

Dr. Smith's Client Education Series

Squalene

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**HealthWalk
5825 Avenida Encinas
Suite 111
Carlsbad, CA 92008
760-929-1520**

www.healthwalk.com

This information is not offered to diagnose or prescribe for medical or psychological conditions nor to claim to prevent, treat, mitigate or cure such conditions, nor to make recommendations for treatment of disease or to provide diagnosis, care, treatment or rehabilitation of individuals, or apply medical, mental health or human development principles (unless provided by an appropriate licensed or certified professional). The use of Shark Liver Oil (Squalene) to support the normal structure and function of the body in persons diagnosed with cancer is based on traditional uses that are only substantiated to the extent discussed in the booklet. This information is offered only as expressive association communication for an informed choice therapy that may offer benefit.

Shark Liver Oil

When I was a kid, it was all I could do to get out of my grandmother's house in the morning before she awakened so I could avoid her morning dose of cod liver oil. She claimed it kept me healthy...yuck!

Historically, fish oils have a longstanding usage in "folk medicine" and, today, fish oil supplements are used by many physicians, alternative practitioners and the general public. And shark liver oil stands above all the rest.¹ Its benefits have been highly researched, especially as an adjunct to cancer treatment.¹

From folklore to front page

Scandinavian and Caribbean fishermen have discovered that oil extracted from the liver of the deep water shark sped up skin tissue repair if applied to wounds. They used it to alleviate respiratory tract infections and also found that the oil strengthened them, especially when taken after illness. Even in Ernest Hemingway's last book, *The Old Man and the Sea*, there is a scene where the old fisherman drinks the shark liver oil for his eyes.

The usage of this "folk remedy" had all but died out by the end of the 19th century, except as practiced in a few isolated fishing communities. This valuable knowledge would have completely disappeared, had it not been for scientists with an avid interest in "lipids."

- In 1906, Dr. Mitsumaru Tsujimoto researched shark liver oil from the deep-sea shark species and discovered it contained an extremely great quantity of unsaturated hydrocarbons. He later called the oil "Squalene."
- In 1931, Professor Calour, a Nobel Prize recipient at Zurich University, Switzerland certified that squalene shark liver oil is a lipoprotein that will "capture hydrogen atoms" from any source available to make it stable and saturated.

The most abundant source of hydrogen is water (H₂O). Our food contains much H₂O, body fluids and blood are mainly H₂O, and the human body is actually 70 percent H₂O. Squalene—through a natural reaction with water—is capable of providing oxygen essential for healthy metabolism.

Following the synthesis of squalene molecules in 1930, research into their versatile healing applications progressed rapidly. The technological advances of the 1940s and 1950s enabled the Swedish researchers, Hallgren and Larsson, to undertake extremely specific studies of shark liver oil in the 1960s.² The liver oil was found to contain

¹ Please note that shark liver oil from HemaTek is sourced from Scandinavia, where the sharks are fished for human consumption and pet food and are not fished exclusively for their oil.

² Hallgren, B. and Larsson, S., *'The Glycerol Ethers in the Liver Oils of Elasmobranch Fish'*, Journal of Lipid Research, 1962: 3, 3238. Hallgren, B. and Larsson, S., *'The Glycerol Ethers in Man and Cow'*, Journal of Lipid Research, 1962: 3, 3943 Hallgren, B., Staelberg, G., and Boeryd, B., *'Occurrence,*

extremely high concentrations of active alkoxyglycerols, usually only found in mother's milk and bone marrow. Further scientific research over the next twenty years revealed Squalene's effectiveness with cancer.³

Squalene works against cancer because it helps inhibit the growth of new blood vessels, which cancer tumors must produce to survive—a process known as angiogenesis. While the mechanism of action is not well understood, it does work to effectively starve cancer tumors to death. The anti-angiogenesis effect can be of further benefit with individuals suffering from macular degeneration. Adult Macular Degeneration (AMD) occurs when the capillaries behind the retina begin to lift the retina from the back of the eye. Squalene reduces the angiogenesis and some have reported very high degrees of reversal of AMD.⁴

Squalene has been clinically proven to protect cells from damage caused by naturally occurring free radicals or radiation and chemotherapy-induced damage. This is good news for those who elect to undergo the rigors of chemotherapy and/or radiation.

