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Cause of Sarcoidosis is Antibiotic-Resistant Bacteria - FDA asked to Designate Orphan Drugs for Further Clinical Trials

<u>Thousand Oaks, California, Oct 4, 2005:</u> The Autoimmunity Research Foundation today announced that its Phase 2 clinical trials had confirmed antibiotic-resistant bacteria as the cause of Sarcoidosis, the deadly disease which took Reggie White's life, and that applications for designation of three antibacterials as Orphan Products have been filed with the Food and Drug Administration.

The Foundation has been conducting Phase 2 trials for the past three years, working with dozens of individual physicians and specialists to establish both an understanding of the pathogenesis, and of effective anti-bacterial dosing regimes. Over two hundred of their patients have subsequently recovered, or are currently recovering, from this debilitating disease. The applications to the FDA will facilitate Phase 3 trials leading to final FDA designation of these drugs for Sarcoidosis.

Trevor G. Marshall, PhD, a Foundation Director, has discovered and published exactly how slow-growing, intra-phagocytic bacteria can cause chronic disease. The antibiotics needed for recovery are neither expensive nor new, but Dr Marshall and his colleagues have developed a method of using them which is both new and revolutionary.

In March 2005, the Foundation held an international conference where physicians and patients attended sessions focused on understanding this deadly disease. Experts described how tiny intra-phagocytic bacteria - called L-forms, after the Lister Institute, where they were discovered – are the cause of Sarcoid inflammation. Patients described what they had experienced as they recovered their health using the innovative antibiotic regimen.

One single mother described how she had struggled to tell her 13 year old son that she was dying, and that she would never be able to leave her wheelchair. Two years later, she is walking again, albeit with a cane, enjoying being a 'soccer mom.' Another patient explained she had been forced to give up competitive show jumping as Sarcoidosis made her weaker, selling her prized horse as she was confined to a spinal brace and anticipating a wheelchair. Now she is riding again in competition, with her health steadily improving.

Earlier today, the Nobel Prize Committee issued a press release announcing the 2005 Nobel Prize in Medicine; stating, inter alia,

"Many diseases in humans such as Crohn's disease, ulcerative colitis, rheumatoid arthritis and atherosclerosis are due to chronic inflammation. The discovery that one of the most common diseases of mankind, peptic ulcer disease, has a microbial cause, has stimulated the search for microbes as possible causes of other chronic inflammatory conditions."

It should be noted that Sarcoidosis is a chronic inflammatory condition, and that Dr. Trevor Marshall is no relation to Dr. Barry Marshall, although they are both alumni of the

University of Western Australia and trained in the same QEII Medical Center in Perth, Western Australia, during the same time period (early '80s). (see URL http://nobelprize.org/medicine/laureates/2005/press.html)

<u>Supporting materials for journalists:</u>

- 1. PDF versions of the three 'Orphan Product' applications to the FDA can be reviewed at URLs http://AutoimmunityResearch.org/orphan-app-benicar.pdf http://AutoimmunityResearch.org/orphan-app-clindy.pdf http://AutoimmunityResearch.org/orphan-app-mino.pdf
- <u>2.</u> A complimentary DVD of the foundation's conference session "What is Cure," where the above patients described their recoveries, is available upon request
- 3. "Before" and "After" photographs of recovered patients, and contact details for interviews, are available from the foundation and from http://AutoimmunityResearch.org/presskits/3oct05.htm

<u>General Foundation Email:</u> Foundation@AutoimmunityResearch.org <u>Foundation Website:</u> http://www.AutoimmunityResearch.org

The Many Faces of Recovery



Meg Mangin, RN



Belinda Fenter





Ms. Dale Thurlow 'Before' photo in her motorized chair, 'after' shown standing beside that, pointing at her wheelchair.

Lowelle Messner 'Before' photo was taken before back brace, 'after' photo taken riding 'Tess.'



