Title: COMPOSITION, ITS USE FOR TREATING SYSTEMIC DISEASES A CONDITIONS, AND PRODUCT CONTAINING SAID COMPOSITION

Abstract: The invention relates to a pharmaceutical composition useful for treating or preventing cancerous diseases, HIV/AIDS, chronic inflammations, certain autoimmune diseases, and secondary conditions of such primary diseases, such as bacterial, viral and fungal infections, inflammations, diarrhea, dehydration, and pain, said composition comprising a catalytic product (based on a serine protease extracted and isolated from fish, molluscs and crustacean species), named Mkowski, and a microbial agent (comprising the strains Pediococcus pentosaceus, Pichia farinosa, Dekkera bruxellensis), named M-powder, to the use of said composition, and to a product containing said composition. The composition may further comprise a chemical agent, named Mesodine, and a herbal component, named Phumpat. The invention also relates to the use of the last mentioned composition, and to a product containing said last mentioned composition.
COMPOSITION, ITS USE FOR TREATING SYSTEMIC DISEASES AND CONDITIONS, AND PRODUCT CONTAINING SAID COMPOSITION

Field of the invention

The present invention relates to a pharmaceutical composition according to claim 1 and 4, to the use according to claim 9 and 13 and to a product according to claim 17.

Background of the invention

A healthy body is dependent on certain basic systemic functions, such as the intestinal tract, immune system and scavenging and removal of cellular by-products, debris and toxic matters.

The intestinal tract is not only a system for digestion of foodstuff into nutrients but it is also closely related to certain immune functions, such as the lymphoid immune system known as Peyer's Patches.

Peyer's Patches appear as oval or round lymphoid follicles located to the mucosa and extending into the submucosa of the ileum. B-lymphocytes predominate in the follicles' germinal centres and T-lymphocytes are found in the zones between the follicles. Peyer's Patches act as immune surveillance of the intestinal lumen and generate the immune response within the mucosa. Pathogenic microbes and other antigens entering the intestinal tract encounter macrophages, dendritic cells, B- and T-lymphocytes found in Peyer's Patches and other gut associated lymphoid tissue.

Specialised M cells from Peyer's Patches sample antigens directly from the mucosa and deliver them to Antigen-Presenting-Cells. B-cells and Memory-cells are stimulated upon
presentation of such antigens in Peyer's Patches and these cells then pass to mesenteric lymph nodes where the immune response is amplified. Activated lymphocytes enter the bloodstream via the thoracic duct and travel to the gut where they carry out their final effector functions.

Also, stem cells migrate to the intestine and Peyer's Patches for programming into specific immune cells, e.g. T- and B-cells, T-helper cells, Killer cells, Memory cells and macrophages. An intestine in balance interacts with the Payer's Patches for formation of certain immune functions and protection against diseases.

Certain clinical conditions may cause severe disturbances to and malfunctions of vital systemic functions, e.g. intestinal functions, immune responses, removal of antigens, debris and toxins from body tissues and organs.

Primary causes of such disturbances and malfunctions may be microbial and viral infections, inflammations, tissue damages and tumour diseases as well as side effects from drug therapies and psychosocial influences. In turn, such primary causes may lead to numerous secondary clinical conditions of transient and/or chronic nature, such as rheumatoid arthritis, ulcerous colitis, Crohn's disease, Irritable Bowel Syndrome, Multiple Sclerosis, cancerous diseases, diarrhoea and constipation, opportunistic infections, immune deficiencies, food intolerances and allergies, stasis wounds, autoimmune diseases etc.

The more protracted such primary cause or secondary condition is, the higher the risk of developing into a chronic condition.
Digestive tract and its functions, i.e. from mouth cavity to large intestine, have been found to be of uttermost importance to this invention as it constitutes a central function for the supply of nutrients and other metabolites and catabolites that are required for syntheses and biochemical reactions for systemic functions and systems, such as maintaining mucosa layers, recovery of essential substances and leaking of stimuli to the immune system to enable formation of antibodies and for programming stem cells into specific immune cells.

A malfunctioning and disturbed digestive tract may yield insufficiently digested, converted or transformed nutrients, metabolites, catabolites etc., i.e. they are not fully recognisable by cells or useful for biological syntheses and biochemical reactions. This may lead to an overload of non-recognisable/non-useful substances, i.e. regarded by the immune system as constituting antigens, debris and toxins to be neutralised by the immune system and finally discarded by liver and kidney functions.

A healthy body most often recovers from transient episodes of a malfunction/ disturbance to the tract but if protracted antigen, debris and toxins can be accumulated in the body tissues and fluids. Finally, the immune system will be impoverished by the overload and become less responsive leading amongst other to clinical conditions.

Basic purpose of the microbial contents of the intestine is to digest and convert foodstuff into nutrients and other essential substances for biological syntheses and reactions of the body. The microbial cells are merely "factories" that excrete a cascade of bioactive organic substances rather than converting the foodstuff themselves.
Such bioactive substances are enzymes, organic acids, hormones, bacteriocins and more that create optimal conditions for the survival and proliferation of each strain of the microflora. Also, such created conditions are optimised for all enzymatic activities that are responsible for amongst other the breakdown and conversion of foodstuff.

This cascade of bioactive substances may be different from strain to strain as the optimal conditions are different for each strain and for each enzyme. Disturbances to the microbial balance of the intestine may lead to accumulation of antigens, debris and toxin in organs, tissues and body fluids, as well as inflammations, mild to severe clinical primary and secondary conditions not only of the intestines but also to related systems and functions, such as enzymatic/catalytic spectrum, programming of stem cells into T- and B-cells, erythrocytes and other specialised cells, Peyer's Patches, liver and kidney performance.

Enzymes and catalytic activities originating from amongst other the intestinal flora and immune cells are believed to be as essential to this invention as a functional intestine. The full mechanism of interaction between the intestine, lymphoid immune system and other immune functions as well as scavenging of the body from antigens, debris, by-products, toxins, free radicals etc. is not absolutely clear.

Hypothetical conclusions drawn from clinical experiences indicate that a restored intestinal function creates proper conditions for excreted and formed bioactive substances, such as enzymes, to establish and maintain catalytic functions of the digestion as well as the conversion, transformation and
stabilisation of by-products, antigens etc. recognisable by immune functions and scavenging and removal of such matters from the body.

Proper catalytic conversion, transformation and stabilisation of antigens, by-products, debris etc. also broadcast proper chemotactic signals, i.e. cellular communication, for immune cells and other defence mechanisms to take adequate actions as well as for the liver and kidneys to entrap and remove certain matters from the body.

