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## Dual bNAb HIV treatment well tolerated in children

ata from the Tatelo Study conducted by the Botswana Harvard AIDS Institute (BHP) has shown that treatment with broadly neutralizing antibodies (bNAbs) has helped to maintain viral suppression for 24 weeks without ART in 44% of early-treated children with HIV. BHP Board Chair and Principal Investigator of the study, Prof Roger Shapiro said this when sharing data from the study with the Ministry of Health and Wellness (MOHW) on March 16, 2022.

Prof Shapiro's presentation to MOHW followed his presentation at virtual CROI 2022. Tatelo Study was a single-arm clinical trial performed among children living with HIV in Botswana and it evaluated monthly intravenous infusion of two bNAbs (VRC01LS and 10-1074) as an alternative to ART in a cohort of very early ART treated children who were virally suppressed.

Study participants were recruited from the Early Infant Treatment (EIT) cohort, who had received continuous ART from the first week of life. Only one child with intrapartum infection started ART at 31 days. To be eligible for inclusion, children had to be at least 96 weeks or older and had HIV RNA < 40 copies for at least 24 weeks prior to entry.

The study had 3 Steps: In the first step, participants received ART + dual bNAbs for 8 weeks. In Step 2, after the ART + bNAb overlap period was completed, ART was withheld and treatment with VRC01LS and 10-1074 was continued for up to 24 weeks. HIV RNA was checked every 1-2 weeks. Children entered Step 3 if any HIV RNA value reached 400 copies/mL, or at 24 weeks. In Step 3, bNAbs were discontinued and ART was restarted. Intravenous bNAbs infusions were given once every 4 weeks.

Of the 40 children who had been followed in the EIT cohort, 28 were eligible and consented to enroll in Step 1 of the study. The first 6 children underwen 32



BHP Board Chairman and Principal Investigator of Tatelo Study presenting findings on the study at the Ministry of Health & Wellness

weeks of bNAbs + ART overlap, and the remaining 22 underwent 8 weeks of overlap. During this overlap period with ART, 3 children had viral rebounds (all in the 8-week overlap group). bNabs were discontinued in these 3 children, and each re-suppressed with adherence efforts alone while continuing ART. Twenty-five (25) children were moved to Step 2, where ART was withheld and bNAbs were continued alone.

Among the 25 children who stopped ART: 11 (44%) maintained HIV RNA <40 copies/mL through 24 weeks of bNAb-only treatment. These children were categorized as successes, with a 95% confidence interval of 24%-65%. One child in this group had a single HIV RNA value of 234 copies/mL at week 16, then returned to <40 copies for the remaining visits.

Fourteen children (56%) had viral rebound to >400 copies before completing 24 weeks of bNAb-only treatment. The Median time to failure was 4 weeks and ranged from 1 to 20 weeks. These results exceeded the study's pre-defined threshold for success (which was 30%).

On characteristics of success, Prof Shapiro noted that children with longer ART + bNAb overlap were more likely to succeed: 5 of 6 (83%). Children enrolled earlier in the study as well as those with favorable clinical and reservoir characteristics were also more likely to succeed.

Importantly, for all children, there were no concerning pattern of CD4 decline. "There were no infusion reactions reported and bNAbs were well tolerated. bNAb concentrations were measured as adequate," said Prof. Shapiro.

He further noted that "newer bNAb combinations with greater breadth and potency used in children with favorable pre-treatment characteristics and possibly with longer bNAb/ART overlap, may improve treatment success for this novel ART-sparing strategy."

He said that bNAbs could be a favorable option and form of HIV treatment in the future as opposed to ART as long-term ART has adherence challenges and side effects. He said bNAbs suppresses HIV-1 RNA and may deplete residual viral reservoirs hence low viral reservoir and limited HIV diversity may be associated with successful outcomes. He also stated that Children who received early ART might be an ideal group to treat with bNAbs.

