

**International Rectal Microbicides Advocates (IRMA)
(formerly the International Rectal Microbicide Working Group)**

**Monthly Teleconference
October 2, 2007**

13 Participants: Jeremy Paull (StarPharma), Jim Pickett (IRMA Chair, AIDS Foundation of Chicago, USA), Marc-André LeBlanc (IRMA Secretary, Global Campaign for Microbicides, Canada), Kim Mulji (IRMA Treasurer, Naz Foundation, UK), Bridget Haire (IRMA Vice-chair, Australian Federation of AIDS Organizations, Australia), Roy Wadia (IRMA SC member, BCCDC, Canada), Rowena Johnston (IRMA SC member, amfAR, USA), Courtney Mulhern-Pearson (San Francisco AIDS Foundation, USA), Leonardo Coleman (UCLA, USA), Charlene Dezutti (Microbicides Trials Network, USA), Ross Cranston (USA), Anna Forbes (Global Campaign for Microbicides, USA), Stephanie Tillman (Alliance for Microbicide Development).

Note – SC = Steering Committee member

1. Jim welcomed participants and acknowledged the great contribution that Steering Committee member John Shaw made to IRMA. Sadly, John passed away last week. A John Shaw Scholarship Memorial Fund has just been announced – info is on the website – www.IRMWG.org. \$5,000 of the Elton John AIDS Foundation grant has been set aside for scholarships to M2008, and we are raising funds to enhance that total.

Jim thanked AFAO for sponsoring this call as well as Jeremy Paull from StarPharma for presenting.

2. After a two-month process of input from the full IRMWG followed by deliberations and voting from the SC, the IRMWG name has now been changed to IRMA: International Rectal Microbicides Advocates! Thank you to everyone for participating in the discussion around the name change. We will be developing a new logo, promoting it in the document we will prepare for Microbicides 2008, and launching a refreshed web site. A new URL has been secured (www.rectalmicrobicides.org) for when we are ready to launch the name and refreshed site. However, we will continue to publicly go by IRMWG until then and will continue to use the www.IRMWG.org site until all these things are in place. We will be engaging on logo development very soon.

2. Dr. Jeremy Paull presented on StarPharma and its current research portfolio related to VivaGel, using his slides as guide. Slides are posted on the website. Supplementary information to the slides is included below.

Slide 3: COG = cost of goods

Slide 8: StarPharma holds the IND for the HIV endpoint of VivaGel.

Slide 14: MTN is running the last trial listed.

Slide 17 and 19: GLP = good laboratory practice. The research described on slide 19 was conducted by Dorothy Patton.

Discussion

Rowena: Why deliver VivaGel through dendrimer rather than just by itself?

JP: The groups outside dendrimers just don't have the same activity. Delivering them via dendrimer increases their activity.

Anna: What target were you hoping for when you mentioned in a press release last year that vivaGel could be licensed by the end of 2008? Was it the HIV, HSV, contraception or condom coating?

JP It would not be HIV, but could be condom coating.

Anna: In relation to community involvement: Initially there were plans to do trials in Australia, then Thailand, and in both cases, StarPharma decided to move them. In the case of Thailand, the Thai Red Cross Community Advisory Committee provided comments on the study protocol, then learned of the decision to move elsewhere. Now there are plans for phase I and II in Africa. What plans are in place for community involvement there?

JP: you are right that there have been no trials in Australia. In Thailand, we did meet with the Thai Advisory board. We were planning a study among HIV+ women. I was not aware of the comments sent to us by the Thai Red Cross. In Africa: in Kenya we are working with the KEMRI Institute, and looking to them for guidance on community involvement.

Kim: How do dendrimers work?

JP: Dendrimer works by binding to GP120, creating a barrier between the virus and target cell. It works similarly for HIV and herpes.

Anna: Can you tell us more about the resistance studies you have done?

JP: A non-clinical study was done by the Burnet Institute in Melbourne.

Anna: Do you have plans to do PK studies in clinical trials to see if the product gets into the blood stream?

JP: We have seen no absorption in human studies so far. At some point, we will stop trying to detect it.

For safety studies, as a field, we need an intermediate step between 14 days and 12 months. We are discussing this with NIH. The results of other microbicides trials raises concerns about the need for something in between.

Bridget: Who sets the agenda for how these trials are sequenced and run? AFAO has been trying to get engaged through community partnership, which is critical, but has not been very successful.

JP: The Clinical group is responsible for coming up with the clinical development plan. We look to NIH for guidance on this.