

The MSG

Mycoses Study Group Quarterly Newsletter Summer 2008

Welcome to the *Mycoses Study Group Quarterly Newsletter, Summer 2008*. This newsletter is intended to keep our investigators and supporters apprised of the developments within the **MSG** and to encourage support and involvement in our ongoing activities.

MSG 2009 Annual Meeting

Mark your calendar! Plans for the **MSG 2009 Annual Meeting** are underway. This will be a “free standing” meeting to be held at the **Courtyard by Marriott Downtown Philadelphia, PA on April 2-3, 2009**. The meeting will begin the afternoon of April ^{2nd} with a 2 hour CME session followed by an informal reception. An all day working meeting (8 AM-4 PM) is planned for April 3rd.

ICAAC/IDSA Joint Meeting October 25-28, 2008

The MSG is co-sponsoring symposia at the joint ICAAC/IDSA meeting in Washington DC this fall. These include three symposia entitled “An Update on Cryptococcosis”, “The Antifungal Formulary”, and “Top Ten Papers in Mycology”. We’ll communicate the specific times for each of these symposia as they are finalized.

The MSG will also be sponsoring a reception with a brief meeting during at ICAAC/IDSA. Further details will be provided once the venue is confirmed.

The MSG Education Committee

The EC is actively working to set the proposed 2009 educational agenda. We are working closely with Debra Joyce of Fallon Medica as we develop this agenda and approach potential sponsors for financial support of these activities. These programs will be developed for variety of venues including, but not limited to traditional grand rounds, regional seminars, national/international meetings, support of Dr. Fungus, and Web-based educational programs.

ISHAM Affiliation

As we have noted previously, we strongly encourage members of the MSG to become official members of ISHAM. Annual dues are very reasonable at \$50 USD. Please carefully review the correspondence from Sybren de Hoog, PhD, ISHAM president at the end of this newsletter. It contains important information regarding the advantages of ISHAM membership, and explains the process of membership application. If you have not already done so, please apply today!

MSG / FDA / EMEA Galactomannan Project

The proposal for the use of galactomannan as a qualified biomarker in the context of a clinical trial for treatment of invasive aspergillosis was judged by the FDA Biomarker Qualification Review Team and the EMEA to have a potentially important impact on drug development and regulatory review. Johan Maertens, Paul Verweij, Barb Alexander, Kieren Marr, and Joe Wheat have spearheaded this effort in the US and Europe. Their leadership and the **MSG**'s supporting role in bringing this effort together culminated in the submission of this document to the FDA/EMEA in March 2008.

On July 2, 2008, The FDA and EMEA conducted their first joint meeting regarding this application. Joe Wheat, MD, and Paul Verweij, MD, PhD were present at this joint meeting as representatives of the **MSG**. The application received favorable reviews, and we have been provided a set of questions and recommendations for further review. This process is ongoing, and clearly has significant influence on the ability to conduct clinical trials of invasive aspergillosis. We will keep you posted on our progress.

'Dr. Fungus' Website

The Dr. Fungus website has agreed to support the **MSG** by allowing us to post our activities via their website. The following web addresses will access **MSG** activities:

<http://mycosesstudygroup.org/> and <http://www.mycosesstudygroup.org/>

The domain - mycosesstudygroup.org - will only be visible on the initial entry page into doctorfungus.org. The **MSG** is working with the Dr. Fungus web development team to create a comprehensive overview of current and future **MSG** activities. Additional details will be provided as they evolve.

MSG Bylaws

The **MSG** Bylaws are under development. A draft of the Bylaws will be reviewed by members of the Steering Committee and Educational Committee. Once a draft has been approved by both committees, this will be distributed for comments to the general membership. After appropriate modifications, we will submit the Bylaws for approval by both committees. A final version of the Bylaws will be provided to each **MSG** member once a final version is approved.

Clinical Trials Update

Below are the currently approved **MSG** projects:

MSG-01: A randomized, double-blind, placebo controlled trial of caspofungin prophylaxis followed by preemptive therapy for invasive candidiasis in high risk adults in the critical care setting.

PI: Luis Ostrosky-Zeichner

Corporate Sponsor: Merck & Co..

At this time, 14 of the 15 sites necessary for this study have been selected. The study is open for enrollment at **11** sites and **51** subjects have been enrolled. The study is registered on Clinicaltrials.gov website.

MSG-02: Candidemia meta-analysis

PIs: Baddley, Andes, Safdar, Playford, Kullberg

Although not formally a “clinical trial”, this concept was presented and approved by the **MSG Steering Committee** and will examine the randomized candidemia treatment trials that have been completed to date. The ‘**working group**’ will consist of junior investigators (John Baddley, David Andes, Nasia Safdar,) and a senior advisory group. Bart-Jan Kullberg will serve as the primary senior advisor to this group, help formulate an analysis plan, assign responsibilities, establish a timetable, etc. Data has begun to flow to the investigators.