## BHP updates MOHW on Tsepamo Study progress

Botswana Harvard AIDS Institute Partnership (BHP) on March 16,2022 updated the Ministry of Health and Wellness (MOHW) on the progress of Tsepamo Study. Tsepamo study is an observational surveillance Study of birth outcomes in 16 public hospitals throughout Botswana. The primary objectives of the study include; comparing birth outcomes (stillbirth, preterm delivery, small for gestational age, congenital abnormalities and in-hospital neonatal deaths) among HIV-infected women and HIV-uninfected women, and initially, to determine whether there is increased neural tube defects among children born to women on TDF/FTC/EFV (Atripla).

The update covered the current status of the study and the next steps for expansion. Updating on the study accomplishment since it started in August 2014, Study Coordinator Modiegi Diseko reported that, of 222,018 deliveries, 6017 abnormalities have been reported. Of these 1346 were major congenital abnormalities/ neural tube defects. 1265 women consented for direct assessment of congenital abnormalities by specialists.

She further updated that following an initial signal for potential association of Neural Tube Defects (NTDs) associated with dolutegravir (DTG) exposure from conception, the most recent prevalence of 9 NTDs among 5,860 exposures is much lower than the original findings in 2018. She noted that it remains unknown why initial NTD prevalence was much higher in 2017-2018. There are plans however for complete analysis of all major congenital abnormalities in late 2022.



Tsepamo Study Coordinator, Modiegi Diseko updating the Ministry of Health and Wellness on study progress

On Birth Outcomes, the study has observed a strong association between "legacy" antiretroviral therapy (ART) and stillbirths as well as other adverse outcomes. The study has also observed high risk for adverse birth outcomes for adolescents, especially with HIV, vertically infected women on legacy regimens, women with hypertension in pregnancy, women with high and low weight, women with syphilis and COVID-19 as well as Non-citizens prior to 2019, before ART guidelines changed to offer ART to non-citizens.

"We have also observed decreased adverse birth outcomes after initial COVID-19 lockdown period, and some seasonality observed, lowest in September. Also observed is high antibiotic use in pregnancy for which there is an ongoing analysis," said Diseko.

Diseko highlighted that Tsepano study has been refunded through 2026 resulting in an extension of the study to analyze new ART regimens in a continuation Study to be called Tsepamo Plus.

"There is a plan for ongoing analysis of all new ART regimens added to the national programme to determine the safest regimens for use in pregnancy including TAF, and long-acting Cabotegravir through 2026. The study will also look at maternal outcomes, birth outcomes and congenital abnormalities. Finally the study will also track HIV prevalence over time in pregnant women, and provide background data for other studies and programmes," she said.

## Civic Leaders welcome Astra Zeneca Vaccine Study



Dr Emily Shava, Study Coordinator for AstraZeneca Study

ouncilors at four Local Authorities being Gaborone City Council, Selebi Phikwe Town Council, Central District Council in Serowe and Northwest District Council in Maun have described the Astrazeneca Vaccine Study being conducted by the Botswana Harvard AIDS Institute Partnership (BHP) as a welcome development that will generate Botswana specific data on COVID-19 vaccines. This follows a presentation to Full Council Meetings at the respective councils to introduce the study to civic leaders so that they can spread the information to their constituents and encourage them to participate.

The study called "Open-Label, Single-Arm, Phase 3b Study of the Incidence of Severe COVID-19 and Adverse Events Following AZD1222 COVID-19 Vaccination in Botswana Against SARS-CoV-2" is being conducted in five regions; Gaborone, Francistown, Selebi Phikwe, Serowe/Palapye and Maun. BHP in collaboration with the Ministry of Health & Wellness (MOHW) and AstraZeneca are conducting a study among individuals willing to be vaccinated with AstraZenca COVID-19 Vaccine to assess the occurrence of severe COVID-19 disease among individuals vaccinated with two doses of AstraZenca vaccine as well as to assess adverse events among individuals vaccinated with at least one dose AstraZeneca vaccine overall and by age group, comorbidity group, number of vaccine doses, and the time since the first or second dose.

