Talactoferrin Shows Anti-Cancer Activity

Baylor College of Medicine

Developed at Baylor College of Medicine in Houston, by Orla M. Conneelly, Ph.D., Bert W. O'Malley, M.D., Denis R. Headon, Ph.D., and Gregory S. May, Ph.D., talactoferrin is a targeted dendritic cell activator with promising anticancer activity. Early research funding was provided by the Baylor College of Medicine's department of genetics, and by Agennix, Inc. The technologies related to the discovery of talactoferrin were disclosed in 1988 and 1992.

Talactoferrin, a novel dendritic cell (or immune cell) activator, is a unique recombinant form of human lactoferrin. After isolating the human lactoferrin gene sequence, the research team then developed a method for producing human lactoferrin (an important protein with immunomodulatory activity) through recombinant gene technology. In 1993 the technology was licensed to Agennix Inc., a biotechnology company that is developing an oral formula of talactoferrin for treating cancer and a topical gel formulation for the treatment of diabetic foot ulcers.

Talactoferrin is an orally active protein that mediates its activity through the gut and the GALT — the largest lymphoid organ in the body — through dendritic cell recruitment and activation. This results in a strong systemic innate and

adaptive immune response, cellular infiltration of distant tumors and tumor- cell death.

Agennix has completed two randomized, double-blind, placebo- controlled Phase II studies evaluating talactoferrin for the treatment of non-small cell lung cancer (NSCLC), which is one of the most common types of cancer worldwide. In the first- line, patients receiving talactoferrin, combined with standard chemotherapy, showed an apparent improvement in response rates, time to disease progression, duration of response and overall survival when compared to standard chemotherapy alone. In a more recent trial in patients with refractory disease who received supportive care plus either talactoferrin or placebo, the median overall survival was 65% higher in the talactoferrin group than in the placebo group.

> *Oral talactoferrin has also demonstrated apparent anti-cancer activity in clinical trials with other tumor types including kidney, breast, ovarian, and prostate cancer and in melanoma.*

Topical talactoferrin was evaluated in a placebo-controlled trial in patients with diabetic foot ulcers and met its primary endpoint of enhanced wound healing. The company has 95 issued patents and 47 pending patents covering talactoferrin and its multiple uses and is preparing to initiate global Phase III trials in both NSCLC indications.

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