



**A New Class of Malaria Drugs:  
The Coartem Breakthrough from Novartis  
and its Chinese Partners**

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 **NOVARTIS**

 **Coartem**  
artemether lumefantrine

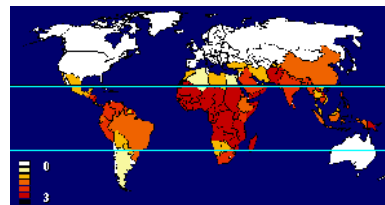
## Agenda

- **Malaria – An African Tragedy**
- A new class of antimalarials – building on Chinese Traditional Medicine
- A short overview of the Coartem program

## Malaria: An African Tragedy!

- 40% of the world population at risk
- 300-500 million clinical cases per year (80% of cases in Africa)
- At least 1 million deaths per year (more than 90% in Africa)
- Children and pregnant women are most at-risk
- Economic burden to African countries is about USD12 billion/year

Malaria index



Source: WHO Roll Back Malaria 2003

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## Strategy against Malaria

Malaria can be prevented and controlled by three main strategies:

### Insecticide Spraying

- Control of the mosquitoes by spraying and drainage of areas where they live
- Indoor residual insecticide spraying (IRS)



### Insecticide-treated Bed Nets (ITN)



### Drug Treatment

- ACT (artemisinin-combination therapies)
- Coartem (artemether – lumefantrine) is the first WHO pre-qualified fixed-dose ACT to be included on the WHO's Model List of Essential Medicines

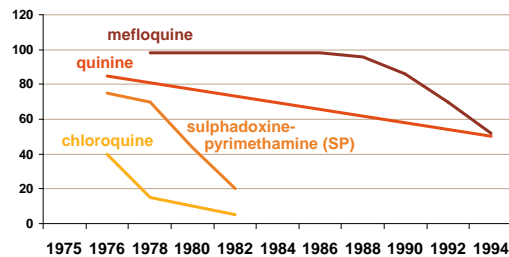


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## The Issue of Resistance... 60-70% Treatment Failures!

- Drug resistance has increased rapidly:
  - Suboptimal dosing
  - Misuse and poor prescribing habits
  - Lack of compliance to the proper dosing regimen by patients



- Serious drug resistance to established therapies e.g. chloroquine and SP exists in much of Africa and South-East Asia (60-70% treatment failure rates); resistance already seen with amodiaquine, especially in East Africa
- World Health Organization (WHO) called for use of artemisinin correctly in combination therapies; in January 2006, WHO called for terminating the distribution and sale of artemisinin monotherapies

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## WHO Malaria Treatment Guidelines (2006)

- Artemether-lumefantrine
- Artesunate-amodiaquine
- Artesunate-mefloquine\*
- Artesunate-SP (sulfadoxine-pyrimethamine)

\*There is currently insufficient safety and tolerability data on artesunate plus mefloquine at the recommended dose of 25mg/kg in African children. Trials with mefloquine monotherapy (25mg/kg) have raised concerns of tolerability in African children

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## A Three-Day Cure to Fight Malaria is Available Now!

- Artemisinin-based Combination Therapy (ACT) is the best available treatment
- ACTs are the only effective treatment in drug resistant areas and are recommended by WHO as first line therapy
- Novartis' ACT, Coartem, is the first fixed-dose artemisinin combination prequalified by WHO



### Coartem provides:

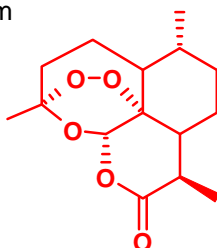
- ✓ **Prompt control of fever in as little as 24 to 36 hours**
- ✓ **Rapid parasite clearance stopping disease propagation**
- ✓ **Cure rates >96% after only three days of therapy!**
- ✓ **Good tolerance throughout treatment**

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## Coartem History

- The active ingredient in Coartem, artemisinin, is a plant-derived product from sweet wormwood or *Artemisia annua*
- Artemisinin is an ancient Chinese medicine used in modern practice
- First used 168 B.C., Coartem was discovered in 1967 by the Chinese to treat malaria-stricken soldiers during the Vietnam war



