Semi-synthetic Artemisinin Project

The 2010 WHO/MMV Artemisinin Conference
Antananarivo, Madagascar
Presented By Tue H. Nguyen, PhD
The Artemisininin Enterprise

- The Artemisininin Enterprise consists of complementary projects funded by BMGF to improve artemisininin production technologies.

- The semi-synthetic artemisininin project is one of several initiatives to ensure global demand for ACTs can be met.

- With progress achieved to date, iOWH recently received a new grant from the Bill and Melinda Gates Foundation to scale up and commercialize ss-artemisininin.
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 high-quality derivative manufacturers

- Contribute to stabilizing the price of ACTs to benefit patients and payers

- Enable millions of people infected with malaria to gain consistent access to lower-cost, high-quality, life-saving ACTs
The Partnership

RESEARCH AND DEVELOPMENT

- Discovery of the Metabolic Pathway and Identification of Genes from the Wormwood Plant Required to Make Artemisinic Acid
- Construct Biosynthetic Artemisinic Acid Pathway and Clone into Microbial Host
- Optimize Artemisinic Acid Production

- Optimize Microbial Strain
- Develop Scalable Processes for Manufacture and Purification of Artemisinin
- Demonstrate Comparability of Plant Derived Versus Semisynthetic Artemisinin

- Fermentation Process Development
- Chemistry Process Development
- Develop scalable industrial manufacturing process

MANUFACTURING

- Project and Alliance Management
- Enable 2nd Source Artemisinin Uptake ACTs
- Apply WHO Sanctioned Global Health Goals to Malaria ACTs

2005 2006 2007 2008 2009 2010 2011 2012
A Second Source Supplements & Stabilizes the Artemisinin Supply Chain

Cultivation

Months

Extraction

Artemisinin

Fermentation

E. coli
Sugar

Weeks

Chemistry

Artemisinic Acid

DERIVATIVES

ACT Therapy

Controlled Process
Artemisinin As A Starting Material

Artemisinic acid → Artemisinin

Raw material
Defined specifications

Artemisinin

Starting material
Defined specifications

Artesunate
Artemether
Dihydroartemisinin
Arteether
Artelinate

GMP manufacturing

API
Compendial specifications
Anticipated Project Outcomes

- Supplement botanical supply to support projected increased demand for ACTs
- Semi-synthetic artemisinin cost is anticipated to be comparable to high quality field production
- Semi-synthetic artemisinin would be made broadly available to derivative manufacturers
- Pursue chemical substitution regulatory strategy (as starting material) for rapid uptake
Outcomes implies that these things have already occurred. You can use different wording, but since you've already used Goals earlier on, I'm not sure what you want here.

User, 10/4/2010
Thank You