



## **MISSION**

**We develop pediatric HIV/AIDS drug products for rare or neglected diseases**

## **VISION**

**We ensure products are affordable and available for children, especially in resource-poor countries**

# **WHY PEDIATRIC HIV/AIDS DRUGS (A CASE STUDY - NIGERIA)**



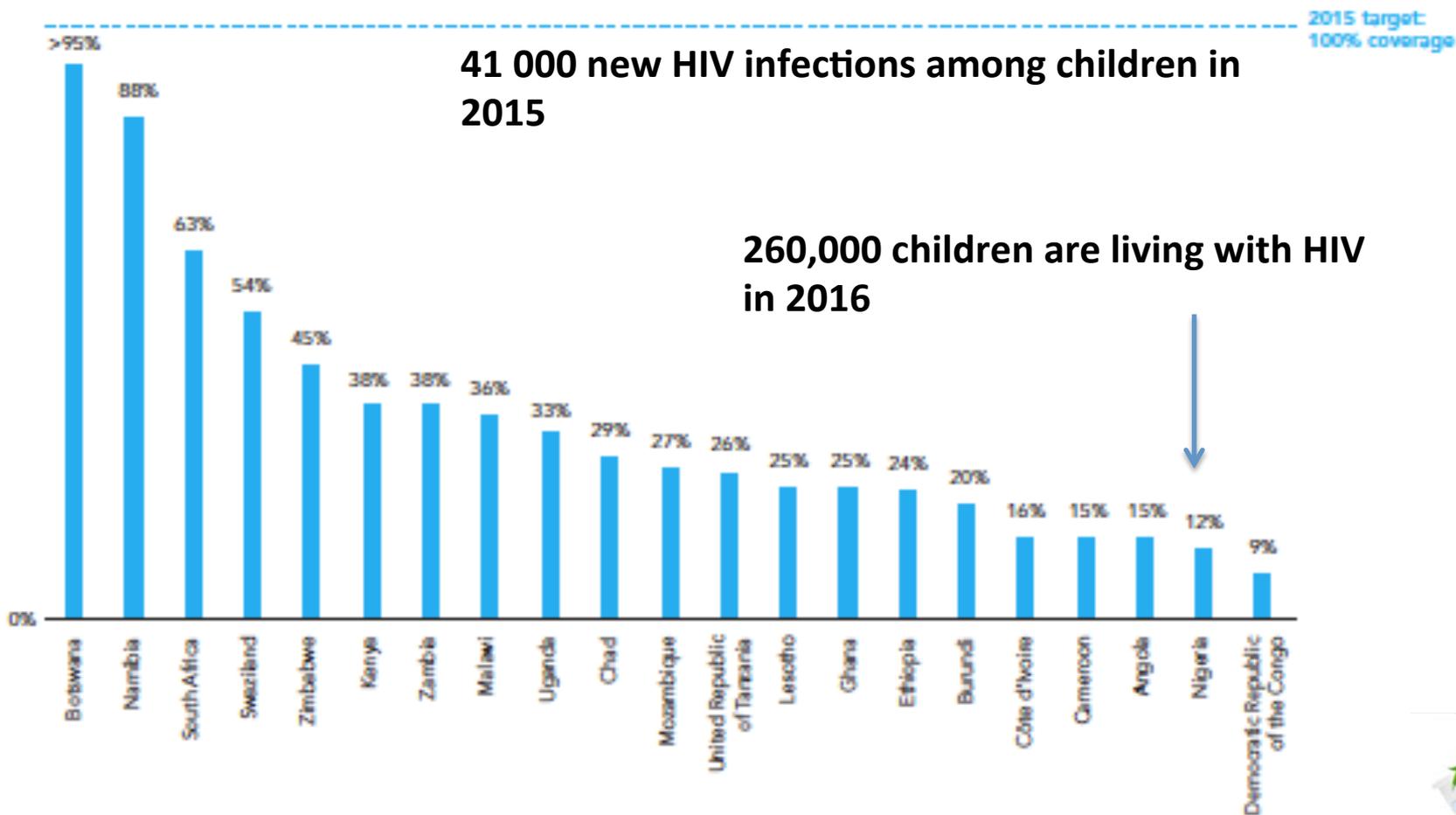
# Global summary of the HIV epidemic in women and children, 2015