MSG-03: Invasive Aspergillosis Combination Study

PI: Kieren Marr

Corporate Sponsor: Pfizer

The **MSG** has endorsed this study sponsored by Pfizer, Inc. (Pfizer protocol A8851009). **MSG** has been involved in the site selection, protocol development, the Data Review Committee and DSMB, statistical analysis, and the submission for publication. At this time, 40 domestic sites and 123 international sites have been selected to participate in this pivotal study. Eight domestic sites are open for enrollment and our first patient has been enrolled (Joe Vazquez, Henry Ford Hospital). We are continuing to recruit additional centers for participation and welcome all suggestions. Please contact Beth Deerman, RN (jbeth@uab.edu) with suggestions regarding additional sites.

Ongoing discussions

We are having ongoing discussions with the following companies concerning the **MSG**’s involvement in the clinical development of these compounds:

SPRI: We are eagerly awaiting the development/availability of the intravenous formulation of posaconazole for evaluation in clinical trials of aspergillosis and zygomycosis.

Novartis: These discussions remain on hold at this time pending further assessment by Novartis regarding the future of efungimab (Mycograb). If the development of this product moves

forward, the MSG remains interested in the clinical development of efungimab in the context of a large international candidemia trial.

Merck : A retrospective study to determine a predictive rule for identifying ICU patients with undifferentiated fever who are high risk of having invasive candidiasis has been completed. The results of this study will be presented at ICAAC/IDSA by Luis Ostrosky-Zeichner. These data may be used as a foundation for a randomized trial examining an empiric approach to antifungal therapy in the ICU setting. Stay tuned.

Eisai Medical Research, Inc: Ongoing discussions concerning the potential clinical development of ravuconazole (iv and po) for a variety of invasive fungal infections.

Basilea: Many of our members are participating in studies involving isavuconazole for the treatment of candidemia and aspergillosis. The MSG has not entered into any formal discussion with Basilea concerning further development of isavuconazole.

MSG Administrative Structure:

MSG Central Unit:

Peter G. Pappas, MD, PI
Beth Deerman, RN, Administrator
Mary Dougherty, Financial Associate
Joyce Kanute, Administrative Assistant

MSG Steering Committee (SC):

Peter G. Pappas, Chair (US)
Carol Kauffman (US) Jack Edwards (US)
Tania Sorrell (AUS) John Wingard (US)
Jack Sobel (US) Eric Bow (CAN)
Tom Patterson (US) John Perfect (US)
Marcio Nucci (BRA) Raoul Herbrecht (FR)
Emilio Bouza (SPA) Thierry Calandra (SU)

Bill Dismukes and John Bennett will serve as non-voting advisors.

MSG Education Committee (EC):

US: Susan Hadley (Chair)	Alison Freifeld
David Andes (Co-chair)	Barbara Alexander
Helen Boucher	John Baddley
L. Ostrosky-Zeichner	Graeme Forest
Tom Patterson	Peter Pappas
John Bennett	Dimitrios Kontoyiannis

Europe: Olivier Lortholary (FR)

Oliver Cornely (FRG)
Bart-Jan Kullberg (NETH)
Latin America: Luis Thompson (CHI)
Marcio Nucci (BRA)

Australia: David Ellis (AUS)

A letter from Sybren de Hoog, PhD, ISHAM President:

Dear MSG participant,

Recently Pete Pappas recommended all MSG members to join ISHAM, the International Society for Human and Animal Mycology. ISHAM is the only organization promoting all aspects of medical and veterinary mycology on a worldwide scale. Our activities cover all areas, from clinical science to fundamental research. Membership of the society is a must for everyone working in any of these areas, see http://www.isham.org/Membership_Form.html.

What do you get from your membership subscription?

- Reduced fees for the **ISHAM congress** in Tokyo / Beijing, May 2009, see <http://www.congre.co.jp/isham2009/>
- Free access to the journal **Medical Mycology**, see <http://www.informaworld.com/smpp/title~content=t713694156~tab=sample> , the electronic version being included in the membership fee (hard copy delivered at a small extra fee). This includes all back-issues of the journal, plus the preceding journals *Sabouraudia* and *Journal of Medical and Veterinary Mycology*, starting at Volume 1 published in 1962,
- Inter-active communication tools with very regular e-mailed **news alerts** on anything significant in mycology, such as forthcoming congresses and courses, important literature, vacancies etc.,
- Access to **discussion forums** where you can share points of view with your colleagues and ask advice,
- An inter-active **SOS-service** on significant clinical cases,

- Free membership of our many **international networks** on themes of your interest: the ISHAM Working Groups, see <http://www.isham.org/Groups.html> . Eighteen such groups have now been established, with themes ranging from clinical trials, antifungals and molecular diagnostics to recalcitrant clinical syndromes and orphan diseases. ISHAM provides logistic and financial support for their activities in the form of sponsorship,
- Coming soon – the ISHAM website will contain a large number of **free protocols** to help you to apply major techniques in antifungal testing, diagnostics and molecular phylogeny.

In addition, sponsoring of regional courses and of young and motivated ISHAM members remains possible. We are in the process of setting up a Global Educational Foundation for awarding **educational grants** to enable young investigators to gain familiarity and experience in fields of interest, and to organize CME activities in all aspects medical mycology.

ISHAM continues to be your central international organization for medical mycology. We are glad to have you as a member, and we invite you to participate in our expanding array of activities.

Sybren de Hoog, PhD

ISHAM-President 2006-2009