Enzymes and catalytic activities are very basic and essential in all life-forms in the vegetable and animal kingdoms. Early evolved life forms, such as prokaryotic cells, like bacteria, to eukaryotic cells in warm-blooded species all are utterly dependent on enzymatic and catalytic activities for their metabolism, communication, defence, survival and multiplication.

Enzymes are part of virtually all catalytic processes in biological systems, such as replicating RNA-sequences, digesting foodstuff into nutrients, configuring and transforming organic sequences, substances and precursors into useful reagents and to act as an immunological defence against amongst other cancer cells, e.g. the complement system.

Another very fundamental property of enzymes is that they can transform different forms of energy into useful energy sources for other biological processes. In the photosynthetic process phytotrophs can accumulate energy from light and certain enzymes may convert this energy into chemical-bond energy.
Also, chemotrophs collect free energy derived from the digestion of food and enzymes convert this energy into chemical-bond ATP, adenosine tri-phosphate. This ATP energy is then used for mechanical energy, such as muscular contraction, and to transport molecules and ions against chemical and electrical gradients.

Species in the early phases of the evolution, such as monocellular life forms and species with lymphatic and/or with lymphatic and early blood systems as well as certain plants, seem to have enzymes of a more multifunctional nature than what is found in more sophisticated warm-blooded species, like mammals. The multi-functionality may pertain to a more limited number of required catalytic activities and that these activities are closely related but also to the relative simplicity of these early species in which for instance food digestion is an integral part of immunological scavenging for foreign intruders and debris.

Also, this differentiation of a basic enzyme into highly specialised actions and targeting seems to be very similar to function and specificity of antibodies in for example mammals.

Such enzymes can be given a variety of chemical/biochemical catalytic activities and biological properties dependent on modification of configuration parameters and formulation procedures. Such modifications seem to diversify the clinical responses of the specific enzyme formulations such as specific targeting of viral host cells, infectious cells, pathogenic bacteria and fungi, inflammatory cells, tumour cells or pain mediators as well as malfunctioning and dead cells. Such cells, cell fragments and molecules that express certain cell surface receptors, so-called CD-molecules, or corresponding structures that are identified by the enzyme's active site as
a substrate or by the enzyme's regulatory sites as an adhesion site.

In formulating catalytic compositions, naturally occurring substances from the species itself as well as certain added substances have been used. These naturally occurring and added substances seem to interact with and to regulate the basic enzyme and to give it new properties and qualities. Such new properties and qualities can be used for more selected and preferential targeting and effects on affected tissues and cells compared to the basic enzyme.

Hypothetically, the basic enzyme structure gives the enzyme its basic or preferential enzymatic activity, such as being a trypsin, a galactosidase, a pepsin, a cellulase etc. by in-vitro methods. This basic structure acts as a scaffold onto which other naturally occurring substances from the species itself and added substances/compounds/molecules/ions may bind for several reasons and for multiple purposes. Such reasons and purposes could be to protect the basic structure, to extend or enhance the dynamic recognition function and to configure the basic enzyme for a specific task or function, such as becoming a scavenger, an immune-stimulator (as the enzyme's actions and formed end products increase the chemotactic intensity and other means of intracellular communication), digestive enzyme etc.

Some of these add-on substances/compounds bind to the basic enzyme's regulatory sites, distinct from the active site, and it is very likely that other add-on substances/compounds bind to these already bound add-ons. Small peptide-sized complexes to macro-sized complexes are formed in a great variety of combinations. These variations are also reflected in the new
complexes' chemical, biochemical, biological and clinical properties, qualities and responses.

These complexes are probably formed and exist in the host and they can only be formed while the basic enzyme is still part of the host's tissues, organ or an in vivo biological system, i.e. where it gets its final programming, i.e. add-ons. Once the basic enzyme has found its stabilised configuration, it is very difficult to reconfigure the enzymatic structure or to form new complexes - it takes chemical/biochemical abuse that does not exist in live species.

It is also likely that the basic enzymes before finding their final configurations are precursors of complexes with add-ons and that the basic enzyme seldom exists only as a configured and stabilised basic enzyme in vivo.

Carotenoid substances, such as astaxanthine, are believed to be very essential add-ons in forming the described complexes and their biological properties. It is also believed that these add-ons may form structures similar to micelles, liposome or even cellular-type membranes around the enzymatic scaffold.

As can be inferred from the above, there remains a continuing need to identify new compositions which are active for restoring certain basic and vital systemic body functions to improve quality of life of persons suffering from severe systemic diseases and conditions.

It is therefore an object of the present invention to provide novel pharmaceutical compositions useful for treating or preventing cancerous diseases, HIV/AIDS, chronic inflammations, certain autoimmune diseases, and secondary conditions of such primary diseases, such as bacterial, viral
and fungous infections, inflammations, diarrhoea, dehydration, and pain.

Another object of the present invention relates to the use of the above-mentioned compositions for the manufacturing of a medicine for treatment or prevention the above-mentioned diseases and conditions.

A further object of the present invention is to provide a product in the form of dietary supplement, additive, food supplement, functional food, homeopathic and natural medicine, nutraceutical and health product comprising the pharmaceutical compositions.

The compositions are preferably administrated as a regiment, leading to three biological phases, i.e. cleansing up of accumulated antigens, debris and toxins, building up of intestinal and immune functions and stabilisation at an improved and maintained quality of life level.

The regiment has been developed and tested in patients suffering from severe systemic conditions, such as cancerous diseases, HIV/AIDS, chronic inflammations and certain autoimmune diseases, and secondary conditions of such primary diseases, such as bacterial, viral and fungous infections, inflammations, diarrhoea, dehydration, and pain.

The focus has been to 1) cleanse the system from antigens, debris, toxins and free radicals, 2) to restore the intestinal functions as the very basis of a functional body and 3) leading to a phase of long-term stabilised conditions with no clinical sign of primary and/or secondary symptoms.
The two components of the MM-regiment are:

i) An catalytic product, named Mecosome, to target malfunctioning cells and to amplify/re-establish chemotactic communication,

ii) A microbial agent, named M-Powder, comprising of well-known and safe microbial strains to restore and maintain a functional intestinal flora.

The four components of the MMPM-regiment are:

i) A chemical agent, named Mesodine, for cleansing of debris, toxins and scavenging of free radicals of the liver, kidneys, and blood/lymph streams.

ii) An catalytic product, named Mecosome, to target malfunctioning cells and to amplify/re-establish chemotactic communication,

iii) A microbial agent, named M-Powder, comprising of well-known and safe microbial strains to restore and maintain a functional intestinal flora,

iv) A herbal component, named Phumpat, to stabilise certain elements of the body.