Scientific research reveals that shark liver oil alkoxyglycerols activated the body's lymphatic immune defense system by:

- stimulating the formation of antibodies and increasing the number of white blood cells and thrombocytes in the blood⁵, and
- diminishing the harmful side-effects following radiation therapy by neutralizing and counteracting detrimental changes in the blood cell ratio caused by radiation treatment.⁶

In the 1990s, Johns Hopkins University found squalene also effective against many yeast, fungus and bacterial infections. It also showed promise for immune-compromised individuals, such as AIDS and cancer patients.

Synthese and Biological Effect of Methoxy-substituted Glycerol Ethers, Progress in Chemistry of Fats and other Lipids, 1978: 16, 45.

³ Brohult, A., *Alkoxyglycerols and their use in Radiation Treatment*, Acta Radio, 1963: Suppl. 223.
Brohult, A., Brohult, J., and Brohult, S., *Biochemical Effects of Alkoxyglycerols and their Use in Cancer Therapy*. Acta. Chem. Scand., 1970: 24, 730. Brohult, A., Brohult, J., and Brohult, S., *Regression of Tumour Growth after Administration of Alkoxyglycerols*. Acta Obstet. Gynecol. Scand., 1978: 57: 1, 79.

⁴ We also recommend AdaptAid as an adjunct to AMD recommendations.

⁵ Boeryd, B. et al, 'Stimulation of Immune Reactivity by Methoxy-substituted Glycerol Ether Incorporated into the feed', European Journal of Immunology, 1978: 8, 678, 680.

⁶ Brohult, A., *Alkoxyglycerols and their use in Radiation Treatment*, Acta Radio, 1963: Suppl. 223.
Brohult, A., Brohult, J., and Brohult, S., *Biochemical Effects of Alkoxyglycerols and their Use in Cancer Therapy*. Acta. Chem. Scand., 1970: 24, 730.

Additionally, squalene has been researched and used for:

- Recurring infections
- Strengthening the immune system, particularly in chronic degenerative diseases
- Coughs, colds and influenza
- Tissue repair, delayed wound healing and acne
- Before, during and after radiation therapy
- Promoting healing and recovery of nervous system
- Combating viral hepatitis and cirrhosis of the liver
- Neutralizing pain
- Lowering serum cholesterol

Based on research and evidence, Squalene in shark liver oil may well contain the secret of improved health and longevity for mankind.

Suggested Dosage

We suggest two capsules per day as an adult maintenance dosage. For intensive use, we recommend 15mg per pound of body weight per day, not to exceed 5,000 mg per day.

For Interested Health Professionals

Genaera Initiates Clinical Trial for Antiangiogenesis Drug Squalamine with IND for the Treatment of Fibrodysplasia Ossificans Progressiva

Plymouth Meeting, PA, January 16, 2002 -- Genaera Corporation. (NASDAQ: GENR) today announced the initiation of a clinical trial for squalamine, its antiangiogenic agent, in fibrodysplasia ossificans progressiva (FOP). The study will be conducted in collaboration with the University of Pennsylvania School of Medicine, under the direction of Frederick Kaplan, M.D., Isaac and Rose Nassau Professor of Orthopedic Molecular Medicine, an internationally recognized authority on FOP. An IND (investigational new drug application) has been accepted by the FDA to support the initiation of the clinical trial, as is required.

FOP is a rare genetic disorder in which there is progressive formation of new bone in the large muscles, leading to progressive immobility and disability. The disease starts in childhood, with initial painful swelling of muscles, which in days to weeks often turns to bone. The disease begins in the neck and upper spine, and progresses over a period of years to the muscles around the hips, jaw, and other major joints. The swollen muscles represent a type of growth very similar in appearance to a sarcoma cancer. Similar to cancer, these growths in the swollen muscles are nourished by a network of newly formed primitive blood vessels, as a result of active angiogenesis in the lesions.

Early research, conducted in collaboration with Dr. Judah Folkman, the world's leading angiogenesis research scientist, and Dr. Michael Zasloff, Genaera's founding scientist, has shown that angiogenic factors, including basic fibroblast growth factor, are elevated during periods of active disease in FOP. By

blocking the angiogenic process, squalamine has the potential to inhibit the progression of the muscle growths seen in FOP, and prevent the muscle turning into bone.

