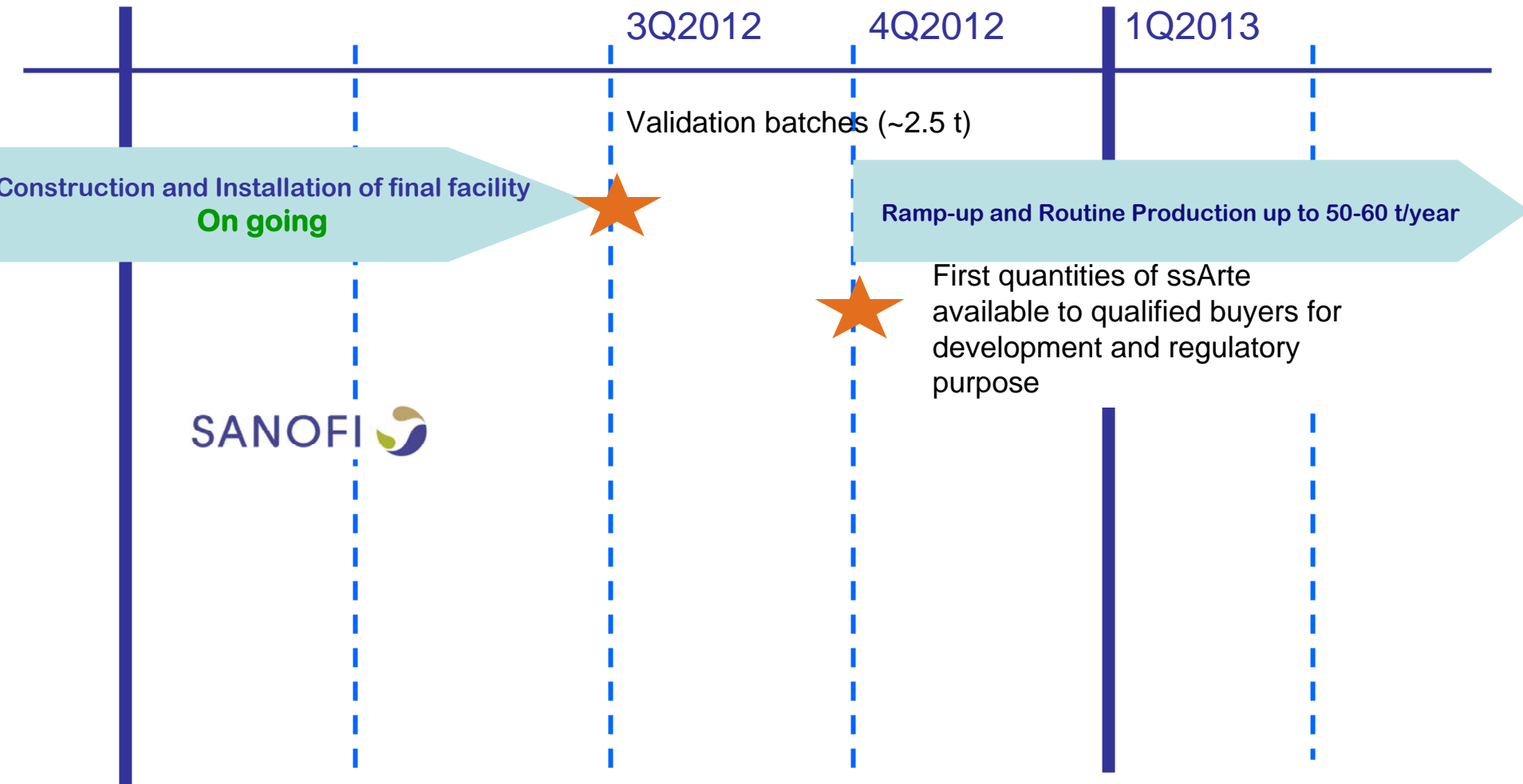
⚡ 150 kg ssArtemisinin produced in July 2011

- Process development and Industrial scale-up completed using current capabilities 😊
- Construction and Installation of final facility on going 😊
- Tech transfer to final manufacturing site on going 😊