The regiments have been evaluated as food/dietary supplement and the components have been administrated orally together with normal food intake.

Summary of the Invention

This invention relates to the findings that a composition comprising of a microbial agent and a catalytic product (the MM-regiment) can alleviate, reduce and completely remove secondary conditions and symptoms, such as infections, inflammations, pain, diarrhoea, food intolerances and
allergies, incontinence, in patients suffering from mild
symptoms to severe systemic disease, such as intestinal
infections and inflammations and autoimmune diseases.

This invention also relates to the findings that a composition
comprising of a microbial agent and a catalytic product
further comprising a chemical agent, named Mesodine and a
herbal component, named Phumpat (the MMPM-regiment) can
alleviate, reduce and completely remove secondary conditions
and symptoms, such as infections, inflammations, itching and
pain, diarrhoea and dehydration, lipodystrophy, insomnia and
tumours, in patients suffering from severe systemic disease,
such as HIV/AIDS, cancer and autoimmune diseases.

According the invention the regiments can also remove the
primary causes of such systemic diseases.

Moreover, according to the invention the regiments can reduce
side effects and adverse reactions from other therapies and
drugs, e.g. HAART, cytostatics, radiation and antiviral, for
treating the primary causes and secondary conditions, e.g.
antibiotics and antiphlogistics, can be reduced and completely
removed and that such therapies and drugs can be re-introduced
without recurrence of side effects/adverse reactions when
taking the regiment as a concurrent treatment.

Furthermore, according to the invention no side effects and
adverse reactions can be detected from oral administration of
the regiments.

Moreover, according to the invention the two or four
components of the MM- and MMPM regiments respectively can be
added to different products in the form of dietary supplement,
additive, food supplement, functional food, homeopathic and
natural medicine, nutraceutical and health product, i.e. formulations for the general well-being such as vitamins salts, minerals, lipids, microbial cells. Functional food is cheese, yoghurt, cereal and sweets, for instance.

**Products and Methods**

The microbial agent, M-Powder, is a blend of naturally-occurring and safe strains harvested from soil.

Typical composition of M-Powder per gram:

- **Pediococcus pentosaceus**, $3.5 \times 10^{-9}$, typically $3 \times 10^7$ c.f.u;
- **Pichia farinosa**, $5.5 \times 10^{-8}$, typically $3 \times 10^8$ c.f.u;
- **Dekkera bruxellensis**, $5.4 \times 10^{-8}$, typically $3 \times 10^5$ c.f.u

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<td>Protein</td>
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Excreted bioactive substances:

- Organic acids, such as lactic acid, acetic acid, succinic acid.
- Digestive enzymes, such as amylase, galactosidase, proteinases, peptidases, lipase, hemicellulase, cellulase, pectinase, and catalase.
- Anti-microbial substances "pediocin" (bacteriocin).
- Vitamin B complex and growth factors.

Final product is an aluminium sachet filled with 1.5 g of M-Powder.
A non-limiting example of a method for obtaining the microbial agent is described below.

Topsoil is harvested from a biotope of an annual mean temperature of minimum +16°C during a period when the relative humidity of the topsoil is above 18%.

A stock Culture is made from 5 kg of collected soil, 25 kg of soya bean flour, 2 kg of hexose sugar, e.g. mannose. Humidity is adjusted to 25-27% with pure water.

The mixture is fermented under aeration, e.g. tumbling, at +32-35°C for 48 hours. A greyish powder is collected and dried at +45°C until rest humidity is below 12%, approximately 4 hours. The yield is approx. 27 kg and it can be stored in paper bags in a dark and dry place for maximum 3 months.

The product, M-Powder, is made from 550 kg of rice bran, 20 kg of soya bean flour and 5 kg of Stock Culture. Humidity is adjusted to 45-47% with pure water. The mixed powder is fermented during 7 days.

The fermentation is stopped by drying the product at +45°C until the rest humidity is below 12%.

The catalytic product, Mecosome, is based on a serine protease extracted and isolated from fish, molluscs and crustacean species. The final product is formulated into a 1 g lozenge containing 1% Mecosome.

The basic enzyme is identified as a member of the chymotrypsin/trypsin/elastase family with a molecular weight of 30-32 kDalton by SDS-electrophoresis.

Native electrophoresis shows that catalytic product forms a complex of up to 400-500 kDaltons.
A non-limiting example of a method for obtaining the catalytic product is described below.

An extraction and isolation method for enzyme fraction was used according to traditional principles for isolating rather pure protein fractions. This method was used for all raw materials tested. All steps were done at +5-8°C.

10 kg of frozen head of Penaeus Monodon was thawed and homogenised in 25 litres of 50 mM TRIS-HCl, pH 7.4, left for 1 h with slow stirring.

After 1 hour of precipitation the supernatant was collected and mixed with 5% ethyl acetate and left for 1 hour before being ultra-centrifuged at 16,000 x g for 15 min.

Residues of the solvent was removed under vacuum, 30 min., from the collected water phase before being diluted 2 times, using 50 mM TRIS-HCl, pH 7.4, to ensure a conductivity corresponding to < 0.1 M NaCl at 22°C.

This aqueous solution was pumped onto an equilibrated, 50 mM TRIS-HCl, pH 7.4, DEAA Sepharose filled column, (Pharmacia, Sweden) and thereafter rinsed with 3 bed volumes of 50 mM TRIS-HCl, pH 7.4, for the A280 detector to register a baseline 0-value with regard to protein detection.

A gradient desorption procedure was applied using two buffers, i.e. 50 mM TRIS-HCl, pH 7.4 and 1 M NaCl + 50 mM TRIS-HCl, pH 7.4. These buffers were mixed to a linear increase of the NaCl-concentration, from 0 M to 1 M NaCl, over 20 bed volumes. Fractions were collected and measured for tryptic activity using SAAP and/or BAEE as substrates and a standardised spectrophotometrical method was used.
Fractions showing tryptic activity were further analysed for molecular size, i.e. SDS- and Native Electrophoresis, isoelectric point, 3.1-3.3, Absorption peak, 273-279 nm and spectrum and other enzymatic activities.

For desalting purposes, Sephadex G-25 (Pharmacia, Sweden) was used and for concentration purposes, a concentration cell with a cut-off 10,000 membrane was used to avoid activity losses. 25-50 mM TRIS-HCl, pH 7.4 buffers were used.

To obtain purer protein fractions a Mono-Q matrix (Pharmacia, Sweden) was used and desorption procedures above were repeated once or twice on already purified fractions, if needed for analytical purposes.