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## Coartem Development and Manufacturing

- Development of Coartem resulted from collaboration between Novartis (Ciba-Geigy) and Chinese partners in 1994- first collaboration of its kind in Chinese history
- Significant technology transfer from Novartis to Chinese partners underway since 1994
- The product is manufactured by Chinese manufacturers and Novartis in China and USA according to Good Manufacturing Practices (GMPs)
- The product was pre-qualified by WHO and included on WHO Model List of Essential Medicines in 2002

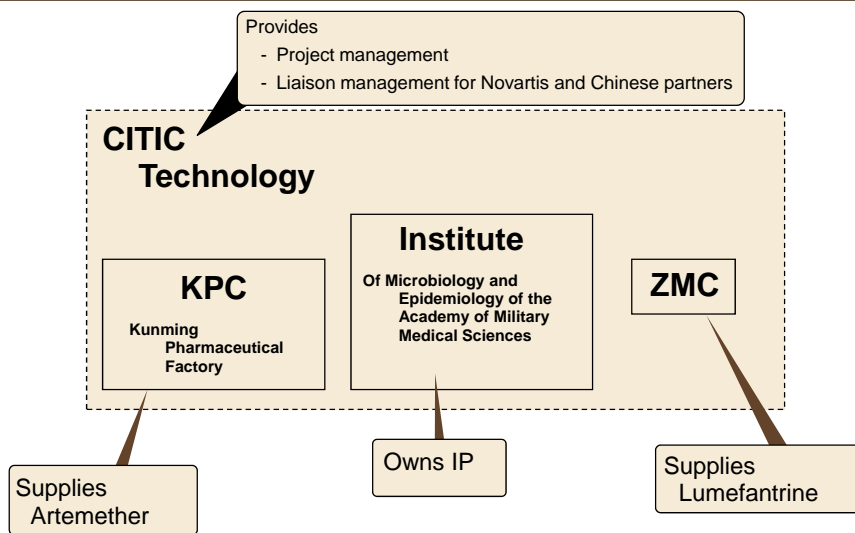


Prof Zhou Yi-qing

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## Collaboration Structure between Novartis and its Chinese Partners



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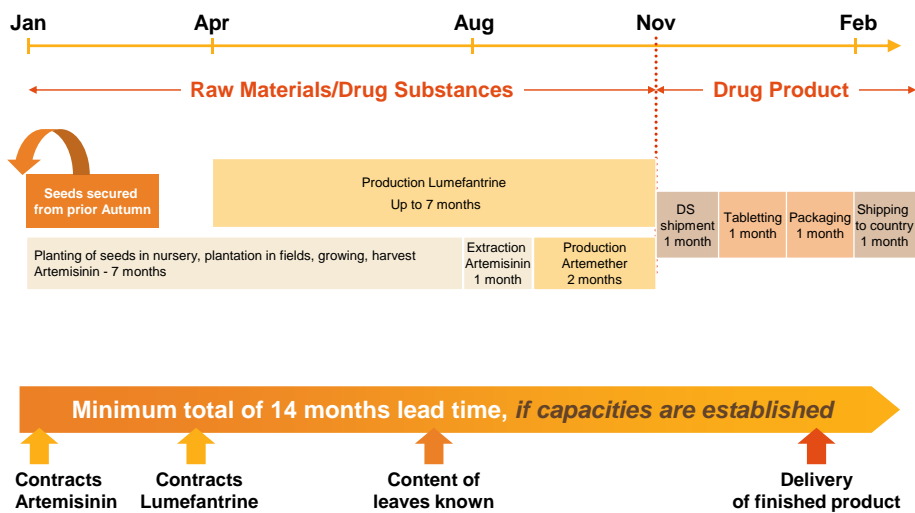
## In 2005, Novartis Took Unprecedented Steps to Ensure Delivery of Millions of Coartem Treatments



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## ACT Production: More Complex than Most Drugs