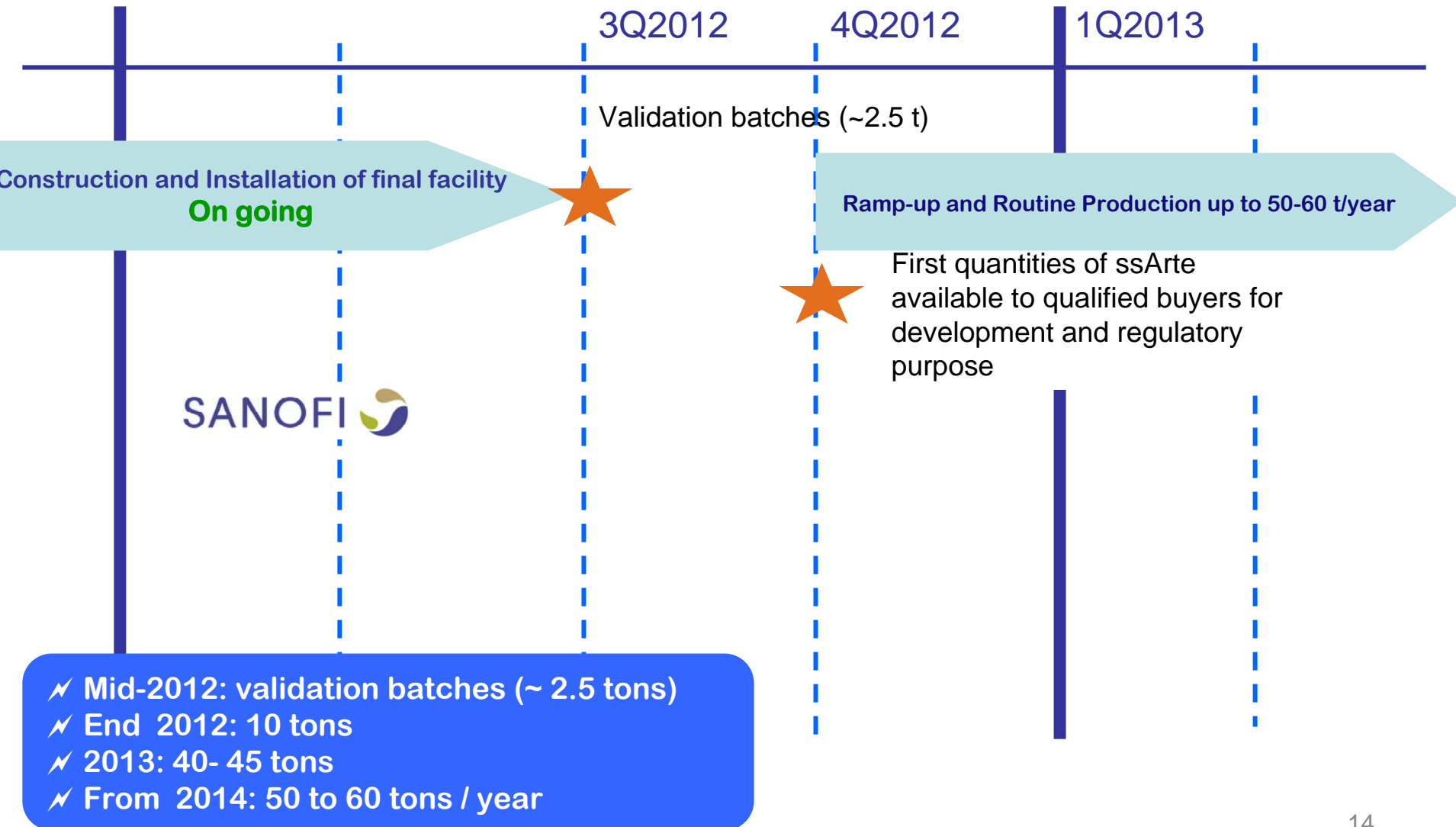
Semi-synthetic Artemisinin – Timeline to Market