Other enzymatic activities from this typical enzyme family, such as chymotryptic and elastase activity, were negligible or not detected.

No changes or alterations of the analytical properties could be detected from freezing, at -20°C or -40°C of the isolated tryptic enzyme.

Repeated freezing, at -20°C or -40°C, and thawing, at room temperature, seems not to affect the enzymatic activity or the catalytic product with regard to its properties/qualities. Freeze-drying, however, seems to make the composition lose most of its new properties/qualities and the freeze-drying process as such make the enzyme lose up to 80% of its main enzymatic activity.

Exposure to light: Standard fine chemical trypsins showed a successive activity loss to >75% after 2 x 10 hours exposure to subtropical sunlight.
Aqueous catalytic products of Mecosome showed an activity increase of up to 10% under identical conditions as above.

Oxygenation: Aqueous catalytic products of Mecosome showed an activity increase of 12 to 23% after 1 minute's aeration and still after 8 hours' continuous aeration. Aerated samples left to rest for 30 minutes returned to their pre-aeration activity level. The aeration procedure was repeated more than 10 times on the same samples and the increased activity level was repeated each time.

Standard fine chemical trypsins showed very quick activity losses, >75%, in minutes to 2 hours, under aeration by an air pump.

Stability: Aqueous catalytic products of Mecosome stored at −20, −40 and −90°C were all within the accuracy of the method, i.e. +3%, during the 12-months' test period. Freeze-dried catalytic products, stored at +4°C, showed an initial activity loss of 50-80% and no further activity losses could be detected during the test period of 24 months.

Aqueous catalytic products of Mecosome stored at +4°C showed an activity loss of <5% in 35 days and stored at room temperature, +20- +24°C, showed an activity loss of in average 12%, ranging from 8 to 17%, in 12 months.

Powder, lozenge, cream, gel and lotion formulations made from aqueous catalytic products of Mecosome showed no activity loss outside the accuracy of the method in 24 months, stored at ambient temperature. Catalytic products were diluted 100 to 400 times in such formulations compared to the purified fractions above.

Native electrophoresis shows that the catalytic products start from approx. 60 kDalton and can be greater than 400 kDalton.
The protein bands are not necessarily absolute distinct in their appearance but rather like more intensely dyed patches or stains. SDS-electrophoresis, i.e. denatured electrophoresis, of the identical fractions shows that the basic tryptic enzyme can be found in all compositions in the mentioned molecular interval.

These catalytic products vary with regard to their net charges, this is not related to their molecular size, e.g. a larger composition is necessarily not more negatively charged than a smaller composition. Ion-exchange methods can therefore be used to further separate catalytic products as such methods seem not to destroy or damage the compositions.

Fractions desorbed from DEAA Sepharose between 0.45 to 0.60 M NaCl were collected and used for final formulations of products tested in clinical use.

The herbal component, Phumpat, is a commercially available herbal remedy, e.g. Registration No. G 729/47 with Thai FDA, used for stabilisation of the elements of the body. The final product is formulated into a 500 mg gelatine capsule.

A capsule of Phumpat contains:

Smilax corbularia kunth
Smilax glabra Wall, ex Roxb.
Boesenbergia rotunda (L.) Mansf.
Albiza procera (Roxb.) Benth
Diospyros rhodocalyx Kurz
Garnoderma lucidium (fr.) Karst, etc.

The chemical component, Mesodine, is a commercially product, e.g. Registration No.: 12-1-09448-1-0037 with Thai FDA, used for balancing of the body fluids. A capsule of Mesodine contains:
L-Glutathion 100,00 mg
Vitamin C 60,00 mg
Melon Extract 25,00 mg
Alpha Lipoic Acid 15,00 mg
Coenzyme Q10 10,00 mg
Vitamin E Complex 5,00 mg
Zinc Chelate (as Zinc 1,00 mg) 5,00 mg
Capsule No. 0 100,00 mg
Other Ingredients:
Microcrystalline Cellulose 85,00 mg
Magnesium Stearate 80,00 mg
Croscarmmelllose Sodium 35,00 mg
Total weight 520,00 mg

Mesodine is based on antioxidants, glutathione, α-lipoic acid and vitamin C and E, that scavenge the liver and kidneys for free radicals, cellular mediators and toxic substances and removes such material from the body system. Antioxidants clear reactive oxygen species, ROS, from the cells. Oxidative stress and ROS-induced alterations of membrane lipids, hyaluronate, essential proteins and DNA are associated Alzheimer's disease, Parkinson's disease, cancer and aging. Antioxidant preparations are used for treating certain inflammations, certain cancers, ischemic conditions as well as for cosmetic products, such as anti-aging and anti-wrinkle products.

The final product is formulated into a 520 mg gelatine capsule.

The regiment is henceforth referred to as MMPM, MM, M-Powder and Mecosome respectively for simplicity purposes.
Examples - Biological Properties and Qualities

MM, M-Powder and Mecosome

The present invention typically involves administering the catalytic product in an amount from 0.01 to 10 mg per day, preferably from 0.1 to 1 mg per day, and the microbial agent in an amount from 0.5 to 10 g per day, preferably from 2 to 4 g.

The two components of the composition can either be administrated concurrently or non-concurrently. The term "concurrently", as used herein, means that the two components are administrated within 1 hour of each other.

Thus, as a non-limiting example the two components MM, i.e. the test treatment, were administered orally or topically once to twice a day:

MM (M-Powder and Mecosome in combination)

Early phase HIV-patients

Three men and two women in early HIV-phase with minor clinical signs of the infection were treated with M-Powder, 2 x 1.5 g per day, and Mecosome Lozenge, 1%, twice per day, for more than 18 months. No antiretroviral therapies were used during this period.

These persons did not develop any of the clinical signs of the primary infection expected within this time frame. All reported a generally good well-being and a normal quality of life situation.

Stabilised AIDS-patients
Two men and two women who had been treated with MMPM for 10 to 14 months and who had reached stabilised clinical conditions and almost pre-disease quality of life standards, were treated with M-Powder, 2 x 1.5 g per day, and Mecosome Lozenge, 1%, twice per day, for 6 to 11 months. No antiretroviral therapies or other drugs were used during this period. All reported a maintained good well-being and a normal quality of life situation. No clinical signs of the primary infection recurred.

Hepatitis

Five patients with hepatitis and jaundice were treated with the M-Powder 1.5 g twice a day and Mecosome Lozenge, 1%, twice a day. After 2 weeks jaundice disappeared and the liver function test showed no clinical signs of infection. All patients stayed on the treatment for more than one year.