This is a single-arm, open-label, interventional, Phase 3b study to determine the incidence of laboratory-confirmed COVID-19 hospitalizations, disease severity, and deaths and attributable adverse events (AEs) in subjects in Botswana given 1 to 2 injections of AstraZeneca Vaccine 8 to 12 weeks apart and followed up to 12 months following the first vaccination dose.

All participants will be assessed for efficacy and safety. A convenience sample of 3,000 of the first 50,000 participants enrolled at designated study sites will also participate in a sub cohort assessing the reactogenicity and immunogenicity of AstraZeneca vaccine and occurrence of symptomatic SARS-CoV-2 infection. The study aims to recruit up to 100,000 adults aged 18 and older not vaccinated or already vaccinated with any COVID-19 vaccine and willing to boost with AstraZeneca Vaccine. As of March 31, 2022, the study has enrolled 8972 study participants.

The total planned duration of study participation for each participant is approximately 12 months: 1 day for enrolment, signing of informed consent, and receiving the first vaccination of AstraZeneca; a second vaccination between week 8 (day 56) and week 12 (day 84); and a 12-month monitoring period starting at Day 0 (date of first

vaccination). As a single-arm study all study participants will receive the same vaccination dosages.

Councilors across the four Councils have hailed BHP for the study, stressing the local data conducted among Botswana communities as contribution to science and most importantly as necessary data that will help inform health polices that will save lives. Some councilors openly pledged to participate in the study thereby leading by example to raise public confidence in participating in human research and in the safety and efficacy of COVID-19 vaccines in particular.

The District Health Management Teams (DHMTs) and Vaccine Committees in the five regions have also pledged their support. Some DHMTs have provided space and furniture to be used by the study teams while others have facilitated other different logistics as well as helping spread the message about the study.

## Botswana records low adverse birth outcomes following lockdown

Botswana has recorded modest adverse birth outcomes during and after the COVID-19 national lockdown that was imposed on the nation in response to the COVID-19 global pandemic. Tsepamo Study Coordinator, Modiegi Diseko when presenting findings from a birth outcomes study at the Health Research Results Dissemination Forum recently, said this. The virtual Forum that was held under the Theme: "When Botswana research "SPEAKS" in the era of COVID-19" was meant to share results from different studies across different disciplines that focused on COVID-19.

The Botswana Harvard AIDS Institute Partnership (BHP) conducted a study that evaluated the association between the COVID-19 lockdown and the risk of adverse birth outcomes in the country during the national lockdown. The study evaluated data from an ongoing nationwide birth outcomes surveillance study (Tsepamo Study) to evaluate adverse outcomes and severe adverse outcomes recorded at three time points; pre lockdown from January 1, 2020 to April 2, 2020, during lockdown from April 3, 2020 to May 7, 2020, and post lockdown from May 8, 2020 to July 20, 2020.

The data was abstracted from the maternity obstetric record at the time of delivery from all women delivering at selected hospitals throughout the country. Diseko revealed that adverse birth outcomes decreased from the prelockdown to post lockdown periods in 2020, relative to the change during the same periods in 2017-2019. Adverse birth outcomes included stillbirth, preterm birth, small-forgestational-age fetuses, and neonatal death while severe adverse outcomes that included stillbirth, very preterm birth, very-small-for-gestational-age fetuses, and as well as neonatal death.

"We used difference-in-differences analyses, and we compared the net change in each outcome from the prelockdown to lockdown periods in 2020 relative to the same 2 periods in 2017-2019 with the net change in each outcome from the prelockdown to post lockdown periods in 2020 relative to the same 2 periods in 2017-2019," Diseko explained the study method.

She stated that 68,448 women delivered a singleton infant in 2017-2020 between January 1 and July 20 and were included in the analysis. Across the included calendar years and periods, she said the risk of any adverse outcome ranged from 27.92% to 31.70%, and the risk of any severe adverse outcome ranged from 8.40% to 11.38%.

Diseko said that the lockdown period was associated with a 0.81 percentage point reduction in the risk of any adverse outcome (3% relative reduction) and a 0.02 percentage point reduction in the risk of any severe adverse outcome (0% relative reduction).