Dr. Kaplan commented, “Our laboratory has studied squalamine and found it to possess potent antiangiogenic properties. I believe antiangiogenic therapies may have important medical benefits in debilitating conditions in which angiogenesis is an important part of the disease process, such as FOP and cancer. I am delighted to have the opportunity to conduct this initial study of squalamine in FOP during periods of active disease.”

Roy C. Levitt, M.D., President and Chief Executive Officer of Genaera, commented, “To date, no current therapy is approved to treat this devastating disease. Due to the rarity and severity of FOP, substantial uncertainties exist when evaluating experimental therapies. We are delighted to further advance the clinical development of squalamine for FOP and aid in the search for a cure, and are hopeful that this approach may provide clinical benefit for this orphan indication.”

This study is partially funded by the International Fibrodysplasia Ossificans Progressiva Association (IFOPA), a non-profit organization that supports education, clinical care, research, and international communication on fibrodysplasia ossificans progressiva.

Squalamine is the first clinical drug candidate in a class of naturally occurring, pharmacologically active, small molecules known as aminosterols. Squalamine is a potent anti-angiogenic molecule with a unique multi-faceted mechanism of action that blocks the action of a number of angiogenic growth factors, including vascular endothelial growth factor (VEGF). The Company currently has ongoing trials evaluating squalamine in the treatment of non-small cell lung cancer, ovarian cancer, and other adult solid tumors. Genaera anticipates the start of clinical trials in age related macular degeneration (AMD) in 2002.

Genaera Corporation is a biopharmaceutical company committed to developing medicines for serious diseases from genomics and natural products. Research and development efforts are focused on anti-angiogenesis, obesity, infectious diseases and respiratory diseases.

This announcement contains forward-looking statements that are subject to risks and uncertainties. Forward-looking statements reflect management's current views and are based on certain expectations and assumptions. Such statements include, among others, statements regarding the preliminary results and future clinical development plans and prospects for squalamine (for lung cancer, ovarian cancer and in other indications), the IL-9 antibody program, the small molecule muco-regulator program, and trodulamine. You may identify some of these forward looking-statements by the use of words in the statements such as “anticipate,” “develop,” “continuing,” and “progress,” or other words of similar meaning. Genaera’s actual results and performance could differ materially from those currently anticipated and expressed in these and other forward-looking statements as a result of a number of factors, including, but not limited to, the additional data to be collected from the clinical trials, results of additional clinical development plans, results of ongoing preclinical and clinical studies in our drug development candidates, general financial, economic, regulatory and political conditions affecting the biotechnology industry and the other risks and uncertainties discussed in this announcement and in Genaera’s filings with the U.S. Securities and Exchange Commission. Genaera does not intend (and it is not obligated) to publicly update, revise or correct these forward-looking statements. This discussion is permitted by the Private Securities Litigation Reform Act of 1995.

Company Profile

Hugh Smith, PhD, is an internationally respected and well-known researcher of chronic illnesses. Many MDs consult with Dr. Smith and often refer their “difficult” patients to him for help.

His background represents 20 years of research in nutrition, bio-psychology, bio-energetics and Targeted Nutritional Intervention (TNI). Dr. Smith writes for several magazines, researches for nutrition companies, and designs training programs for health care professionals interested in adding nutritional counseling to their practices. His expertise in nutrition is represented in nationwide seminars.

Based upon his clinical observations, Dr. Smith has developed several innovative products formulated to slow the aging process and naturally combat chronic illnesses. In his practice, he has found nutritional counseling to be effective with ADD/ADHD, fibromyalgia, chronic fatigue syndrome, irritable bowel syndrome, weight loss, arthritis, candidiasis and more.

Dr. Smith specializes in Vital Hematology (or Real Time Microscopy) as a means of examining and conducting live blood analysis of clients. Through scientific assessments, he then recommends nutritional interventions to reverse risk factors for chronic disease and nutritional deficiencies. An initial client visit includes the observation of living blood (with a video tape of the observation included), and nutritional counseling for chronic illness and potential risk factors.

To contact Dr. Smith

Currently, Dr. Smith’s research facility is located at 5825 Avenida Encinas, Suite 111 Carlsbad, California 92008. For more information, please email info@healthwalk.com or call the office at 760-929-1520.

Please note: Several of Dr. Smith’s colleagues are available for demonstrations to groups, health food stores and/or practices wishing to offer nutritional interventions to their clients and practice. For details, please call the office.