Liver cancer

One patient with surgically removed colon tumour had metastasised to the liver. After 3 months of treatment the liver metastases were basically gone and only shades of the metastases could be detected by CT scan.

Colon cancer

One patient with huge tumour (1.9 kg) on the colon, surgically removed, received M-Powder and Mecosome Lozenge, standard treatment twice a day, after removal of the tumour. During 6 months of chemotherapy and concurrent M-Powder/Mecosome treatment the patient did not experience the typical side effects from chemotherapy. After 2 years on the treatment he declared free from cancer.

Prostate cancer
One male suffered from prostate cancer and was in very severe situation. After 4 months on M-Powder and Mecosome Lozenge, standard treatment, he was given a clear bill of health and could go back to his job again. Unfortunately he died 1.5 years later of different reasons.

Cystic fibrosis

One male 24 years old with CF used the standard treatment, M-powder and Mecosome Lozenge, and Mecosome mouth spray, 2%, twice a day.

After 5 days treatment he was in a much better condition with less problem of the stomach and less viscous secret from his lungs. After 2 weeks treatment his condition had improved remarkably, i.e. normal stool and less coughing.

Pulmonary Infections

Pulmonary complications of HIV infection are very common and especially Pneumocystis carinii pneumonia. 35 patients in the AIDS stage showing clear respiratory symptoms and confirmed P. carinii infection were treated with M-Powder, 1.5 g twice a day, and Mecosome Lozenge, 1%, twice a day. After a few days, 2-7, the symptoms disappeared. After 5 weeks into the treatment all patients were confirmed free from clinical infection.

M-Powder as single treatment
**High Cholesterol**

A male person suffered from very high cholesterol levels, 254 despite medical treatment. He received M-Powder, 2 x 1.5 g per day: After 1 month his cholesterol level decreased to 230 and after an additional month the level was 180-190, i.e. normal level.

Cholesterol levels stayed between 180 to 220 during a 12 months' period, he regained weight and his joint pain and other related problems decreased to acceptable levels.

**HIV/AIDS**

Thirty-two patients were treated with 2 x 1.5 grams of M-Powder per day, with the morning and evening meals, during 3 months.

The clinical conditions varied from late HIV-phases to terminal AIDS-cases. Within 4 to 7 days the diarrhoea stopped and the patients started to regain weight.

Secondary infections, such as oral Candida and herpes infections healed out in 5 to 8 weeks. Blisters, cracked lips and topical wounds healed and oedemas and swollen tissues, such as the tongue, were resorbed within 4 weeks as well. Pain and aching muscles and joints as well as itching were substantially relieved during the treatment.

Four patients who were bed-bound and tube-fed at the start of trial were able lead a life with increased movability and to eat normal food within 6 months.

**Rheumatoid arthritis**
A group of 5 people, aged 55 to 72, with a long medical history of the inflammation, i.e. deformed fingers and other joints, permanent ache/pain, movability disabilities and digestion deficiencies from time to time with severe diarrhoeas.

All patients reported a quick improvement, in 10-14 days regarding pain relief and increased movability. Recurrent diarrhoeas and constipation never occurred during the 4-7 months of treatment, M-Powder 2 x 1.5 g per day for the initial month and M-Powder 1.5 g per day thereafter, and the general well-being has constantly improved and was maintained.

Due to travel arrangements two patient stopped taking the daily maintenance doses over the Christmas season. Upon their return both experienced a substantial deterioration of their conditions in 2-3 weeks and the typical symptoms re-appeared. They immediately resumed the treatment, M-Powder 1.5 g per day, and in 7-10 days they reported that their general well-being had reach a comparable level as before the treatment was discontinued.

**Stomach diseases/Tourist diarrhoea**

This group includes a large population of all ages and it refers to a short-term treatment of typical symptoms of stomach diseases, food poisoning and tourist diarrhoea. M-Powder 1.5 g was taken twice a day. The onset of the effects was very quick and tummy aches disappeared within 2 hours and no one stayed on the treatment for more than 4 days to fully recover.

**Food intolerances**
Eight youngster, age 8 to 14, suffering from lactose intolerance and 5 persons, age 11 to 44, suffering from gluten intolerance were given 2 x 1.5 g of M-Powder once a day.

After 14 days on M-Powder the test persons began to test foodstuff containing lactose and gluten respectively. Two persons from the lactose group and 1 person from the gluten group experienced mild allergy symptoms but after 22 days on M-Powder all test person could eat normal foodstuff without experience food intolerance.

After 4 months all test persons were eating normal food without restrictions.

**Food poisoning**

Around 80 people of different ages suffering from acute food poisoning were given M-Powder 1.5 g within 2 to 12 hours from experiencing the typical symptoms of nausea, vomiting, and fever. Stomach pain disappeared within 2 hours and all symptoms faded away in 24 hours, including normal defecation.

In all the cases the recovery pattern was the same.

**Preventive**

This group includes more than 40 individuals on a daily maintenance dose of 1.5 g of M-Powder. The group is classified as "otherwise-healthy-people" without any specific clinical symptoms or only minor. The main purpose of this group was to evaluate any possible side effects from the M-Powder treatment as such effects are very unlikely to be observed in other groups with more complex clinical conditions. This group reported subjective assessments of improved health and general well being but no possible or likely side effects or adverse
reaction could be observed. The time frame for some of the individuals is more than a year.

**Side effects from drugs**

Gastrointestinal functions were restored in 2-7 days, i.e. diarrhoea stopped and within 1 month abdominal pain, nausea and vomiting stopped as well.

CNS disorders vanished over a period of 1 to 3 months.

Renal problems such as discoloration and odour normalised in 2 weeks' time.

Liver dysfunctions, such as hepatotoxicity and jaundice, normalised in 1-4 weeks regarding elevated liver enzyme concentrations and yellow discoloration of the skin.

Lipodystrophy improved continuously during the treatment. Severe cases normalised in 6-8 months, i.e. re-distribution of subcutaneous fat from lower trunk/hips to arms and face. Early phase symptoms normalised in 1-2 months.

Mecosome as single treatment

**Common cold and flu**

Fifty people, age from 9 to 70 years, and in different stage of the infection was treated with Mecosome Lozenge, 1%, and Mecosome spray, 2%.

They took Mecosome Lozenge every 4 hours and spray between 5-10 times per day.

Children with an early signs of infection used only 1-2 tablets and about 5 sprayings during the first 6 hours and could then stop without recurrence of symptoms or infection.
People who had infection/symptoms started 12 hours back, received the treatment during the first 24 hours and common cold as well as flu disappeared totally.

People at the peak of eposiode of common cold and flu were free of symptoms after 36-48 hours of treatment and no recurrence of symptom or infection.