	Global	sub-Saharan Africa	% of global
<b>Estimated number of women (15+ yrs.) living with HIV</b>	17,800,000	14,200,000	80
<b>Estimated number of pregnant women living with HIV</b>	1,400,000	1,300,000	90
<b>Estimated number of children (&lt;15 yrs.) living with HIV</b>	1,800,000	1,600,000	87
<b>Estimated number of children (&lt;15 yrs.) newly infected with HIV</b>	150,000	120,000	84
<b>Estimated number of children (&lt;15 yrs.) dying of AIDS-related causes</b>	110,000	91,000	86

Source: UNAIDS 2016 estimates.

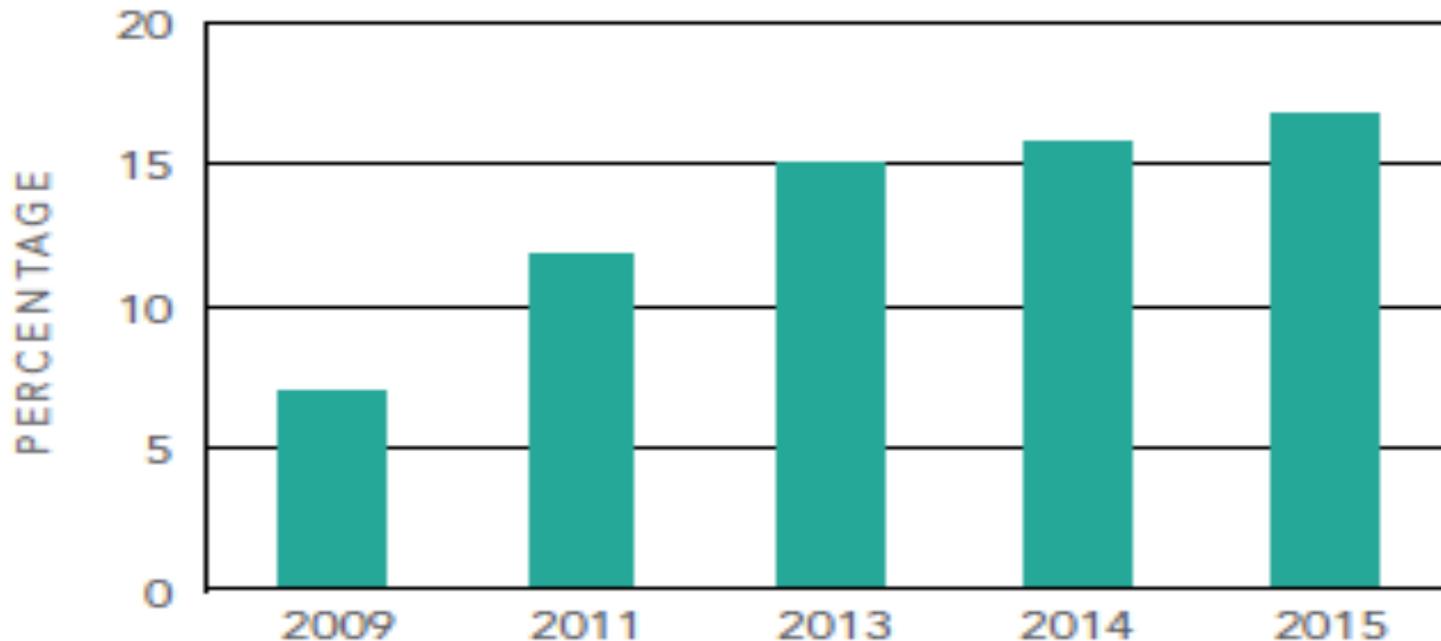


# Percentage of eligible children (0–14 years old) receiving antiretroviral therapy, 2012 (Nigeria)



# ART Coverage Among Nigerian Children

Percentage of children (aged 0–14 years) living with HIV who have access to antiretroviral therapy

