TITLE: Compositions for Cancer Treatment
INVENTOR(S): Jin Zeng

BACKGROUND

Cancer is responsible for over 15% of global human deaths, emerging as the leading cause of mortality in some countries. It manifests as a intricate spectrum of more than 200 distinct diseases, all characterized by uncontrolled cell growth. Cancer cells possess the unique ability to divide endlessly, forming malignant tumors, infiltrating nearby tissues, and potentially metastasizing to distant parts of the body via the lymphatic system.

In contrast, normal somatic cells are mortal and undergo a loss of proliferative capacity during senescence. At the molecular level, scientists have identified telomeres—tandemly repeated simple DNA sequences at the ends of eukaryotic chromosomes—as key players in the cellular aging process. The cumulative loss of telomeric DNA through successive cell divisions serves as an activating signal for cellular senescence and aging.

Maintaining the length of telomeres is crucial, and this is orchestrated by an enzyme known as telomerase. Telomerase operates by adding bases to the ends of telomeres, thus playing a pivotal role in cellular longevity.

Telomerase activity is typically low or absent in somatic cells, contrasting with its elevated presence in cancerous cells. By up-regulating telomerase, cancer cells can effectively prevent the shortening of telomeres. This enzyme complex, responsible for elongating telomeres, is activated in approximately 90% of tumors, showcasing a significant increase in cellular telomerase activity associated with detrimental human proliferative diseases, particularly cancer.

Further supporting this connection, studies using knockout mice have confirmed the pivotal role of telomeres in promoting tumorigenesis. Notably, inhibiting cancer cell proliferation in vitro has been achieved by suppressing telomerase activity through various means, such as dominant-negative cDNA or RNAi targeting the telomerase catalytic subunit (hTERT), anti-sense RNA targeting the template RNA subunit (hTR) of telomerase, or blocking the recruitment of telomerase. These findings underscore the crucial involvement of telomerase in the process of tumorigenesis.

The Great Basin Bristlecone Pine (Pinus longaeva) holds the distinction of being the oldest known living eukaryote, with the oldest specimen on record dating back to 4777 years in 2012. A study conducted by Lanner and Connor in 2001 examined senescence by comparing putative biomarkers of aging in Great Basin Bristlecone Pines ranging from 23 to 4713 years old. Notably, these ancient trees do not undergo mutational aging.

Furthermore, the Bristlecone Pine exhibits remarkable longevity without experiencing deterioration in meristem function across embryos, seedlings, or mature trees. This observation leads to the conclusion that the Great Basin Bristlecone Pine follows a distinctive path, devoid of the ordinary senescence process.

A recent study by Flanary and Kletetschka, comparing telomere length and telomerase activity among Bristlecone Pine trees with varying lifespans (long-lived: 2000- to 5000-year lifespan, medium-lived: 400- to

500-year lifespan, and short-lived: 100- to 200-year lifespan), reveals a correlation between increased telomere length, enhanced telomerase activity, and extended lifespan.

In 1972, 96 seeds were collected from a small cone on a Great Basin Bristlecone Pine tree that has been thriving for almost 4 3/4 millennia. Each seed was meticulously planted in a growth medium, and astonishingly, every seed sprouted into a seedling. Additionally, the needles of the Bristlecone Pine are known to retain their green color for over 45 years. These findings suggest that the Bristlecone Pine exhibits an anti-aging capability, potentially enabling it to thrive indefinitely.

The inventor, as previously disclosed in provisional patent applications #61676909 and #61692708, has made a groundbreaking discovery regarding the use of topical or oral compositions. These compositions incorporate telomerase, extracts or components from the Bristlecone Pine, or extracts and components from other varieties of long-lived Pine plants (genus Pinus). The application of such compositions demonstrates a remarkable enhancement in the overall quality of the body and skin.

These formulations exhibit the potential to reverse the general aging process, rejuvenating aged tissues and restoring their physiological functions. The intake of these compositions has been associated with notable benefits, including a significant reduction in wrinkles, increased skin thickness, improved circulation, digestive ability, metabolic rate, vitality, stamina, and reserves. Furthermore, they invigorate sexual function, enhance memory retention, muscle tone, bone density, lipolysis, sleep, vision, and contribute to improved hair and nail growth.

