IVERMEN Briefing Summary Report

November 3rd, 2022
Seattle Convention Centre, Seattle

BACKGROUND & INTRODUCTION

This report summarizes an overview of the discussions taken place during the ivermen meeting held on November 1st during the 2022 ASTMH congress, as a follow-up to the last Ivermen meeting almost 3 years ago, convened by Carlos Chaccour and Kevin Kobylinski. The aim was to brief a range of interested and active stakeholders, including partners, donors, civil society, academia, and industry, on the status of studies from investigators and companies involved in ivermectin for malaria vector control, timelines to reporting results, and challenges ahead.

Updates from human ivermectin trials for malaria

Link to the presentations of this session 1

There are five trials using ivermectin to reduce malaria transmission. The MASSIV trial, conducted in The Gambia was not presented since the main results have been already published

1. Mass drug administration of ivermectin and dihydroartemisinin-piperaquine as an additional intervention for malaria elimination (MASSIV) in The Gambia. Results are already published.
2. Repeat ivermectin mass drug administrations for malaria control II (RIMDAMAL II) in Burkina Faso, presented by Dr. Sunil Parikh.
3. Broad one health endectocide-based malaria intervention in Africa (BOHEMIA) in Mozambique and Tanzania, presented by Dr Carlos Chaccour. Prior to the BOHEMIA project, Dr. Marta Maia presented the results of the PK400 conducted in Kenya.
4. Adjunctive ivermectin mass drug administration for malaria control (MATAMAL) in Guinea-Bissau, presented by Dr John Bradley on behalf of Dr. Anna Last.
5. And Ivermectin Mass Drug Administration in Thailand, presented by Dr Jetsumon Prachusmri.

Discussion

- It was questioned why there was no difference between the pk 300x3 and pk400. The reason is unclear, and the bioanalysis results are pending. The posters related to this disucssions can be found in the Session 1 link
- It was suggested that it would be interesting to pull the data of malnourished children to understand the pharmacokinetics of ivermectin in those children.
- Responding on how to optimize what has been established for covid-19 distribution for other treatments, the answer is that each country implements MDA depending on its infrastructure, culture, etc. It is basically community led and different in each country

Emerging issues/ challenges

Link to session 2 presentations

Patricia Nicolás presented the pregnancy outcomes (presentation).

Discussion:

- Once there is more pregnancy data from the other studies, this is an issue that should merit further discussion.

Dr. Carlos Chaccour presented the challenges in terms of study designed and more specifically on buffer zones, co-administration of the drug and delivery that BOHEMIA faced and how it could impact the project.

Disucssion:

- Time for delivery and its impact on efficacy was discussed. The fact that it took 3 weeks to implement the whole MDA could translate into a reduction of the efficacy. In that sense the team is analysing and trying to match the speed of distribution with the effect after every round.

Innovation on ivermectin and its co-formulation with albendazole

Link to session 3 presentations

The last session was dedicated to innovation with the most updated outcomes of ivermectin formulation and co-formulation with albendazole. The following presentations took place:

- MedinCell presented the results from the IMPACT project: Update on the pK/efficacy data in animals and key challenges for the next steps (presentation).
- Lyndra presented the results of the Oral Biweekly Ivermectin (LYN-163) as a Tool in the Fight Against Malaria (presentation).
- Mundo Sano/UNCPBA presented the progress and plans in the development of an albendazole-ivermectin co-formulation (presentation).

Disucssion:

- MedinCell has no interest into IM administration because it is painful and needs specific blood resource structures. The presentation is polymer-based bio soluble technology, so after the 3 months the formulation is completely reabsorbed. The volume of injection would range from 0.1mL -1mL depending on the weight.
- In terms of implementation, discussions were raised around the distribution, country selection and seasonality. Further thinking on this needs to be taken into account, considering also NTDs campaigns, SMCs and potential synergies with the deliveries of other treatment.
- Mundo Sano clarifies that their co-formulation would be delivered mainly through MDA. Implementation studies will use the three doses where the first one is observational. More data is needed for WHO to take a position on this topic.
- It was suggested to take into account the scabies community in terms of acceptability and including scabies people in the new meeting. Ivermectin+albendazole and

azythromicine is a new formulation they are considering. BOHEMIA will be collecting some data on scabies.