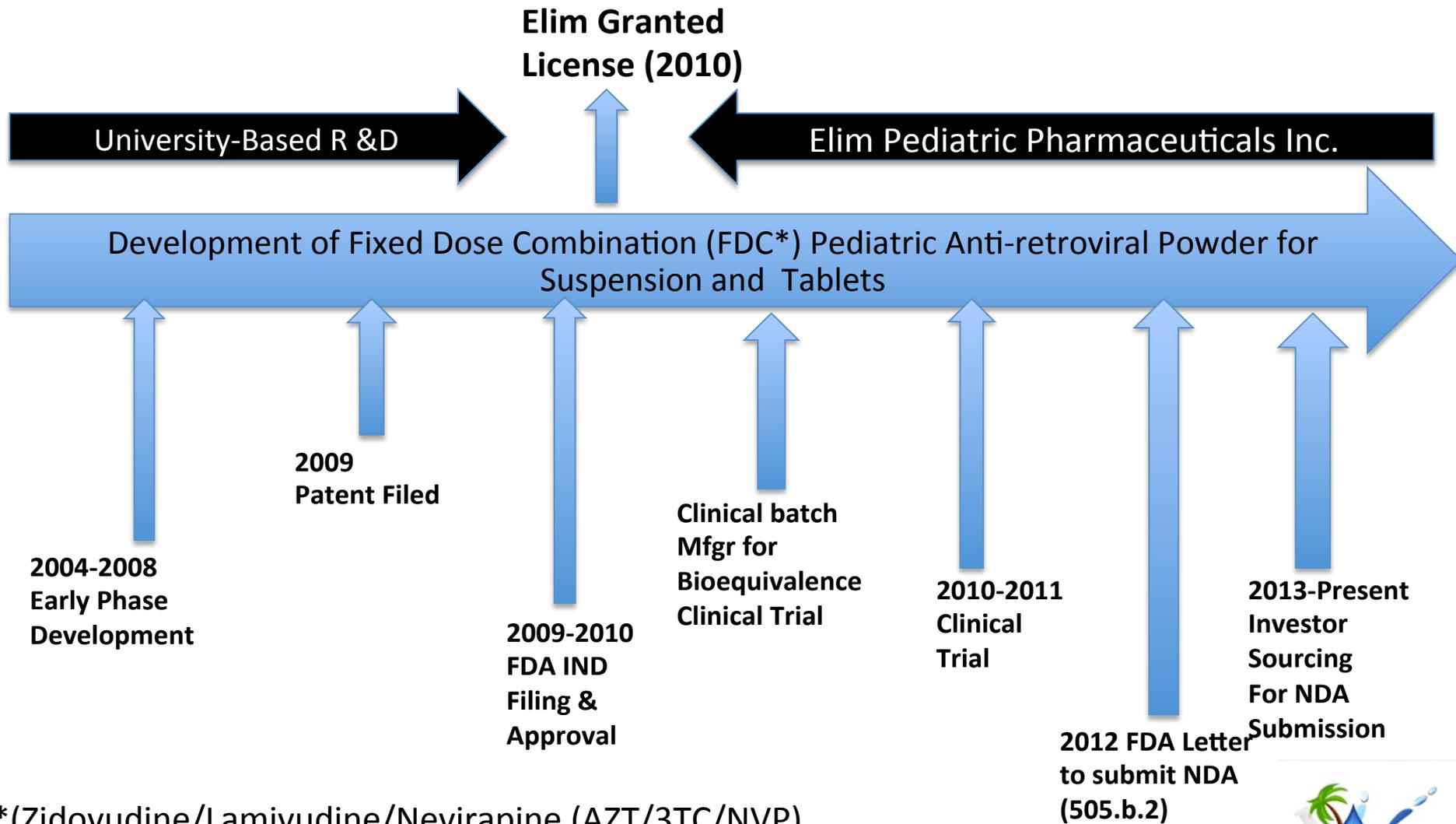


[http://www.unaids.org/sites/default/files/media/documents/UNAIDS\\_GlobalplanCountryfactsheet\\_nigeria\\_en.pdf](http://www.unaids.org/sites/default/files/media/documents/UNAIDS_GlobalplanCountryfactsheet_nigeria_en.pdf)