Concerns arose regarding the potential for Bristlecone Pine extract, with its telomerase activity, used in anti-aging applications, to promote cancer and elevate the risk of tumorigenesis due to the role of telomerase in human proliferative diseases. However, contrary to initial expectations, this inventor has made an unexpected and counter-intuitive discovery. The long-lived Pine extract, rather than posing a risk, demonstrates remarkably potent anti-cancer therapeutic activity.

Abnormally high telomerase activity in cancerous and somatic cells is associated with tumorigenesis and proliferative disorders, including bone marrow failure, acute myeloid leukemia (AML), and pulmonary and hepatic fibrosis. Conversely, active telomerase is implicated in prolonging lifespan; without it, cells undergo aging. Most organisms face a trade-off between choosing longevity with the risk of over-proliferation or senescence with controlled proliferation.

However, our groundbreaking discovery reveals, for the first time, that the remarkable Great Basin Bristlecone Pine plant defies this dichotomy. It has the extraordinary ability to simultaneously achieve supreme longevity while effectively managing proliferation.

Hence, the molecular composition of the Great Basin Bristlecone Pine stands out as exceptionally unique among the 8.7 million species on Earth. There exists a distinctive molecular mechanism that underlies the Pine plant's longevity, a mechanism yet to be fully explored. This mechanism endows the Pine with the remarkable ability to live indefinitely without succumbing to mutational aging—a phenomenon unattainable by the vast majority of species on Earth. Telomerase, along with other exceedingly rare and/or unique unidentified natural constituents in the long-lived Pine plant, may synergistically interact to combat aging and regulate cellular proliferation limitlessly. The Bristlecone Pine extract exhibits an extraordinary physiological activity, combining both anti-aging and anti-cancer capabilities.

To combat cancer, various types of anti-cancer drugs are utilized. These encompass drugs derived from biological molecules, such as peptides, proteins, enzymes, or vaccines; synthetic chemotherapeutics like taxol, among others; and drugs sourced from natural origins. Given the extended clinical development timelines for biological drugs and the high toxicity associated with chemotherapeutic agents, there is a significant demand for anti-cancer agents derived from natural sources. These agents aim to provide maximal therapeutic efficacy with minimal or no side effects. Humanity has a longstanding history of using plants for treating illnesses, extracting active ingredients for traditional medicines, and exploring drug leads to develop novel therapeutic interventions.

Sakagami, Konno, and Nonoyama reported in U.S. Pat. No. 4,985,249 the anti-HIV activity of pine cone extract. Xin Yaolu revealed in Chinese patent CN 1279107 a Chinese medicine comprising phytolaccatoxin, phytolaccapolyose, ricin, glycyrrhizic acid, pineal acidic polyose extracted from castor, phytolacca root, liquorice root, and pine cone. Xiyun Sun and Yinglong Wang disclosed in another Chinese patent abstract CN 1122206 a low-salt soy sauce supplemented with pine nut kernel and Xinggu mushroom extracts, exhibiting certain anti-cancer properties. Tanaka and Bradley disclosed in U.S. Pat. No. 7,371,417 the use of pine cone extract in enhancing the effects of nucleic acid vaccines and the production of phenotypically immature and/or mature dendritic and/or fibrocyte cells.

The mentioned patents highlight certain non-specific immuno-modulating adjuvant properties of pine extracts. However, they do not specifically reveal the absolutely exceptional and unparalleled anti-cancer capability of Bristlecone Pine extract, especially in the context of its inherent high telomerase activity that could otherwise promote tumor progression. The credit goes to this inventor for showcasing the extraordinary utility of Bristlecone Pine extracts in both the prevention and treatment of proliferative disorders, notably cancer

Given the conflicting implications of telomerase activity in human aging and cancer, there exists an unmet need for novel compounds and/or their combinations that can decelerate human tissue decay without heightening the risk of cancer. Additionally, there is a pressing demand for compounds with the potential to treat specific cancers. The scientific and medical communities are actively seeking such novel compounds, and their discovery would mark a significant advancement in the field.