Tooth ache

Seven people with painful tooth/gum infections were treated with 5 ml of Mecosome aqueous solution, 1%, three times a day. The mouth cavity was rinsed with the solution for minimum 30 seconds each time.

Pain relief was experienced in 30 minutes and all pain was gone in 4-18 hours. A certain soreness and oedema remained for up to 48 hours.

No one used more than 6 treatments, i.e. 48 hours, and neither infection nor pain recurred in the follow-up period of 3 weeks.

Gingivitis

Eleven people, age 32-46, suffering from gingivitis caused by accumulation of soft plaques and excessive tartar formation, were treated with Mecosome Lonzenge, 1%, twice a day. The lozenge lasted for minimum 15 minutes. Treatment period was 30 days. All persons used their normal dental hygiene routines during the test period. Plaques were detected by red dye. No one suffered from any clinical signs of infection.

After the first treatment all persons reported soft and smooth surfaces of gum and teeth.
No visible traces of red dye could be detected in any of the persons after 6 treatments, i.e. three days.

Bleeding gum, 7 of 11 persons, disappeared gradually and was not reported after 16 days' treatment.

Signs of inflammation, e.g. soreness, oedema, redness and pale spots, disappeared gradually over 6 to 22 days.

No effect on tartar formation could be observed from Mecosome treatment.

Safety

No side effects, likely or probable, were reported from patients using M-Powder and Mecosome in combination or as single treatments.

MMPM

The present invention typically involves administering the chemical agent in an amount from 0.1 to 10 g per day, preferably from 0.5 to 4 g per day; the catalytic product in an amount from 0.01 to 10 mg per day, preferably from 0.1 to 1 mg per day; the microbial agent in an amount from 0.5 to 10 g per day, preferably from 2 to 4 g; and the herbal component in an amount from 0.1 to 10 g per day, preferably from 0.5 to 5 gram per day.

The four components of the composition can either be administrated concurrently or non-concurrently. The term "concurrently", as used herein, means that the four components are administrated within 1 hour of each other.
Thus, as a non-limiting example the four components were administered orally together with food intakes in the morning, midday and evening:

**Morning:**

5 Phumpat, 2 capsules à 500 mg,
Mesodine, 2 capsules à 520 mg,
M-Powder, 1 sachet ≈ 1.5 g,
M-Lozenge, 1 lozenge à 1 g.

**Midday:**

10 Phumpat, 2 capsules à 500 mg

**Evening:**

Phumpat, 2 capsules à 500 mg,
Mesodine, 2 capsules à 520 mg,
M-Powder, 1 sachet ≈ 1.5 g,
15 M-Lozenge, 1 lozenge à 1 g.

**HIV/AIDS**

An open case study was designed and conducted as a quality of life evaluation using the food supplement regiment, MMPM, for the treatment of secondary conditions and symptoms in patients suffering from a primary HIV-infection.

Patients included range from early stages of HIV to terminal AIDS phases. Approximately 30% of the patients were on antiviral therapies and a majority of those patients suffered mild to severe side effects from such therapies.

Each and every one of the 169 patients responded positively to the test regiment. Development of Quality of life parameters is shown in Table 1.
First signs of response were detectable already in the first 7 days as diarrhoea and vomiting stopped and after 3 weeks the intestinal functions were reported to be normal.

In the very first days darker urine, increased lachrymal secretion and saliva production were frequently reported. This was appraised to be signs of disposal of accumulated debris and cellular by-products as cells and tissues regained an improved liquid balance. Conditions normalised in 1-2 weeks.

Dehydration was a severe condition in all patients suffering from diarrhoea. The condition stabilised as diarrhoea stopped and was normalised within 7 days based on drinking and urination patterns.

Weight gain was approximately 2-4% in the first month for patients with severe diarrhoea and dehydration symptoms. A more moderate but steady weight gain was recorded for all other patients. Patients with pre-treatment eating difficulties, i.e. wounds, blister and soreness of tongue, lips and throat, showed a continued weight loss in the first month but the trend turned as these conditions faded.

Skin rash and eczema improved continuously as general conditions improved. Skin rash disappeared quicker, in the first 4 weeks, and eczematous symptoms lingered on for longer and signs of transient recurrences were reported during the evaluation period.

Itching was reported from almost every patient, mild to unbearable, and the condition disappeared in almost all patients in 2 months. Recurrences were reported but much milder with regard to intensity and duration.
Insomnia and sleeping disturbances were common problems. Patients reported resumed and normalised habits within a broad time span, up to 10 months.

Opportunistic type infections of the mouth cavity, tongue and lips faded and showed no clinical signs after 4 weeks in to the treatment.

Inflammations of the digestive tract also vanished within the initial 4 weeks.

Liver problems and jaundice disappeared in the first 4 weeks in to the treatment.

Fever was rarely reported after the first 2 weeks.

CD4 counts increased about 40% in about 3 months' time in patients on concurrent antiretroviral therapies and this increase was detectable after approximately 3-4 weeks in to the treatment.

CD4 counts in patients on no concurrent antiretroviral therapy showed an initial decrease of about 25% in the first month of treatment and stayed at low levels for the next 3 months. Thereafter, the CD4 counts started to rise and after 4 months, i.e. 8 months in to the treatment, the CD4 counts were above pre-treatment levels. None of the patients showed the expected clinical signs of dropping CD4 levels.

Lipodystrophy was assessed to improve by 50% in 4 months with regard to re-distribution of subcutaneous fat from lower trunk/hips to face and arms. After 8 months' treatment the skin conditions were more or less normalised and with that also the liver problems related to lipodystrophy.
Social life and habits of most patients were affected to various degrees depending much on the pathological phase of the primary condition. Subjective perceptions were dramatic positive changes and improvements of social life situations as conspicuous clinical signs faded and normal habits could be resumed.

No side effects, possible or likely, were reported from the test regimen.

No dropouts or withdrawals were reported.

Table 1. Quality of Life situation

<table>
<thead>
<tr>
<th></th>
<th>Pre-treatment score</th>
<th>1-month score</th>
<th>6-month score</th>
<th>10-month score</th>
<th>+15-month score</th>
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<tr>
<td></td>
<td>Average # of Cases:</td>
<td>Average # of Cases:</td>
<td>Average # of Cases:</td>
<td>Average # of Cases:</td>
<td>Average # of Cases:</td>
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<tr>
<td>General well-being</td>
<td>169</td>
<td>169</td>
<td>161</td>
<td>164</td>
<td>132</td>
</tr>
<tr>
<td>Eating/drinking</td>
<td>4</td>
<td>13</td>
<td>16</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Stool/Urination</td>
<td>3</td>
<td>9</td>
<td>18</td>
<td>19</td>
<td>20</td>
</tr>
<tr>
<td>Sleeping</td>
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<td>11</td>
<td>18</td>
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<td>20</td>
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<tr>
<td>Work</td>
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<td>5</td>
<td>17</td>
<td>19</td>
<td>20</td>
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<td>Family/Social</td>
<td>2</td>
<td>7</td>
<td>19</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

0 = poor quality of life situation; 20 = very good/pre-disease standard quality of life situation
Elimination of HIV-infection

A woman, age 34, with an 8-year history of HIV/AIDS was included into the evaluation study. She had taken only herbal treatments before inclusion.