# Products

## Development Timeline and Growth

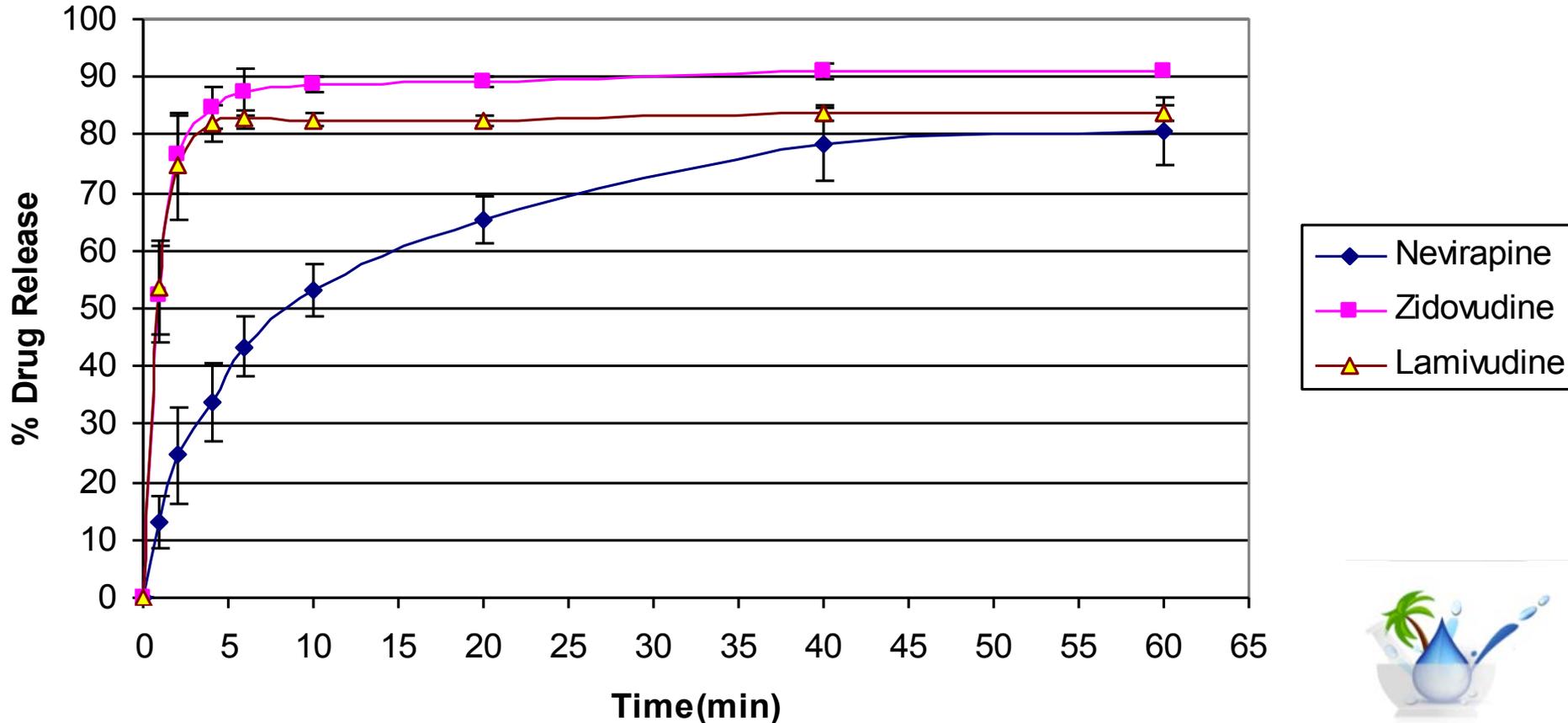


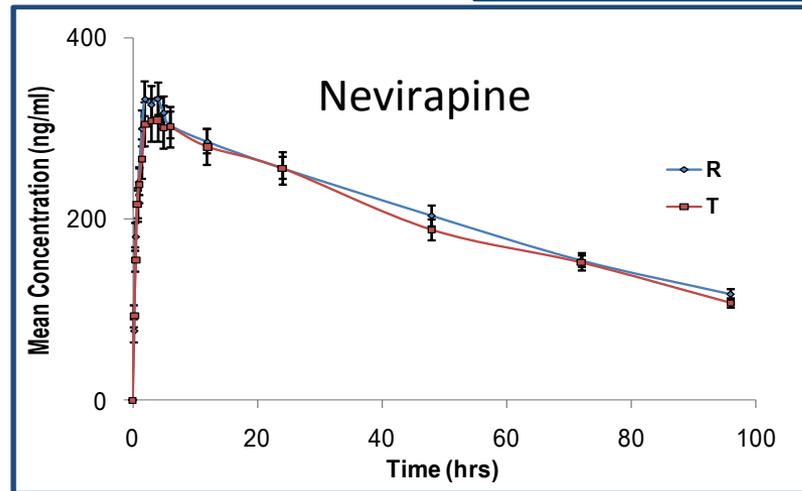