As a result, there is a demand for effective compositions and efficient delivery approaches that incorporate extracts or components of the Great Basin Bristlecone Pine (Pinus longaeva) for the prevention and treatment of cancer and other proliferative diseases. Furthermore, this inventor suggests that, owing to common or similar cellular constituents, other species within the long-lived Pinus genus, such as the Rocky Mountains Bristlecone Pine (Pinus aristata) and the Foxtail Pine (Pinus balfouriana), may exhibit comparable therapeutic advantages.

BRIEF SUMMARY OF THE INVENTION

The following terms are defined below for the purpose of the present invention.

The term "anti-cancer therapy" is intended to encompass the growth inhibition/eradication of primary tumors, stabilization of tumor growth, inhibition of metastasis formation, or prevention of tumor formation. Additionally, anti-cancer activity includes any combination of our substances with other known or investigational anti-cancer agents to enhance the therapeutic efficacy of drugs.

This inventor has made a groundbreaking discovery that the incorporation of extracts or components from the long-lived Bristlecone Pine into novel compositions and delivery systems yields remarkably effective results in the prevention and treatment of cancer and other proliferative diseases.

The primary objective of the present invention is thus related to a composition comprising an extract of the Bristlecone Pine plant.

Another objective of this invention pertains to a composition comprising an extract of the Bristlecone Pine plant, which may be optionally combined with one or more pharmaceutically acceptable auxiliaries, carriers, vehicles, excipients, and/or diluents.

Yet another objective of this invention is associated with a method for manufacturing a composition comprising an extract of the Bristlecone Pine plant, and optionally formulating the extract with one or more pharmaceutically acceptable auxiliaries, carriers, vehicles, excipients, and/or diluents.

Another objective of this invention is concerned with utilizing an extract from the Bristlecone Pine plant for the production of a medicament designed for the prophylaxis, treatment, amelioration, or defense against cancer.

Yet another objective of this invention is related to a process for the treatment, amelioration, prevention, or protection against cancer, involving the administration of an effective amount of a composition as described herein to a subject in need of such care.

Yet another objective of this invention is concerned with enhancing an anti-cancer composition by incorporating an extract of the Bristlecone Pine.

Yet another objective of this invention is associated with the utilization of other parts of the Bristlecone Pine plant or extracts from other parts, or their combinations, in formulating pharmaceutical compositions for combatting cancer.

Yet another objective of this invention pertains to the use of other varieties within the long-lived Bristlecone Pine family, such as Great Basin Bristlecone Pine (Pinus longaeva), Rocky Mountains Bristlecone Pine (Pinus aristata), Foxtail Pine (Pinus balfouriana), and so forth. This includes different parts and extracts of these parts or their combinations in formulating pharmaceutical compositions for combatting cancer.

These and other aspects of the present invention are described in further detail below through a number of non-limiting examples

DETAILED DESCRIPTION AND BEST MODE OF IMPLEMENTATION

The following provides a detailed description and examples to illustrate the surprising and potent advantages of this invention and the benefits derived from novel delivery systems incorporating extracts or components

of the Bristlecone Pine plant for combating cancer, even in the presence of inherent high telomerase activity, along with methods of using the same.

In its broadest aspect, this invention is centered around a composition comprising an extract of the Bristlecone Pine plant in which telomerase activity is present. Such compositions may take the form of pharmaceutical compositions, combined with one or more pharmaceutically acceptable excipients, carriers, vehicles, auxiliaries, and/or diluents. Compositions, as described in this invention, exhibit remarkable anti-cancer capabilities, thereby facilitating the prophylaxis, amelioration, prevention, and/or treatment of cancer.

According to one objective of this invention, pharmaceutical formulations containing Bristlecone Pine needle extract are utilized for the treatment and prevention of cancer. Certain immunostimulating agents, such as pineal acidic polyose, and antioxidants, such as Pycnogenol, may function as adjuvants in enhancing the anti-cancer effects of the long-lived Pine plant. However, these molecules alone cannot fully elucidate how the Great Basin Bristlecone Pine manages to overcome its intrinsic high telomerase activity and prevent over-proliferation. It is believed that there exist ingenious yet-to-be-determined molecules produced by the Pine plant and quintessential molecular mechanism(s) that remain to be explored, contributing to its phenomenal anti-cancer ability.

