

August 5, 2002

Re: Immunocal® and Nutritional Support of HIV/AIDS

Dear Healthcare Provider:

NuMedTec is pleased to announce the completion of a recent open label trial conducted by Louisa Pacheco, M.D. and her colleagues on the therapeutic use of Immunocal with HIV/AIDS patients. Dr. Pacheco performed the study at the Tidewater AIDS Crisis Task Force in Norfolk, Virginia. The Institute of Human Virology accepted the study for presentation at its 2002 International Meeting of the Institute of Human Virology in Baltimore, Maryland on September 9-13. Dr. Pacheco will offer the data in a poster presentation.

We are attaching an Information Sheet outlining the results of the trial for your review. As you will see, the AIDS patients who were on Immunocal, a bioactive-cysteine rich nutraceutical, gained an average of 11.9 lbs in 8 weeks. These same patients experienced a marked improvement in gastrointestinal symptoms such as diarrhea, nausea, and impaired appetite. Additional, they were able to adhere to their HAART medications as prescribed, which they had previously been unable to do. A retrospective analysis of 20 matched non-participating patients revealed that these subjects experienced an average weight loss of 8.5 lbs and remained non-adherent with anti-retroviral therapy.

Immunocal is a broad-spectrum nutraceutical food derivative with biologic capability to modulate cellular function. It is a patented milk protein isolate affirmed as "Generally Recognized As Safe" according to the FDA under 21CFR §184.1979c. More than 100,000 people have used Immunocal with no significant adverse side effects. You may read more about Immunocal in the PDR (Physicians Desk Reference), or visit our website: <a href="www.numedtec.com">www.numedtec.com</a>.

NuMedTec

Annibale "Ni" Orsi

By: <u>Annibale Or</u>si

President

# BIOACTIVE CYSTEINE-RICH NUTRACEUTICAL PROMOTES WEIGHT GAIN AND HAART ADHERENCE IN HIV/AIDS PATIENTS

## THREE OF THE MAJOR PROBLEMS ENCOUNTERED IN HIV/AIDS ARE

- Immune deficiency
- Weight loss and wasting
- Inability to tolerate HAART

# LOW GLUTATHIONE (GSH) AND CYSTEINE VALUES

 Are held to be responsible, at least in part, for immune deficiency, weight loss and wasting in HIV/AIDS <sup>1-3</sup>

## TREATMENT OF AIDS PATIENTS WITH HAART

 Does not address the problem of low glutathione/cysteine, even if the patients are able to tolerate these drugs

# IMMUNOCAL® IS A BIOACTIVE CYSTEINE-RICH MILK PROTEIN SUPPLEMENT THAT

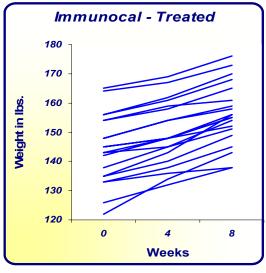
- Delivers cysteine in bio-available form for the cells to synthesize GSH
- Is proven to raise intracellular glutathione 4
- Enhances the response of the immune system <sup>5</sup>
- Does not interact with any other drug regimen
- Has no known toxicity
- Is GRAS (Generally Recognized As Safe 21 Code of Federal Regulations §184.1979c)

#### References

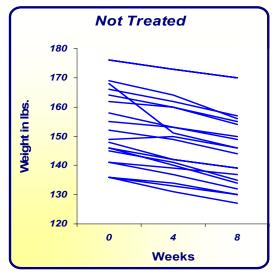
- Herzenberg LA et al. Glutathione deficiency is associated with impaired survival in HIV disease. Proc Natl Acad Sci 94:1967-72, 1997
- 2. Droge W and Holm E. Role of cysteine and glutathione in HIV infection and other diseases associated with muscle wasting and immunological dysfunction. FASEB J 11:1077-89,1997
- 3. Breitkreutz R et al. Massive loss of sulfur in HIV infection. AIDS Res Hum Retroviruses 10;16:203-9, 2000
- 4. Lands L et al. Effect of supplementation with a cysteine donor on muscular performance. J. Appl Physiol 87:1381-1385, 1999.
- 5. Bounous G, Gold P. The biological activity of undenatured dietary whey proteins: role of glutathione. Clin Invest Med 14:296-309, 1991

# STUDY USING IMMUNOCAL® WITH AIDS PATIENTS NON-ADHERENT WITH HAART

# CHANGE IN BODY WEIGHT OF AIDS PATIENTS (INDIVIDUAL VALUES)



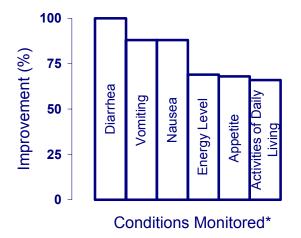
Twenty (20) patients with a history of non-adherence with HAART received Immunocal, 20g BID for 4 weeks followed by 10g BID for an additional 4 weeks.



Twenty (20) matched non-participating control AIDS patients were selected retrospectively.

Patients using Immunocal had an average weight gain of 11.9 lbs. Control patients had an average weight loss of 8.5 lbs.

### IMPROVEMENT IN HEALTH STATUS



Patients taking Immunocal achieved significant reduction in gastrointestinal side effects (diarrhea, nausea, vomiting, impaired appetite), as well as improved energy levels.

### ADHERENCE TO HAART

Patients using Immunocal became 100% adherent to HAART by the end of the 8-week trial.

# **SUMMARY AND CONCLUSIONS**

Immunocal is an immune-enhancing GRAS nutraceutical that can be used beneficially in AIDS patients to promote weight gain, improve their health status and tolerance for taking HAART.

Thus, including Immunocal as part of an AIDS patient's therapeutic regimen may improve three major conditions - immune deficiency, weight loss, and adherence to HAART.

\*Patients were rated weekly on a 1 to 5 scale (1=no problems to 5=significant problems) for gastrointestinal signs and symptoms and quality of life indicators.