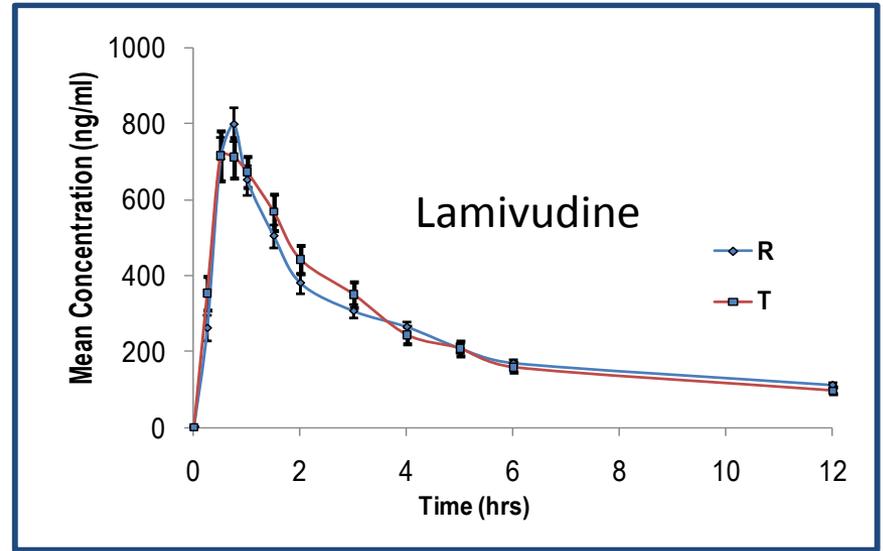
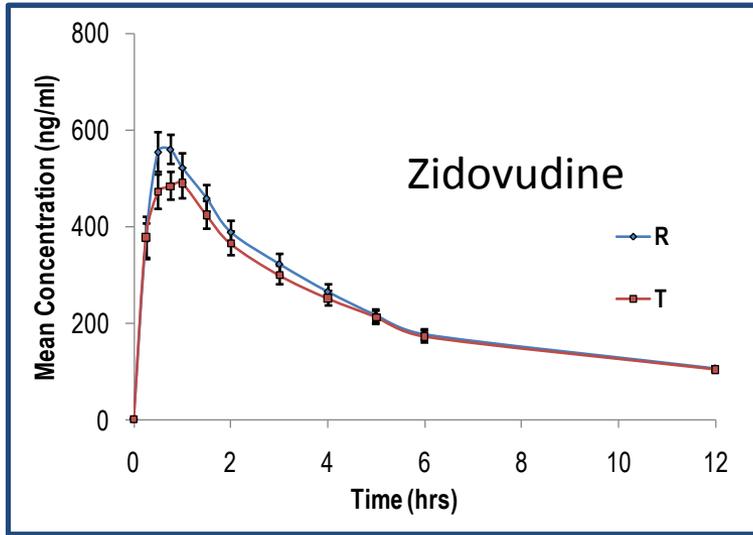
\*(Zidovudine/Lamivudine/Nevirapine (AZT/3TC/NVP))