The post lockdown period was associated with a 1.72 percentage point reduction in the risk of any adverse outcome (5% relative reduction) and a 1.62 percentage point reduction in the risk of any severe adverse outcome (14% relative reduction).

"Reductions in adverse outcomes were largest among women with human immunodeficiency virus and among women delivering at urban delivery sites, driven primarily by reductions in preterm birth and small-for-gestationalage fetuses and these findings may provide insights into associations between mobility and birth outcomes in Botswana and other low- and middle-income countries," she said.

### Dr Moyo wins German Africa Award



Dr Sikhulile Moyo, BHP Laboratory Director

BHP Laboratory Director, Dr Sikhulile Moyo and fellow scientist, Tulio de Oliveira of South Africa have been chosen as winners of the German Africa Award 2022 by the German Africa Foundation for the roles they have both played in the discovery of the Omicron SARS-CoV-2 variant in November 2021.

According to the Secretary General of the German Africa Foundation, Sabine Odhiambo, nominations for the German Africa Award are sent in by German embassies in Africa as well as by a number of German institutions with offices in African countries and by African diaspora organisations in Germany. This year, 25 candidates were presented to the independent jury and Dr Moyo and Tulio emerged the joint winners.

"I am very glad and honoured to inform you that the jury came to the conclusion to award this year's German Africa Award to you two as the leaders of the research teams that, among others, discovered the Omicron variant. By discovering and immediately reporting the new variant to the WHO, you made a huge contribution to the worldwide fight against the pandemic and set new standards for excellent research, cooperation and integrity," said Odhiambo in his communication to the winners.

He also highlighted that the award also "shines a light on the excellent research facilities and relations on the African continent that unfortunately do not receive the acclaim they should in Germany and Europe as was seen during the unreasonable reaction of European countries to the discovery of Omicron in form of the infamous travel restrictions."

According to the Secretary General, the Foundation has been committed to strengthening German-African relations for more than 40 years As a non-partisan political foundation, mainly funded by Germany's Foreign Ministry, with the main mandate being to support the implementation of Germany's Africa policy guidelines by organizing exchanges, political discussions and expert talks between German and African political, economic and scientific stakeholders and promoting a differentiated image of the African continent both in politics and in public.

Since 1993 the Foundation has been awarding the German Africa Award to outstanding personalities on the continent who have contributed to democracy, peace, human rights, arts and culture, economic development, science and society in an outstanding manner.

Dr Moyo has been invited to receive the award during a festive ceremony in Berlin during autumn where he will attend meetings in parliament, with ministries, research and health facilities, civil society and business representatives.

"The award is, due to its awareness at the highest political level, considered the most important of its kind in Germany," said Sabine Odhiambo, Secretary General oft he German Africa Foudation.

Dr Moyo was also awarded the Jesse Jackson International Humanitarian Award at the 32nd Annual Rev Dr Martin Luther King Jr Celebration. This was capped by special commendation by the Rev Dr Jesse Jackson during his annual speech at the celebration.

# New cryptococcal meningitis treatment as good as current care with far fewer serious side effects

'Streamlined' single-dose strategy could transform the way deadly infection is treated in sub-Saharan



Professor Joe Jarvis, the lead author of the study

new short course of treatment for HIV-associated cryptococcal meningitis is as effective at preventing deaths as the current longer recommended regimen but causes far fewer serious side effects, according to research in the New England Journal of Medicine. The study involved a randomised trial in southern and eastern Africa and was conducted by an international research team led from the Botswana Harvard Partnership, including scientists from the London School of Hygiene & Tropical Medicine, and partners in Botswana, France, Malawi, South Africa, Uganda, the United Kingdom and Zimbabwe.

The researchers say the new 'one-dose' approach offers a practical, easier-to-administer and better tolerated treatment for HIV-associated cryptococcal meningitis in Africa with the potential to reduce the length and cost of hospital admissions.

Cryptococcal meningitis is a fungal infection that affects the brain, and causes a serious disease in immunosuppressed people living with HIV across the globe. There are around 180,000 cryptococcal meningitis-related deaths each year, the majority of which occur in sub-Saharan Africa. Current treatments are either a 7 or 14-day course of amphotericin-B, combined with either oral antifungal tablets or oral fluconazole.

