ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES

Mr. Clifford Samuel

Vice President, International Access Operations

Gilead Sciences

Geneva, 16 Feb 2017

Dear Mr. Samuel,

In September 2016, Gilead extended its program to donate Liposomal Amphotericin B (L-AMB) via WHO to six countries with endemic kala-azar through $20 million in funding and drug donations. In addition, we understand that other low- and middle-income countries (LMICs) are able to procure L-AMB at the not-for-profit cost of approximately US$16.25 per vial, provided it is for the indication of treatment of kala-azar, or visceral leishmaniasis.

Amphotericin B, in combination with flucytosine, is also the gold standard for the two-week induction phase of treatment of cryptococcal meningitis[1]. Cryptococcal meningitis is a disease that affects hundreds of thousands of people with HIV every year, and is the cause of 15-20% of AIDS-related deaths[2]. The mortality rate of cryptococcal meningitis is high in LMICs at around 70% in routine care with the available sub-standard fluconazole induction therapy, and 100% without treatment. There is no indication currently that the number of cases of cryptococcal meningitis in LMICs is declining despite the roll out of ART. Studies have shown a 58% response rate in HIV patients treated with L-AMB[3]. The liposomal formulation of Amphotericin B has been shown to have comparable efficacy to conventional amphotericin B but causes significantly less nephrotoxicity[3,4] (which is associated with increased mortality[5]), and yet it is not recommended as the preferred first-line treatment because of cost.[1] It is hoped that treatment with L-AMB could eventually be reduced to one high dose (backed by oral therapy), as suggested by very promising results from a phase II study, supported by Gilead, reported this week at CROI, showing similar rates of clearance of infection with one high dose compared to daily therapy[6]. Currently however, people in the most resource-constrained settings – where monitoring is challenging – would stand to benefit most from this medicine, yet they are least likely to be able to access it. In developed countries, L-AMB is the preferred formulation for the induction phase treatment of cryptococcal meningitis[2].

The undersigned request that Gilead expand its not-for-profit price of L-AMB to include the indication of cryptococcal meningitis for all LMICs, where the disease burden is greatest, such that people with HIV may access the best possible treatment with fewer side effects, regardless of where they live.

Given the complex manufacturing process of L-AMB and the supply chain instability and delayed deliveries over the past year, we also request that Gilead ensure adequate capacity for production of L-AMB, or allow for technology transfer to interested generic companies, to permit other manufacturers the ability to enter the market and provide access to quality-assured L-AMB, as countries add it to their HIV/cryptococcal meningitis guidelines and begin implementation for treatment of advanced-stage HIV.

We are looking forward to hearing from Gilead regarding this request. For further discussion, please feel free to contact Jessica Burry or Rohit Malpani at MSF Access Campaign.

Sincerely,

Sophie Delaunay

Executive Director

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