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BCG Trial Updates

We are happy to bring you updates on our clinical trial program. We have good news to report today. We have concluded the enrollment into Phase I of the BCG trial, which represents a double-blinded placebo, controlled trial. We have also filed all safety reports to both the FDA and the Massachusetts General Hospital data safety monitoring boards; there were no severe reactions to the vaccine other than the expected inflammation at the injection sites. This safety report has now been filed with the government on their web site (clinicaltrials.gov).

This now allows us to start the planning and process of moving forward into Phase II testing. The goal of the Phase II study will be to identify the best dose and timing of administration for BCG.

We can begin working on Phase II as soon as we have secured the necessary funding. The funding will allow us to write and submit the proposed Phase II study design to the FDA and the MGH. When funding is secured, it will also be used to hire a regulatory team and start the processes that will allow us to have BCG manufactured in a form that can be used in the trials, as single dose vials. In our Summer/Fall 2009 Lab Newsletter (posted on the faustmanlab.org site under "News" then "Lab Newsletter"), we detail these and other steps that we will take (see pages 3 and 4).

We are actively working to raise the funds needed for these next steps. Please continue to spread the word to others about these trials. What you hear so often is true--every dollar counts. Every day we wait to start these pivotal next steps is a day lost. As you know, donations can be made directly to this research through the faustmanlab.org site (under the "Support" tab), which links to the MGH donation site. We also provide updates on our research through this site and through our Faustman Lab fan page on Facebook.

Thank you all for your support!

As always, checks should be made to 'MGH-Faustman lab' and can be mailed to:

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