This new trial, the largest of its kind, investigated whether a single high dose of liposomal amphotericin-B (L-AmB, Ambisome) paired with two oral antifungals, fluconazole and flucytosine, was as effective at reducing deaths as the currently recommended WHO first-line treatment based on seven days of Amphotericin-B therapy.

Dr Melanie Alufandika-Moyo, study author and the lead research doctor at the Malawi-Liverpool Wellcome Unit, said: "Cryptococcal meningitis is the most common type of adult meningitis in much of Africa. Without effective treatment, infection progresses quickly, often resulting in deaths. Current treatment requires prolonged hospitalisation, intensive nursing care and costly laboratory monitoring which can be expensive for the healthcare system and the patient. Amphotericin-B can also cause kidney damage and blood problems.

"We urgently need new ways of treating the disease, so it's fantastic that we were able to show a new streamlined treatment, requiring just one intravenous infusion, is as effective and less dangerous for patients."

More than 800 adult patients with a first episode of HIV-associated cryptococcal meningitis, from five countries in southern and eastern Africa, took part in the trial. Half received the new intervention (AmBisome arm), and

half received the current recommended standard care (control arm). After 10 weeks, 25% (101/407) of people in the AmBisome arm died compared to 29% (117/407) in the control arm - this is among the lowest mortality rate reported from a major cryptococcal meningitis trial in Africa, despite more than a quarter of participants presenting with very severe disease.

As well as being as effective at saving lives, drug-related toxicity was significantly lower in the new 'one-dose' AmBisome arm. Anaemia occurred in 13% of AmBisome participants compared to 39% in the control arm. More participants in the control arm needed blood transfusions. There was also a difference in the impact on kidney function with far less drug related kidney toxicity in the one dose AmBisome arm than in the control arm.

AmBisome, a liposomal formulation of amphotericin-B, was suspected to be an effective cryptococcal meningitis treatment as it is less toxic and can be given in large doses that remain in the brain for some time.

Previous work had found that a single, high-dose of AmBisome was effective at clearing Cryptococcus from around the brain - the catalyst for this new trial which tested AmBisome's impact on a large number of patients in real-world settings.

Professor Tom Harrison from St George's, University of London, who co-led the trial with Professor Joe Jarvis from the London School of Hygiene & Tropical Medicine and Botswana Harvard AIDS Institute Partnership, said:

"These exciting results represent the culmination of a long programme of collaborative work to optimise antifungal drug combinations and reduce deaths from this terrible infection, and provide the strong evidence needed for policymakers to decide how cryptococcal meningitis should be treated going forward. Fortunately, with the support of advocates and funders, Ambisome and flucytosine are now becoming more available, which is essential to enable wide-scale implementation of this novel treatment regimen."

Professor Joe Jarvis, the lead author of the study and research associate at the Botswana Harvard Partnership, said: "The results of this trial have the potential to transform how cryptococcal meningitis is treated and the management of advanced HIV-related disease in sub-Saharan Africa. It has far fewer significant side effects, which is obviously hugely important, and has the potential to prevent a large number of deaths in low-resource settings by being both easier to administer and cost-effective."

The authors acknowledge limitations of the study, including the current lack of access to Ambisome and flucytosine, the key components of this novel treatment regimen, in many low-resource settings. To address this, Professor Jarvis and Dr David Lawrence, lead clinician on the trial, have recently been awarded a further five years of funding from the US Centers for Disease Control and Prevention (CDC) to help implement the study findings. They will work with the research teams in Botswana, Malawi, Uganda, and Zimbabwe to ensure that the novel treatment regimen reaches the patients who need it most.