In alignment with this invention, an extract of Great Basin Bristlecone Pine needles may be incorporated into pharmaceutical regimens for the prophylaxis, amelioration, prevention, and/or treatment of cancer. Those skilled in the art can leverage components from the Great Basin Bristlecone Pine, extracts from Rocky Mountain Bristlecone Pine needles or their components, extracts from Foxtail Pine needles or their components, as well as extracts or components from other long-lived organisms, including individual trees such as Limber Pine (Pinus flexilis), Patagonian Cypress (Fitzroya cupressoides), Giant Sequoia (Sequoiadendron giganteum), Western Juniper (Juniperus occidentalis), Sacred Fig (Ficus religiosa), Coast Redwood (Sequoia sempervirens), Subalpine Larch (Larix lyallii), Rocky Mountain Juniper (Juniperus scopulorum), Sugi (Cryptomeria japonica), Northern Whitecedar (Thuja occidentalis), Nootka Cypress (Callitropsis nootkatensis), Bald Cypress (Taxodium distichum), European Yew (Taxus baccata), Mediterranean Cypress (Cupressus sempervirens), Pond Cypress (Taxodium ascendens), Formosan Cypress (Chamaecyparis formosensis), Olive (Olea europaea), Cariniana Legalis, Japanese Cedar (Cryptomeria japonica), Sweet Chestnuts (Castanea sativa), Kauri (Agathis australis), Chinese Juniper (Juniperus chinensis), Oriental Plane (Platanus orientalis), Coast Live Oak (Quercus agrifolia), Yew (Taxus), Pedunculate Oak (Quercus robur), Montezuma Cypress (Taxodium mucronatum), and clonal trees such as Quaking Aspen (Populus tremuloides), Palmer Oak (Quercus palmeri), Norway Spruce (Picea abies), and animals such as Hydra. Additionally, beyond the needles of the Bristlecone Pine, other parts such as seeds, bark, stalk, or sheath can also be utilized for the same purpose

According to this invention, compositions containing Bristlecone Pine plant extract for combating cancer can be formulated with various pharmaceutically acceptable, non-toxic, and non-allergic vehicles, carriers, adjuvants, additives, solvents, filters, lubricants, excipients, binders, stabilizers, and/or diluents to facilitate the delivery of therapeutic molecules. Non-limiting examples of such components include water, sodium chloride, zinc salts, colloidal silica, magnesium trisilicate, alumina, aluminum stearate, ion exchangers, lecithin, serum proteins like human serum albumin, self-emulsifying drug delivery systems (SEDDS) such as d alpha-tocopherol polyethylene glycol 1000 succinate, or other similar polymeric delivery matrices or systems, buffer compounds like glycine, phosphates, sorbic acid, potassium sorbate, partial glyceride mixtures of saturated vegetable fatty acids, salts or electrolytes such as disodium hydrogen phosphate, protamine sulfate,

potassium hydrogen phosphate, sugars such as saccharose, mannitol, sorbitol, or lactose, cellulose preparations and/or calcium phosphates like tricalcium phosphate or calcium hydrogen phosphate, starch pastes such as corn, wheat, rice, or potato starch, gelatin, tragacanth, methylcellulose, and/or polyvinylpyrrolidone, polyethylene-polyoxypropylene-block polymers, polyethylene glycol, sodium carboxymethylcellulose, polyacrylates, waxes, polyethylene glycol, and wool fat, carboxymethyl starch, cross-linked polyvinyl pyrrolidone, agar or alginic acid or a salt thereof, such as sodium alginate, cyclodextrins like alpha-, beta-, and gamma-cyclodextrin, or chemically modified derivatives such as hydroxyalkylcyclodextrins, including 2- and 3-hydroxypropyl-beta-cyclodextrins, or other solubilized derivatives, silicic acid, talc, stearic acid, or salts thereof, such as magnesium or calcium stearate, and/or polyethylene glycol, among others.

