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Cipla and DNDi to develop cut-price paediatric antiretroviral combination
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Cipla and the Drugs for Neglected Diseases initiative (DNDi) have announced a collaboration to develop a four-in-one antiretroviral (ARV) combination for HIV-infected children.

The Indian company said that it will provide its recently produced lopinavir/ritonavir 40mg/10mg sprinkle formulation (Lopimune Sprinkles) and work with the DNDi and other partners to test new combinations of HIV treatments for infants and young children.

Cipla, which claims to be the largest single supplier of HIV and antimalarial drugs in the world by volume, expects to produce a sachet product, in which four ARV drugs will be taste-masked and in granular form, for easy mixing into food or liquids such as water, juice or breast milk. Registration of the drug is anticipated by 2015.

The alliance hopes to offer a cut-price final ARV product in the public sector at substantially lower than the cost of the products used separately. Both partners will establish a detailed drug access and implementation plan to ensure that the product reaches patients.

Cipla's chairman and managing director, Dr Yusuf Hamied, said that the company had been working with the Medical Research Council Clinical Trials Unit (MRC CTU) in the UK and their paediatric colleagues in Zambia and Uganda for many years producing several "baby pill" formulations for infants and children. "Cipla and DNDi are now joining forces to produce further drug formulations for HIV-infected children in poor countries," Dr Hamied said.

The initial data on the lopinavir-ritonavir sprinkle - being generated by Ugandan paediatricians and the MRC CTU in alliance with Cipla in the CHAPAS 2 trial - would be essential for DNDi and its partners to develop a first-line therapy in a fixed-dose combination. This would be Lopimune Sprinkles plus one of two other ARV drug combinations, abacavir/lamivudine or zidovudine/lamivudine.

The primary outcomes of the CHAPAS-2 study include determining the pharmacokinetics of ritonavir-boosted lopinavir (LPV/r) in a twice daily paediatric co-formulated, fixed-dose sprinkle combination (Lopimune) and comparing it to LPV/r in a twice-daily paediatric co-formulated syrup (Abbott Pharmaceuticals), both with food, in HIV-infected African infants under one year of age.

intellectual property

Cipla will handle production, registration and distribution of the product being developed under the alliance with the DNDi and will retain all intellectual property related to the new formulations.

The company said that should it opt out as industrial partner, the DNDi will get non-exclusive, worldwide, royalty-free licences to the intellectual property.

More than 600 HIV-positive children die every day and the DNDi said that the partnership with Cipla and other collaborators provided a "critical path" to develop better paediatric antiretroviral formulations for the youngest, most vulnerable patients living with HIV/AIDS. An estimated 3.4 million children have HIV/AIDS, but less than a quarter currently have access to antiretroviral therapy, compared with 54% of adults.

Current therapeutic options for HIV-positive children have their limitations. For example, the lopinavir-ritonavir protease inhibitor combination, mainly used in South Africa, has problems such as poor taste, impractical multiple liquid preparations that are cumbersome to transport, requirements for refrigeration, and negative interactions with tuberculosis drugs.

Cipla and DNDi say the new four-in-one ARV combination aims to target HIV-infected children under the age of three, including those who have been exposed to drugs while in the womb, and also those co-infected with tuberculosis.