- New data will be generated in about 2 years on ivermectin safety and Pk in children under 15kg using scabies as the disease because that is an indication.

Conclusions:

- This community is aware of the different stakeholders that need to get involved to move this forward (WHO, regulatory, The Global Fund, World Bank, NMCPs, generic manufacturers, etc), but to start the discussions with them, more efficacy data is needed. The same applies for pregnancy. Data from the different trials on pregnancy outcomes is needed to conduct specific trial on that, as FDA suggested
- In that sense the communication from the results of each individual trial must be taken cautiously as it impacts on the rest of the trials.
- Agreed to convene in about a year in a stand-alone meeting or taking into consideration other meetings such as PAMCA, ASTMH or MIM.

LIST OF PARTICIPANTS:

- Adrian Lifschiftz, Faculty of Veterinary Sciences, UNCPBA and Center for Veterinary Research of Tandil (CIVETAN, CONICET), Argentina (on-line)
- Alejandro Krolewiecki, Instituto de investigaciones en Enfermedades Tropicales, Unviersidad de Salta, Argentina
- Anna Last, Faculty of Infectious and Tropical Diseases, LSHTM, UK
- Arjen Dondorp, Mahidol-Oxford Tropical Medicine Research Unit, Mahidol University
- Brian Foy, Colorado School of Public Health, Colorado State University
- Carlos Chaccour, Barcelona Institute for Global Health, Spain
- Christophe Roberge, MedinCell, France
- Christopher Lourenço, PSI, USA
- Felix Hamann, Clinical Pharmacology & Toxicology University Hosptial-Inselspital Bern, Switzerland.
- Hannah Slater, PATH, USA
- Helen Martin, MedinCell, France
- Helen Jamet, Bill and Melinda gates Foundation, USA.
- Jessica Ballinger, Lyndra Therapeutics, USA. (on-line)
- Jessica Rockwood, IPHA, USA.
- Jetsumon Prachumsri, Mahidol University, Thailand.
- Jimee Hwang, CDC, USA
- Joel Tarning, Centre for Tropical Medicine and Global Health, UK
- John Gimnig, CDC, USA
- Julie Jacobson, Bridges to Development, USA
- Karin Mouline, Institute of Research for Development, France
- Kelsey Barrett, Unitaid, Switzerland
- Magali Hickey, Lyndra Therapeutics, USA. (on-line)
- Maria-Gloria Basañez, Imperial College London, UK
- Marta Maia, KEMRI- Wellcome Trust, Kenya
- Mary Christian, Lyndra Therapeutics, USA.(on-line)
- Maureen Chlopik, Lyndra Therapeutics, USA.(on-line)
- Maureen Walters, Lyndra Therapeutics, USA.(on-line)
- Michael Marks, LSHTM. UK (on-line)
- Nana Williams, MESA, Barcelona Institute for Global Health, Spain
- Nilani Chandradeva, Imperial College London, UK
- Patrick Boen; Lyndra Therapeutics, USA.(on-line)
- Prashant Selvaraj, iMOD, USA
- Regina Rabinovich, Barcelona Institute for Global Health, Spain
- Richard Scranton; Lyndra, USA
- Rose Zulliger, U.S. President's Malaria Initiative, USAID, USA
- Steven Gowelo, USCF, USA.(on-line)
- Sunil Parikh, Yale School of Public Health, USA
- Teun Bousema, Radboud University Medical Centre (Radboudumc), The Netherlands
- Thomas Churcher (on-line), Imperial College London, UK