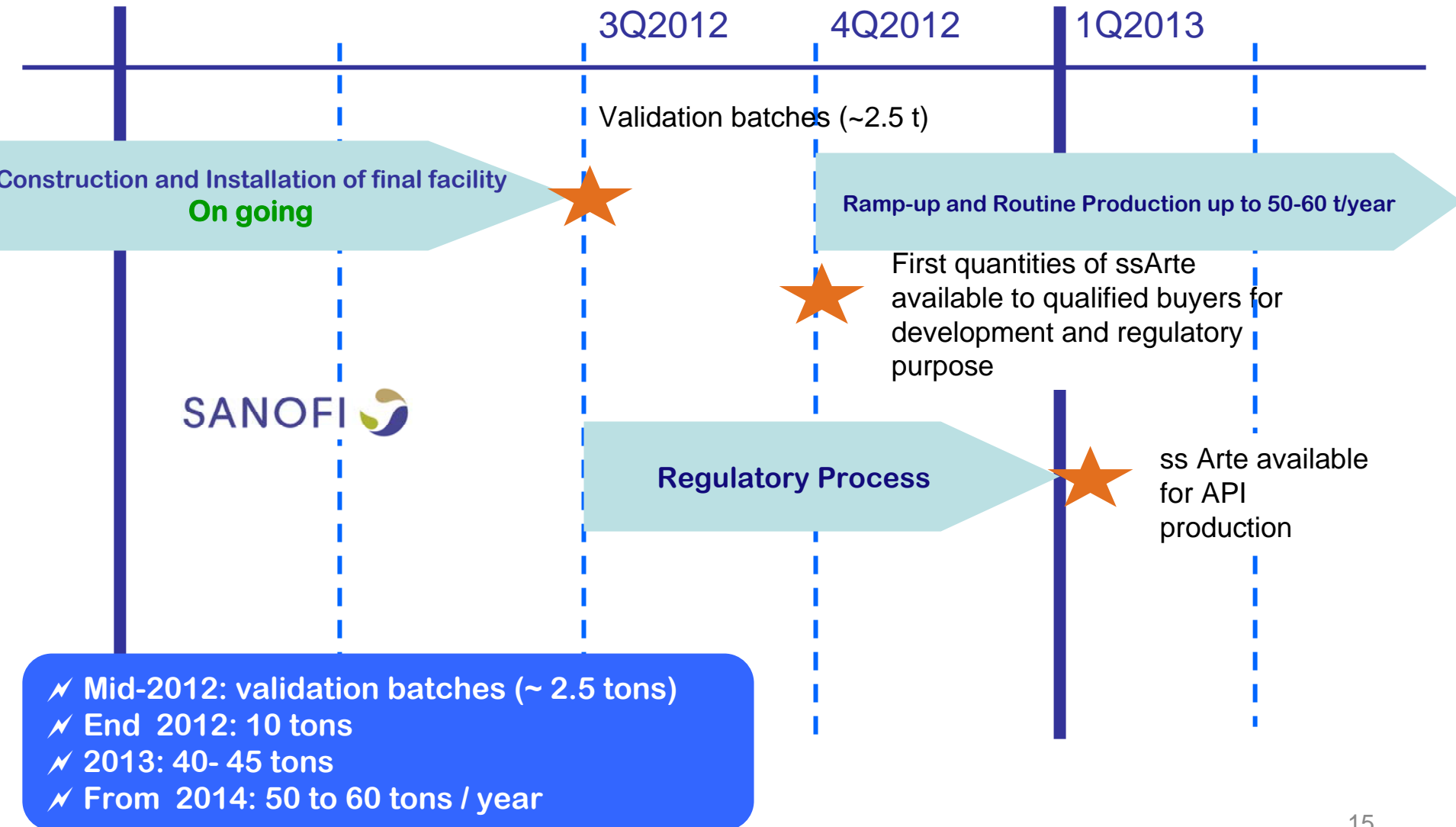
Semi-synthetic Artemisinin – Timeline to Market