The study was conducted by the London School of Hygiene & Tropical Medicine, St George's, University of London, the Infectious Diseases Institute at Makerere University, Kampala, Uganda, the Malawi-Liverpool Wellcome Trust Clinical Research Unit, University of North Carolina Project in Malawi, University of North Carolina Project in Malawi, the University of Cape Town in South Africa, the Botswana-Harvard AIDS Institute Partnership, and the University of Zimbabwe, with European partners at the Liverpool School of Tropical Medicine and University of Liverpool, and the Institut Pasteur in Paris.

The study was funded by the European and Developing Countries Clinical Trials Partnership (EDCTP), the Swedish International Development Agency, and the UK Department of Health and Social Care, the UK Foreign Commonwealth and Development Office, the UK Medical Research Council and Wellcome Trust, through the Joint Global Health Trials scheme.

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## Ponatshego and Youssouf receive Grant Awards





Dr Nabila Youssouf, InterCARE Study Manager

InterCARE Study Physician, Dr Ponego Ponatshego and InterCARE Study Manager Dr Nabila Youssouf have been awarded \$5,000 each to complete two research projects under the Small Research Project (RSP) program as part of the Heart, Lung and Blood Co-MorbiditieS Implementation Models in People Living with HIV (HLB-SIMPLe) Alliance.

Dr Ponatshego's project is entitled "Acceptability and Feasibility of using Treatment Partners to Support Hypertension Management in People living with HIV" and it aims to apply implementation research mixed

methods to measure implementation outcomes facilitating or hindering contextual determinants for successful implementation of this treatment partner strategy.

Dr Nabila's project is entitled "Investigating the impact of COVID-19 pandemic on the delivery of Heart, Lung, and Blood Co-morbidities Implementation Models in People Living with HIV" research programs (2020-2025 awardees)' and aims to use mixed methods implementation research to understand cross-projects and individual country facilitating and hindering determinants and the

strategies and implementation outcomes in supporting safe and effective research during a pandemic.

Both colleagues are mentored by Professors Mosepele Mosepele (University of Botswana) and Lisa Ruth Hirschhorn (North Western University) and Dr Laura Bogart (BHP/RAND) as part of their Early-Stage Investigators mentorship, which aims to prepare promising researchers with the necessary skills and experience to apply for future K-awards.

#### **ACTG Award**

Dr Ponego Ponatshego who is also a Study Physician for ACTG studies at BHP, has received a \$50,000 award from the AIDS Clinical Trials Group (ACTG) to conduct a pilot study on HIV and aging utilizing the data and specimen from the HIV Infection, Aging and Immune Function Long –Term Observational Study (HAILO), with a focus on age-related issues. The HAILO study assesses clinical, immunological and functional health of older U.S persons living with HIV.

Dr Ponatshego responded to a Request for Applications for funding from the ACTG with a proposal titled

"Comparative Analysis of Frailty Prevalence, Association with Levels of Systemic Biomarkers of Inflammation and Immune Function in HIV Infection in HAILO VS in a sub-Saharan Africa (Botswana) Cohort."

The ACTG Request for Application (RFA) targeted early career investigators to submit proposals for pilot studies for completion within one year. Dr Ponatshego is the Principal Investigator of the study and he will be working with Kesaobaka Molebatsi (UB) and Prof Monty Montano (BWH).

The primary aim of the study is to compare frailty risk factors and biomarker predictors of the frailty phenotype in HAILO and in a cohort of people living with HIV in Botswana. The study will also identify demographics and systemic biomarkers of inflammation and immune function that predict frailty in the two cohorts.

A related secondary objective of the study is to assess weather albuminuria is associated with or predicts frailty for each cohort and overall. The comparison has a good potential of determining whether the burden of frailty in the aging HIV population in Sun-Saharan Africa is comparable to that of the U.S.

## Selected BHP Associated Research, and Associated Investigators Publications

- 1. Cross-sectional trends in HIV prevalence among pregnant women in Botswana: an opportunity for PrEP? Kapoor A, Mussa A, Diseko M, Mayondi G, Mabuta J, Mmalane M, Makhema J, Morroni C, Lockman S, Zash R, Shapiro R.J Int AIDS Soc. 2022 Mar;25(3):e25892. doi: 10.1002/jia2.25892.PMID: 35324084
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