5 Pre-MMPM treatment viral load was 8,000.

Recovery pattern with regard to secondary condition was identical to the main group.

12 months into the MMPM treatment she was routinely checked up for viral load. First and second sample showed a viral load of zero.

Colon Cancer

A woman, age 65, had been treated with traditional anti-tumour treatment. Side effects were very severe and all kind of anticancer drugs had been withdrawn. She suffered from severe diarrhoea and poor appetite. Her overall condition was very serious.

After one week only, taking MMPM daily, her diarrhoea stopped and she got her appetite back and started to regain weight.

Still, after 24 months of treatment her general condition and well-being was much better and she basically lived a normal life.

Side effects from chemotherapy

One patient on chemotherapy treatment for colon cancer suffered severe side effects, including drastic drop in white blood cells. The side effects were reduced after 10 days MMPM treatment to a level so that the patient could continue chemotherapy treatment.
Side effects from radiation

Female patient on radiation therapy suffered from severe side effects and the radiation had to stop. After taking MMPM for one week the radiation therapy could continue and no side effects recurred.

Side effects from drugs

This group includes around 45 patients with side effects/adverse reactions from HAART therapies, antibiotics and anti-inflammatory drugs, such as gastrointestinal, e.g. abdominal pain, diarrhoea, constipation, nausea and vomiting; CNS disorders, e.g. dizziness, insomnia, mood fluctuations, depressions and confusion; renal problems; liver dysfunction, e.g. hepatotoxicity. MMPM was taken for as long as each patient stayed on prescribed medication, i.e. 7 days to 14 months.

Gastrointestinal functions were restored in 2-7 days, i.e. diarrhoea stopped and within 1 month abdominal pain, nausea and vomiting stopped as well.

CNS disorders vanished over a period of 1 to 3 months.

Renal problems such as discoloration and odour normalised in 2 weeks' time.

Liver dysfunctions, such as hepatotoxicity and jaundice, normalised in 1-4 weeks regarding elevated liver enzyme concentrations and yellow discoloration of the skin.

Lipodystrophy improved continuously during the treatment. Severe cases normalised in 6-8 months, i.e. re-distribution of subcutaneous fat from lower trunk/hips to arms and face. Early phase symptoms normalised in 1-2 months.
Recurrence of drug-related side effects/adverse reactions

Patients with severe side effects that were withdrawn from HAART-therapies were able to return to such therapies using MMPM as a concurrent treatment. No to mild recurrence of side effects were reported from 26 patients.

Safety

No side effects, likely or probable, were reported from patients using only MMPM.

Comparative studies M-Powder, MM and MMPM

Comparative study in 35 HIV-patients with CD4 counts >200

The test persons served as their own historical controls. There was no change made to any prescribed conventional concurrent therapies or drugs during the test period. All persons were experiencing deterioration conditions in the 6 months prior to the test. The test period was 35 days.

<table>
<thead>
<tr>
<th>Days to symptom-free, average</th>
<th>Diarrhoea</th>
<th>Fever</th>
<th>Fatigue</th>
<th>Infection Mouth</th>
<th>Infection Genital</th>
<th>Infection Feet</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Powder 12 pat.</td>
<td>6.2</td>
<td>14.2</td>
<td>32.6</td>
<td>24.2</td>
<td>&gt;35</td>
<td>&gt;35</td>
</tr>
<tr>
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<td>10.9</td>
<td>24.0</td>
<td>12.6</td>
<td>24.1</td>
<td>19.8</td>
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<tr>
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<td>4.7</td>
<td>6.7</td>
<td>16.4</td>
<td>9.8</td>
<td>13.0</td>
<td>13.8</td>
</tr>
</tbody>
</table>
Comparative study in 41 AIDS-patients with CD4 counts <200

The test persons served as their own historical controls. There was no change made to any prescribed conventional concurrent therapies or drugs during the test period. All persons were experiencing deterioration conditions in the 6 months prior to the test. The test period was 35 days.

<table>
<thead>
<tr>
<th>Days to symptom-free, average</th>
<th>Diarrhoea</th>
<th>Fever</th>
<th>Fatigue</th>
<th>Infection Mouth</th>
<th>Infection Genital</th>
<th>Infection Feet</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Powder 14 pat.</td>
<td>5.9</td>
<td>27.0</td>
<td>30.1</td>
<td>&gt;35</td>
<td>&gt;35</td>
<td>&gt;35</td>
</tr>
<tr>
<td>MM 12 pat.</td>
<td>5.1</td>
<td>16.4</td>
<td>22.8</td>
<td>23.5</td>
<td>34.0</td>
<td>32.2</td>
</tr>
<tr>
<td>MMPM 15 pat.</td>
<td>4.4</td>
<td>9.6</td>
<td>17.0</td>
<td>14.6</td>
<td>17.5</td>
<td>18.2</td>
</tr>
</tbody>
</table>

Comparative study in 95 patients suffering from IBS/intestinal inflammations

The test persons served as their own historical controls. There was no change made to any prescribed conventional concurrent therapies or drugs during the test period. All persons were included upon experiencing an episode. The test period was 30 days.
### Discussion and Conclusions

It is common knowledge that also minor disturbances to the digestive tract may lead to serious problems. Especially in HIV/AIDS patients that in relatively early phases of the disease suffer from opportunistic infections, such as Candida infections, that will cover the tissues and mucosa layers from the mouth cavity all the way through the stomach and the small and large intestines.

Such infections may prevent normal food digestion and destroy the micro flora as well as preventing Peyer's Patches system of the small intestine to properly respond, immunologically. An affected Peyer's Patches system may also cut off the immunological signals between CD4 and CD8 cells and other immune cells as well as affecting the programming of stem cells into functional immune cells.

The regiment has been designed to clean up the digestive tract and to restore its basic functions, to target and destroy
infected cells and to neutralise and to remove toxic products and free radicals from the liver and kidneys.