Additionally, concentrated sugar solutions that may comprise gum arabic, talc, polyvinylpyrrolidone, polyethylene glycol, and/or titanium dioxide, or coating solutions, solutions of suitable cellulose preparations, such as acetylcellulose phthalate or hydroxypropylmethylcellulose phthalate, can also be included. Dyes or pigments may be added to the tablets or dragee coatings for identification or indicating different doses of active ingredients and other purposes. The pharmaceutical compositions of this invention may contain any conventional non-toxic pharmaceutically-acceptable carriers, adjuvants, or vehicles. When necessary, pharmaceutically acceptable acids, bases, or buffers may be employed to adjust the pH of the formulation to enhance the stability of the final product.

According to this invention, pharmaceutical compositions containing Bristlecone Pine plant extract can be administered through various routes, including topically, orally, via inhalation spray, buccally, nasally, optically, parenterally, rectally, vaginally, via an implanted reservoir, or transdermally. The term 'parenteral,' as used herein, encompasses subcutaneous, intracutaneous, intravenous, intramuscular, intraarticular, intrasynovial, intrasternal, intrathecal, intralesional, and intracranial injection or infusion techniques. Preferred administration techniques include oral administration or injection.

According to this invention, pharmaceutical compositions containing Bristlecone Pine plant extract for oral administration can be prepared in any orally acceptable dosage form, including but not limited to beverages, caplets, capsules, drops, food additives, gels, gelcaps, gums, pastes, powders, liquids, pills, lozenges, rinses, soft gels, and tablets, among others.

Similarly, for injectable administration, pharmaceutical compositions containing Bristlecone Pine plant extract may be formulated as a sterile aqueous or oleaginous suspension. Commonly used vehicles for aqueous injection suspensions include isotonic sodium chloride solution, water, Ringer's solution, mannitol, sodium carboxymethylcellulose, sorbitol, and/or dextran. Lipophilic solvents or carriers for oily injection suspensions, such as fatty oils (e.g., sesame oil, oleic acid and its glyceride derivatives, olive oil, or castor oil), particularly in their polyoxyethylated versions, or synthetic fatty acid esters like ethyl oleate or triglycerides, can also be employed.

The pharmaceutical compositions containing Bristlecone Pine plant extract may also be formulated in an encapsulated form for oral or injectable administration, facilitating the controlled release of therapeutic compounds over desired time intervals, ranging from minutes to months. Such formulations may include, but are not limited to, vesicles, liposomes, and/or nanoparticles (e.g., biodegradable and non-biodegradable colloidal particles comprising polymeric materials such as nanospheres and nanocapsules).

For buccal or sublingual administration, lozenges may be utilized as carriers for the pharmaceutical compositions containing Bristlecone Pine plant extract, with a flavored base such as acacia and sucrose or tragacanth. Additionally, pastilles can be employed in an inert base, such as glycerin and gelatin or sucrose and acacia.

According to this invention, pharmaceutical compositions containing Bristlecone Pine plant extract for rectal administration are preferably presented in the form of unit dose suppositories. These compositions can be prepared by blending the extract of this invention with one or more suitable non-irritating vehicles. Carriers that are solid at room temperature but liquid at rectal temperature, thus melting in the rectum to release the active components, may include, but are not limited to, beeswax, cocoa butter, and polyethylene glycols.

According to this invention, the pharmaceutical compositions containing the Bristlecone Pine plant extract can be administered through nasal aerosol or inhalation. These compositions may be prepared using established techniques, such as solutions in saline, incorporating absorption promoters, solubilizing or dispersing agents, and preservatives.

For topical administration, the pharmaceutical compositions containing the Bristlecone Pine plant extract are preferably formulated as aerosols, creams, gels, ointments, lotions, oils, pastes, or sprays. This is particularly beneficial when areas or organs requiring treatment are readily accessible by topical application. In such cases, the pharmaceutical composition should be formulated with one or more carriers, including, but not limited to, water, benzyl alcohol, mineral oil, alcohols, petroleum jelly, lanolin, polyethylene glycols, liquid petroleum, cetearyl alcohol, acetyl esters wax, 2-octyldodecanol, white petroleum, propylene glycol, polyoxyethylene polyoxypropylene compound, 2-octyldodecanol, and emulsifying wax. The pharmaceutical compositions, as per this invention, may also be topically applied using transdermal patches in close contact with the epidermis or iontophoresis. Additionally, rectal suppository formulations or proper enema formulations for the lower intestinal tract are considered suitable.