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## Novartis Commitment to the Fight Against Malaria

- In May 2001, Novartis committed to a unique public-private agreement with WHO
  - To make Coartem available without profit for distribution to public sector agencies in malaria-endemic developing countries
  - To supply Coartem, procured through WHO with funds from donors; grants are provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) to public sector agencies
  - To establish sustainable supply chains for distribution
- In September 2006, Novartis reduced the average price of Coartem from USD 1.57 to USD 1.00 to help expand access to medicine
- In April 2008, Novartis reduced the average price to USD 0.80
- **And...patients in the public sector receive Coartem for free!**

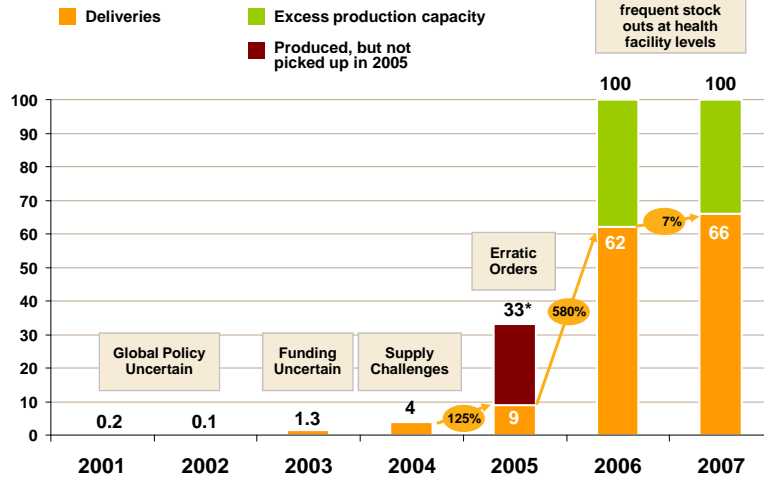
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## The Frame in Which We Operate

### The challenge of unprecedented scale-up

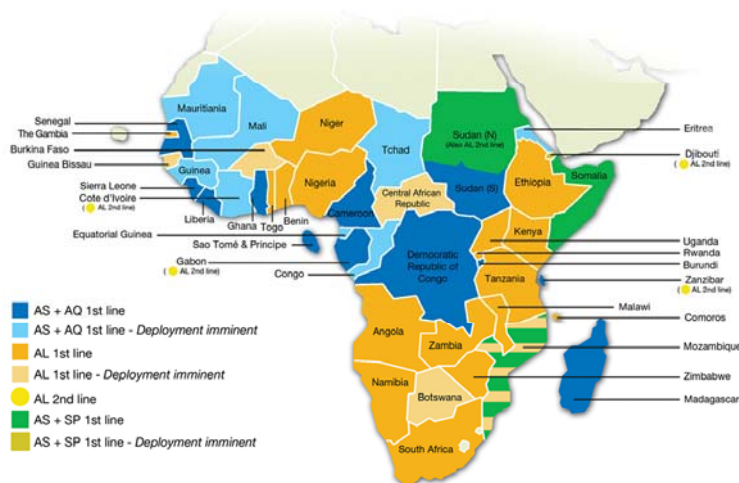
In millions of treatments



\*14 mio Tx were ordered for delivery in 2005, but only 9 mio were picked up  
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## ACT Adoption in Africa



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## Training of Healthcare Professionals

- Coartem/WHO Field training
- Materials consisting of:
  - Training manual
  - Detailed cards
  - Surgery posters
- Produced in 5 official languages and many local languages. All distributed for free in conjunction with WHO



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## Coartem's Impact on Patients

- Novartis scaled up production capacity from 4 million treatments in 2004 to 62 million treatments in 2006, a 15-fold increase over two years!
- Since 2001, >160 million treatments delivered which contributed to saving estimated 450,000 lives
- Novartis, along with its partner Medicines for Malaria Venture, is committed to the development of a pediatric formulation to be launched in 2008



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**Saving Precious Lives**  
An Achievable Goal in Malaria