# PRODUCT PERFORMANCE

## Dissolution Profile of Zidovudine, Lamivudine and Nevirapine in 3 in 1 tablet





**Mean ( $\pm$ S.E) plasma concentration-time profile of test product (T) Vs reference (R) after a single dose administration**

Joshi, A., Gbadero, D., Esseku, F., Adesanya, O. J. and **Adeyeye, M. C.** (2016), A randomized two-way crossover bioequivalence study in healthy adult volunteers of paediatric zidovudine/lamivudine/nevirapine fast-disintegrating fixed-dose combination tablet. J Pharm Pharmacol. doi:10.1111/jphp.12666



# TEAM

- **Dr. Adeyeye**

- Over 30 years of experience in preformulation, formulation development, preclinical and clinical trials
- Developed the two products from her university lab
- Successfully managed the filing of the Investigational New Drug Application (IND)
- Published 60 peer-reviewed manuscripts
- Published 5 Patents including the 2 antiretroviral patents
  - Assigned UK Patent – GB 2479494. 2012
  - US Patent Application – 12/863,111
  - Assigned South Africa Patent Application – 2010/05070
- Research Team (Research Manager (More than 10 years of industry experience) and Pediatrician (37+ years experience))



# Market Opportunities

- **Generic-accessible HIV/AIDS drug market represents 94 % of patients in low- and middle-income countries (LMICs)**
- **The global market was US\$1.52 billion in 2014 and it is expected to increase to US\$2 billion by 2019**
- **In 2014, our product AZT/3TC/NVP is one of the top five formulations used in the treatment of HIV/AIDS**
  - **Currently: Alternative first line treatment**
- **Ref: Clinton Health Access Initiative (CHA)**



# Market Opportunities (Nigeria Example)

- **41,000 new HIV infections among children in 2015**
- **260,000 children are living with HIV in 2016 (Ref: UNAids)**
- **80% of the children are not receiving treatment**
- **Estimated number of children in need of drugs – 240,000**
- **Estimated cost for a year treatment/child**
  - \$120/year
- **If 50% of market is captured = 120,000 children**
  - **Estimated Revenue**
    - **\$120 x 120,000 Or \$14,400,000**



# **Business Model: Key Revenue Streams**

- **AGENCIES AND FOUNDATION FUNDING**
  - **PEPFAR**
  - **Clinton Foundation**
  - **UNITAIDS/WHO**
  - **Melinda and Bill Gates Foundation**
  - **Children's Investment Fund Foundation (CIFF)**
  - **Individual Countries (Less Revenue Stream)**



# Point-of-Care Treatment/Business Strategy

- **Collaboration with funding agencies and country Ministry of Health**
- **Goal: To ensure accessibility of children to treatment**
  - **Treatment and monitoring of adherence of use of antiretroviral drugs in selected community pharmacies**
    - **Leveraging Dr. Adeyeye's experience**
      - **Registered pharmacist in Nigeria**
      - **Conducted studies on prevention of mother-to-child (PMTCT)**
        - » **Testing of 9,8000 women in three states of Nigeria to identify sero-positive women**
        - » **Coordinated caesarean delivery of 45 babies of some of the sero-positive women in one hospital**
        - » **Organized HIV/AIDS prevention and education campaigns to about 4000 secondary schools students in three states of Nigeria**



# COMPETITION

**Cipla**

**Mylan**

**Strides**



# INVESTMENT

- **Funding for NDA (505.b.2) Filing and Post-approval Marketing**
  - 2 million dollars
- **Networking to buyer agencies/foundations**

