

# Mylan a champion in the fight against Infectious Disease

**\$250M**

INVESTED IN  
EXPANDING ARV  
PRODUCTION  
CAPACITY

to enable

**4B**

ARV TABLETS  
AND CAPSULES MADE  
EACH YEAR

thanks to



TOTAL COMPANY  
API CAPACITY  
DEVOTED TO ARVS

More than 8 million people, nearly half of all patients on treatment for HIV in developing countries, depend on a Mylan antiretroviral every day.



## MYLAN HAS A STRONG – AND DISTINCTIVE – FOCUS ON INFECTIOUS DISEASE IN THE DEVELOPING WORLD

Mylan's commitment to providing patients in developing countries with access to high quality medicine is unique among Western pharmaceutical companies. For example: We are – by far – the world's largest producer by volume of antiretroviral (ARV) drugs. Nearly half of the approximately 16.5 million people currently on antiretroviral therapy (ART) in developing countries (out of a total of 18 million worldwide) use a Mylan ARV every day. That's more than 8 million people, compared to 1.5 million on any ARV treatment in the U.S. and Western Europe combined.

We believe that people everywhere deserve access to life-saving medications. To that end, we have invested more than \$250 million to expand our ARV production capacity, and we now manufacture more than 4 billion ARV tablets and capsules each year. Today, more than 50% of our company's active pharmaceutical ingredient (API) manufacturing capacity is devoted to ARVs.

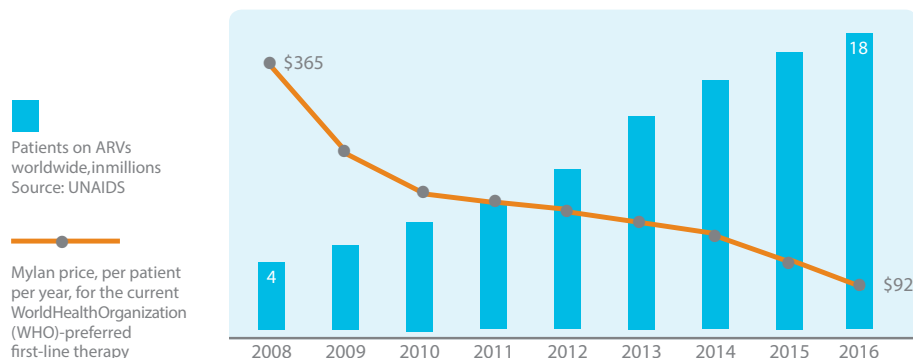
## WE HAVE BEEN A LEADER IN INTRODUCING NEW GENERIC MEDICATIONS AND DRIVING DOWN PRICES

We know that developing vital drugs doesn't matter if people can't access them. In 2009, with a license from the branded originator and approval from the U.S. Food and Drug Administration (FDA), we introduced the first generic one-tablet-once-a-day combination for developing countries – only three years after the originator product launched in the U.S. (In contrast, low-cost generic versions of other critical ARVs have taken nearly a decade or longer to reach patients in the developing world). At the time, we were able to price it for developing countries at less than half the originator's price. Though we continued to be the product's sole generic supplier for nearly three years, we cut its price further – by more than half – over that period. Today, our price is less than one quarter of what it was at launch.

These savings add up: For this combination alone, Mylan and other generic manufacturers save the U.S. government, other international donors and national programs more than \$4.5 billion every year compared with the current originator list price for developing countries.

We have been able to achieve these cost reductions without sacrificing reliability. In fact, several times over the past two years Mylan has been asked to step in when other companies experienced breaks in supply.

## Ensuring Access to Life-Saving Medications Worldwide



# Mylan a champion in the fight against Infectious Disease

## INNOVATING TO SATISFY UNMET NEEDS



### Cost savings

First company to market, in 2017, with a reduced-dose, lower-cost version of the WHO's current recommended first-line HIV regimen



### Heat stable

First generic drug maker to develop a heat-stable version of a drug critical for second-line regimens



### Pediatrics

Developed child-friendly forms of the current WHO-recommended pediatric HIV drug combination



### Convenience

Developing multi-month tablet packs as prioritized by PEPFAR



### Next generation

Working to be first to market with next-generation, lower-cost, HIV therapies

## WE INNOVATE TO MAKE MEDICINES ACCESSIBLE TO PATIENTS AROUND THE WORLD

Patients in developing countries often have different needs than those in the U.S. and Europe. Meeting them is the mission of the 350 Mylan colleagues in our R&D group who work on infectious disease, finding new processes and formulations to make our drugs more cost-effective and patient-friendly.

A great example is our work to extend treatment to HIV-positive children. In developed countries, children's medicine often takes the form of syrups. But these can be bulky for parents to store, heavy and difficult to transport, and sometimes need refrigeration. Our scientists developed heat-stable, taste-masked, dispersible tablets that are easily dispensed and incorporated into children's food. And we haven't stopped there. We now are launching a version for infants in the developing world that comes in the equivalent of a sugar packet: granules in a sachet that can be mixed into fluids that even newborns can take.

Another example of our innovation: We were the first generics company to market heat-stable formulations of second-line medicines for adult patients who develop resistance to initial ARVs. Since 2009, in fact, Mylan has been the first to market with nearly half of new products approved under the FDA's U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program.

Mylan also supports clinical trials focused on finding new approaches to treating HIV. For instance, we provided study medications to support the Kirby Institute's ENCORE1 trial, which developed a reduced-dose version of the world's most commonly used regimen. This version is designed to be just as effective as the original but use less API in each tablet, making it less costly to produce and saving money for governments and donors.

We support such trials not because we'll gain any marketable intellectual property – we won't – but because it's the right way to advance the science and improve treatment.

We also have submitted for approval under the FDA's PEPFAR program our application for a single-tablet version of the next-generation ARV combination. Further, we are working to develop multi-month packs for our products. These have been identified as a PEPFAR priority, to spare patients from having to make long, costly journeys to refill their prescriptions.

Since our founding in 1961, Mylan has been a champion for those living with or at risk for infection. An antibiotic, in fact, was our first-ever product approved by the U.S. FDA. We are proud of our commitment to fighting HIV and look forward to leveraging our investments and expertise to stem the tide of other infectious diseases, such as tuberculosis, viral hepatitis and malaria.



**Product Inquiries:**  
Arvind.Kanda@mylan.in

**Media Relations:**  
Communications@mylan.com

**Government Relations:**  
GovernmentRelations@mylan.com

Stay Connected: [Mylan.com](http://Mylan.com)