The pharmaceutical compositions of this invention can be administered to a patient known or suspected to have metastases through systemic administration. A combination of inhalation and parenteral administration is a non-limiting example of systemic administration. This ensures that all tumor sites, whether primary or secondary, receive treatment with the therapeutic compounds.

Regarding one objective of this invention, various common techniques like water-extraction, water-alcohol extraction, alcohol extraction, etc., can be employed for extracting Bristlecone Pine needles. The preferred method is maceration. Those skilled in the art can explore alternative extraction processes such as settling, leaching, distillation, infusion, digestion, decoction, pressing, mixing, percolation, etc., as scientific knowledge advances through further studies. The following provides a non-limiting example of extract preparation.

To prepare the Bristlecone Pine extract, pine needles, preferably in triturated powder form, are mixed with at least 2 times by weight, preferably 4-6 times, of distilled water. The mixture undergoes incubation for several days under constant agitation, with an incubation time of 1-5 days, preferably 3 days. Following filtration, the mixture solution is concentrated. The condensed stock solution can be further dried into powder form using various techniques such as the spray drying method, vacuum drying method, and freeze-drying method, among others. The extract may

exist in its final form as a powder, slurry, aqueous solution, particulate form, or dissolved in an organic solvent like ethanol or dimethyl sulphoxide.

A person with ordinary skill in the art can utilize varying ratios of needles to water or any part of the plant, following established practices as outlined in authoritative reference books such as "The Pharmacological Basis of Therapeutics" (Goodman & Gillman, 7th Edition, 1985) and "Remington's Pharmaceutical Science" (Mack Publishing Company, 10th Edition).

As long as it aligns with the objectives of the present invention, Bristlecone Pine extract of any suitable dosage strength can be administered at any time interval for the prevention and treatment of cancer. Generally, dosages ranging between 0.0005 and 200 mg/kg body weight per day may be employed, with a preference for the range between 0.1 and 50 mg/kg body weight per day. Recipients may take the pharmaceutical compositions of this invention 1 to 5 times per day or undergo continuous infusion as part of an acute or chronic treatment. Depending on the individual recipient and the chosen method of administration, Bristlecone Pine extract may be blended in various ratios with carrier materials to form a single dosage form, typically comprising 1% to 95% active ingredient (w/w), preferably 10% to 85%, and even more preferably 25% to 65%.

If a patient experiences relief from symptoms after receiving a pharmaceutical composition of this invention, they may opt to continue with a maintenance dose at a reduced strength or frequency of administration, or both, to maintain the improved condition. Therapy should be discontinued when the condition has ameliorated to a healthy level. To prevent the recurrence of disease symptoms over the long term, intermittent treatment may be necessary.

For cancer prevention, recipients may consider taking a daily prophylactic dose of the pharmaceutical composition of this invention.

The dosage levels provided above serve as non-limiting examples. Those skilled in the art can customize doses and design different treatment regimens for individual patients, considering various factors such as the patient's sex, age, body weight, diet, general health condition, the development and severity of cancer, the patient's disposition to cancer, the healthcare provider's judgment, the specific activity of the pharmaceutical composition of this invention, time of administration, rate of excretion, drug combination, etc.

While Great Basin Bristlecone Pine (Pinus Longaeva) is highlighted as a preferred species, and needles are the preferred part, any portion of the plant, including seeds, bark, stalk, or sheath, or other species like the Rocky Mountain Bristlecone Pine (Pinus Aristata), Foxtail Pine (Pinus Balfouriana), producing known and/or yet-to-be-determined native molecules exhibiting remarkable anti-proliferative and anti-cancer capabilities, even in the presence of significant tumor-promoting telomerase activity, could serve as appropriate alternatives beneficial for the present invention.

As per this invention, formulations containing Bristlecone Pine plant extract may integrate other agents recognized in the field for combined anti-cancer therapy. These may include, but are not limited to, anti-proliferative drugs, anti-cancer drugs, cytostatic compounds, anti-angiogenic and anti-metastasis compounds, along with supplementary anti-cancer potentiating compounds. The selection of these agents should align with the objectives of this invention. A comprehensive list of such agents, along with non-limiting examples, is compiled in U.S. Patent # 6949514 titled "Anti-tumor agents."