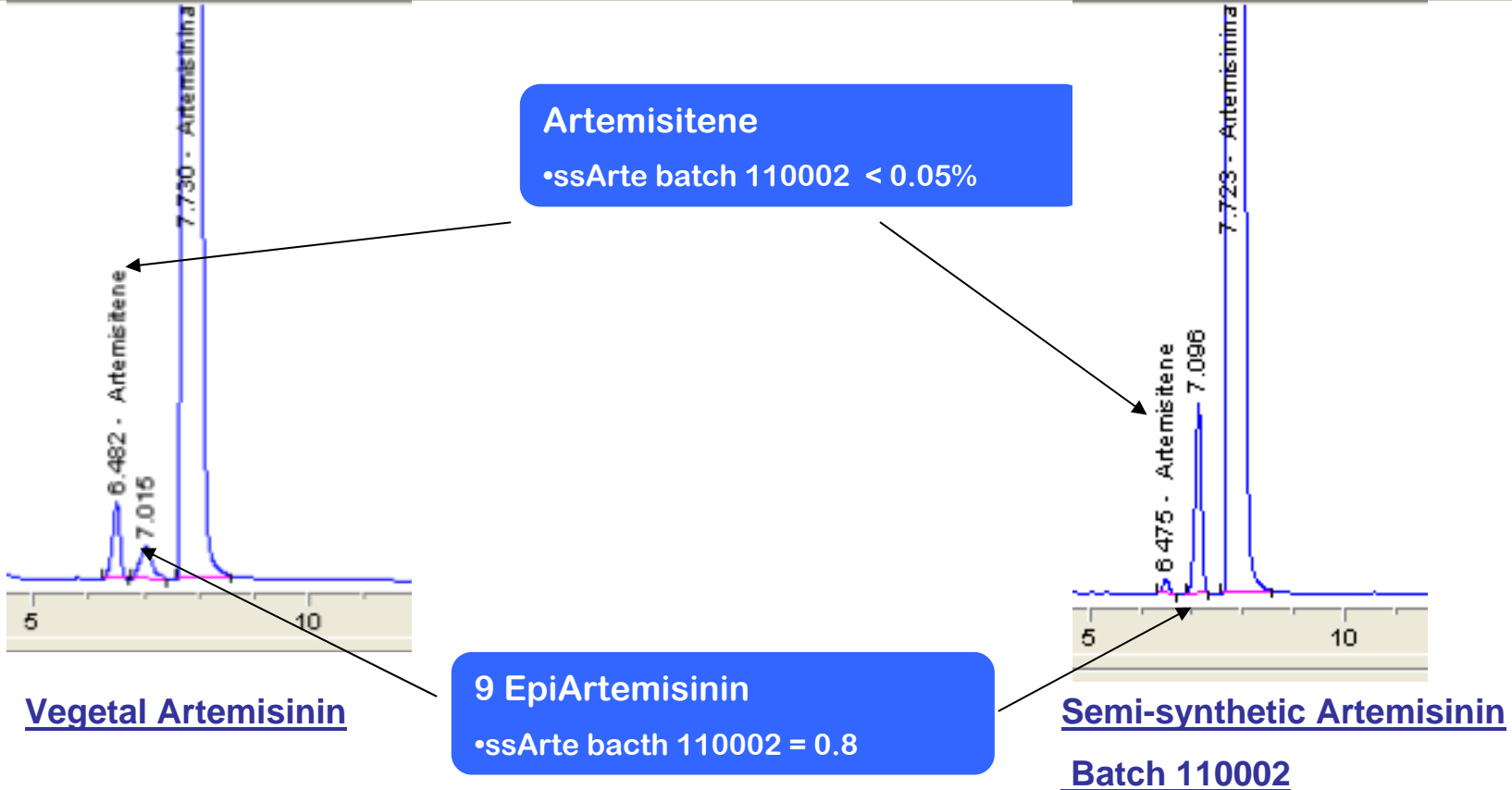
Semi-synthetic Artemisinin – Timeline to Market



Semi-synthetic Artemisinin – Timeline to Market



Semi-synthetic Artemisinin – Analytical data

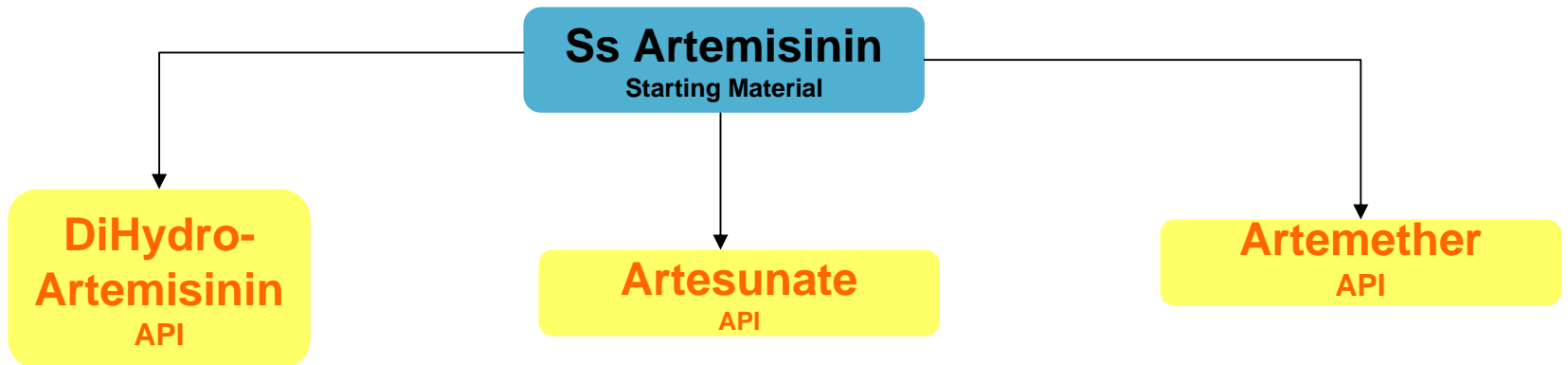


Semi-synthetic Artemisinin was transformed successfully using current chemistry process at Lab. scale to:

- Artesunate
- Artemether
- DHA

Commercial Planning of Semi-synthetic Artemisinin

Alternate Source to vegetal artemisinin
Stable supply and price



- 2013: 40-45 tons
- From 2014: 50 - 60 tons/year
- Material from semi-industrial campaign currently available for testing by potential customers

Thank You

BILL & MELINDA
GATES foundation

Berkeley
University of California



Plant Biotechnology Institute
National Research Council of Canada