The pharmaceutical compositions featuring Bristlecone Pine plant extract demonstrate a diverse range of activities against cancer cells through various mechanisms, notably including growth inhibition, apoptosis (programmed cell death), DNA fragmentation, cell cycle blocking, induction of cell differentiation, and inhibition of angiogenesis and metastasis. These compositions exhibit an unparalleled and miraculous anti-cancer competence even in the presence of significant telomerase activity, facilitated by unique and unprecedented mechanisms within the long-lived Pine plant. As such, these formulations find application in the treatment, amelioration, prophylaxis, defense against, and prevention of a wide array of cancers. Non-limiting examples of such cancers include breast cancer, benign prostatic hypertrophy, brain tumor, prostatic cancer, uterine cancer, skin cancer, leukemia, ovarian cancer, endometrial cancer, stomach (gastric) cancer, bladder cancer, cervical cancer, colon (large bowel) cancer, testicular cancer, Hodgkin's disease, pancreatic cancer, lymphoma, nasopharyngeal carcinoma, rhabdomyosarcoma, neuroblastoma, lung cancer, oral cancer, liver cancer, laryngeal cancer, thyroid cancer, among others.

Evidence gathered from preliminary clinical trials indicates a definite improvement in the condition of cancer patients administered with the pharmaceutical compositions of this invention. Patients report enhanced appetite, strengthened vitality, improved psychological well-being, and general health, along with better prognoses. Biochemical tests reveal a significantly improved physiological condition. Imaging techniques such as X-ray, ultrasonography, C.T. Scan, and MRI demonstrate a reduction in tumor size and even cessation of metastasis in certain cases.

The formulation of this invention originates from the natural product of Bristlecone Pine extract and exhibits no side effects in all tests conducted thus far. Consequently, it proves remarkably useful as a prophylactic measure against all cancers, particularly prevalent ones such as breast cancer in women and prostate cancer in men. This formulation, when taken as a dietary supplement, contributes to overall well-being, reduces healthcare expenses, and lowers mortality and morbidity rates.

For patients grappling with any form of cancer, the pharmaceutical composition of this invention can be utilized either independently or as an adjuvant, for instance, as a dietary supplement in conjunction with conventional anticancer chemotherapy, radiotherapy, and/or surgery. It can also be employed to stimulate appetite, restore health, enhance ambulatory capacity, and improve overall well-being. As documented in our prior patent applications #61676909 and #61692708, compositions containing Bristlecone Pine extract demonstrate robust anti-aging capabilities.

Patients undergoing cancer treatment can leverage this composition to regulate metabolism, fostering anabolism, promoting catabolism, facilitating the swift elimination of toxic metabolites, and mitigating the side effects of conventional cancer therapies. Additionally, it aids in invigorating the nervous system, enhancing psychological well-being, boosting vitality and stamina, ameliorating and preventing aging, supporting tissue and organ regeneration, and ultimately extending lifespan.

Alternatively, the pharmaceutical composition of this invention may be combined with the oral composition outlined in our prior patent application #61692708, designed for the prevention and treatment of cancer, aging, or both.

As one objective of this invention, a composition can be integrated into a kit featuring surface indicia, such as a word, phrase, abbreviation, picture, or symbol. The kit includes a container housing a composition of this invention along with other optional compounds, accompanied by

instructions detailing the kit's use.

The following examples are provided to showcase specific non-limiting features of the invention. It is important for those skilled in the art to recognize that the disclosed teachings in the following examples illustrate techniques devised by the inventor to perform effectively in the practice of the invention. In light of this disclosure, individuals skilled in the art will acknowledge that numerous variations and modifications can be made to the specific aspects without deviating from the spirit and scope of the invention.

In the examples below, quantities are expressed in approximate weight (% wt) or approximate units (I.U.), unless otherwise specified, based on the total weight of the composition. The term "qs" denotes using a sufficient quantity by weight to bring the entire composition to 100%. Whenever possible, International Nomenclature Cosmetic Ingredient (INCI) names are utilized.

EXAMPLE 1

To formulate preparations for oral administration, all ingredients were blended to achieve a homogeneous mixture. Subsequently, the blend was compressed into tablets using a tablet press.

This example presents a formulation containing Bristlecone Pine needles extract alone for oral administration.

- Bristlecone Pine needles extract: 200 mg, packaged in gelatin capsules.

EXAMPLE 2

This example showcases a formulation comprising a combination of Bristlecone Pine needles extract and other compounds designed to combat cancer. These compounds include Broccoli Sprouts and Citrus Bioflavonoids for cancer prevention, and Modified Citrus Pectin for inhibiting cancer metastasis.

- Bristlecone Pine needles extract: 100 mg
- Broccoli Whole Plant: 400 mg
- Citrus Fruit Bioflavonoids: 200 mg
- Vitamin C: 200 mg
- Modified Citrus Pectin: 100 mg
- d-Alpha Tocopheryl: 100 IU
- Superoxide Dismutase: 5000 U
- Pycnogenol: 50 mg
- Magnesium Stearate: 8.8 mg
- Stearic Acid: 46 mg
- Microcrystalline Cellulose qs: 1000 mg

EXAMPLE 3

Bristlecone Pine needles extract underwent testing for its anti-cancer activity on various cancer cell lines representing human breast, prostate, colon, lung, liver, leukaemia, neuroblastoma, mouth, and ovary cancers. The tested cell lines included human breast MCF-7 & ZR-75-1, prostate DU-145 & LNCaP, colon Colo-205, HT-29 & SW-620, lung A-549, HOP-18 & NCI-H23, liver HEP-2 & HEP-G-2, leukaemia cell lines HL60 & K562, neuroblastoma SK-N-MC & IMR-32, oral KB, ovary NIH-OVCAR-3, OVCAR-5 & SK-OV-3.

These cell lines were cultured in a medium with varying amounts of candidate anti-cancer compounds containing Bristlecone Pine needles extract, as prepared according to this invention. Corresponding controls included either culture medium alone or medium plus pharmaceutical carrier(s). Anti-cancer activity was assessed through standard studies, including growth inhibition, cell proliferation inhibition by the MTT assay, induction of differentiation, apoptosis, DNA fragmentation, and cell cycle analysis by flow cytometry (References: Marks et al, 1992, Leukaemia Research, 16:1165-1173; McCloskey et al, 1994, Clinical Immunology and Immunopathology, 71:14-15).

In conclusion, in the course of anti-cancer studies involving pharmaceutical compositions containing Bristlecone Pine needles extract, a robust anti-cancer effect was observed across all cancer cell lines, resulting in more than 97% average cell death and prominent cellular abnormalities in the remaining cells. This outcome was particularly surprising, considering the Pine extract's inherent high telomerase activity, typically associated with tumor promotion.

EXAMPLE 4

A 65-year-old male habitual smoker experienced chest pain, observed blood in sputum, and was diagnosed with Stage III squamous cell carcinoma of the lung. Opting out of conventional therapy, the patient commenced the formulation from this invention, as per Example 1. The patient took two capsules three times a day. After two months, haemoptysis ceased, and chest pain alleviated. Four months later, it was noted that the tumor had not continued to grow. The patient reported a significantly improved sense of well-being.

EXAMPLE 5

A 68-year-old female patient received a diagnosis of terminal stage IV gastric cancer and was informed by her physician of only having 4 months to live. Unable to undergo surgery and declining classic therapy, the patient adopted the formulation from this invention, as per Example 2. She took two capsules three times a day. Two years later, the patient was still alive, with X-ray and MRI confirming an absence of metastases.

Hence, the compositions containing Bristlecone Pine extract seem highly specific to cancer cells, sparing healthy cells and resulting in undetectable side effects. Therapy with the pharmaceutical formulation of this invention demonstrates remarkable efficacy for cancer patients afflicted by malignant tumors, including metastatic carcinomas, even in terminal cases.

Given an analogous underlying pathological mechanism involving abnormal telomerase activity, the pharmaceutical formulations of this invention could potentially find application in preventing and treating various proliferative disorders, such as bone marrow failure, acute myeloid leukemia (AML), pulmonary fibrosis, and hepatic cirrhosis, among others.