M-Powder is a consortium of natural and live microbial strains and metabolites from such strains. This stabilised consortium restores the basic functions of the small intestine including the Peyer's Patches. Experiences from tests in other clinical conditions, such as ulcerous colitis, Crohn's disease, IBS, RA and food intolerances, indicate that M-Powder may restore and maintain the basic functions of the small intestine and Peyer's Patches if taken daily or on a regular basis. If a regular intake of the product is disrupted, pre-treatment symptoms and conditions start to recur after 10 to 14 days. It is therefore suggested that the intestinal flora and functions must be supported as long as the underlying systemic insufficiencies/deficiencies/malfunctions persist. M-Powder is likely to be one such product.

Mecosome is a catalytic product that targets amongst other infected cells and destroys such cells. Hypothetical mode of action is that the catalytic product identifies specific cell surface receptors expressed by malfunctioning cells. Such cells are identified, neutralised and destroyed, including their contents.

Fragments of cellular membrane and certain substances from the contents of such destroyed cells are regarded by T-cells and APCs (Antigen-Presenting-Cells) as antigens and this will increase the chemotactic stimuli for other immune cells, such as lymphocytes and macrophages, to travel to the area and to perform their intended actions.

This hypothesis may to a certain extent be supported by observations made from treating topical conditions using the
catalytic composition, e.g. melasma, haematomas and wound infections.

Darkened melanocytes are identified and removed also from deeper skin layers and the dark patches fade and disappear without affecting surrounding tissues.

Dead erythrocytes are digested from haematomas and bruises.

Infections are killed, bacterial, fungus and viral such as Staphylococcus aureus, Candida albicans and Herpes simplex I.

The enzyme composition leaves healthy and functional cells intact as can be seen from the development of red and healthy granulation tissue as well as proliferation and migration of dermal cells when treating topical wounds and blisters.

Recorded drops in CD4 counts may be referred to the catalytic product alone or to combine effects of the regiment. At this point it has not been established whether this drop pictures a true biological profile of the T-helper cell or it should be referred to methodological procedures focusing on the CD4-receptors on such cells. Recorded drops and levels were likely to have shown clinical consequences, maybe fatal, but contradictory to what was expected all patients experienced improved conditions and general well-being throughout this period of low CD4 counts.

It seems as if the basic T-lymphocyte - B-lymphocyte - MHC pathways were functional despite the recorded low CD4 levels.

Phumpat is a traditional herbal remedy that interacts with the body's natural responses and activities for the purpose of bringing balance and equilibrium to metabolic and protective functions.
Mesodine is based on antioxidants, glutathione, α-lipoic acid
and vitamin C and E, that scavenge the liver and kidneys for
free radicals, cellular mediators and toxic substances and
removes such material from the body system. Antioxidants clear
reactive oxygen species, ROS, from the cells. Oxidative stress
and ROS-induced alterations of membrane lipids, hyaluronate,
essential proteins and DNA are associated with Alzheimer's
disease, Parkinson's disease, cancer and aging. Antioxidant
preparations are used for treating certain inflammations,
certain cancers, ischemic conditions as well as for cosmetic
products, such as anti-aging and anti-wrinkle products.

Evaluations of each single product included in the regiment
may show some of the results and observations reported but
only the complete regiment will result in such extensive and
lasting effects. No attempt is made for full understanding of
the complex biochemical, immunological and biological
mechanisms related to the regiment as hypotheses and
speculations would be too far-reaching and without references
to literature and publications.

A most important consequence of the regiment is the quick
onset of effects and that a major part of improved conditions
basically happen in the first month. This is important as many
patients suffering from severe diseases and conditions most
often die from acquired secondary conditions, such as
infections and inflammations, that may cause sepsis, high TNF-
releases, pulmonary and kidney failures etc. - not from the
primary causes. One possible application of a modified
regiment may be to focus on treating secondary conditions and
symptoms as this is likely to relieve the basic systemic
functions from such actions and to let such basic functions
target on the primary causes.
Also, side effects and adverse reactions from other therapies follow a similar pattern of relief and elimination as for secondary conditions and symptoms using the regiment. Therefore, it is plausible that the intended effects and actions from antiviral and other therapies would be perceived as more effective if certain side effects/adverse reactions could be eliminated or reduced. Improved CD4 counts indicate this possibility.

Concept of the regiment has been confirmed, i.e. cleansing - building up - stabilisation of certain basic systemic functions, and the concept is not specific for secondary conditions in HIV-positive patients. Case studies from other severe conditions, such as chronic intestinal inflammations, cancerous diseases and autoimmune diseases, show similar patterns with regard to restored basic functions and alleviation and/or elimination of secondary symptoms and conditions as well as side effects from other therapies.
Claims

1. Pharmaceutical composition useful for treating or preventing cancerous diseases, HIV/AIDS, chronic inflammations, certain autoimmune diseases, and secondary conditions of such primary diseases, such as bacterial, viral and fungous infections, inflammations, diarrhoea, dehydration and pain, said composition comprising:
   (a) a catalytic product, named Mecosome; and
   (b) a microbial agent, named M-Powder.

2. Pharmaceutical composition according to claim 1, wherein the catalytic product is based on serine protease extracted and isolated from fish, molluscs and crustacean species, having a basic enzyme identified as a member of the chymotrypsin/trypsin/elastase family with a molecular weight of 30-32 kDalton by SDS-electrophoresis, and native electrophoresis shows that said catalytic product forms a complex of up to 400-500 kDalton.

3. Pharmaceutical composition according to claim 1, wherein the microbial agent comprises per gram:
   Pediococcus pentosaceus, $3.5 \times 10^4$^9, typically $3 \times 10^7$ c.f.u;
   Pichia farinosa, $5.5 \times 10^4$^8, typically $3 \times 10^5$ c.f.u;
   Dekkera bruxellensis, $5.4 \times 10^3$^8, typically $3 \times 10^8$ c.f.u.

4. Pharmaceutical composition according to claim 1, wherein said composition further comprises:
   (c) a chemical agent, named Mesodine; and
   (d) a herbal component, named Phumpat.
5. Pharmaceutical composition according to claim 4, wherein the chemical agent is a commercially-product, Registration No.: 12-1-09448-1-0037 with Thai FDA.

6. Pharmaceutical composition according to claim 4, wherein the herbal component is a commercially available herbal remedy, Registration No. G 729/47 with Thai FDA.

7. Pharmaceutical composition according to claim 1, wherein said composition is in the form of dosage units for oral or topical administration.

8. Pharmaceutical composition according to claim 4, characterized that said composition is in the form of dosage units for oral administration.

9. Use of a composition comprising a catalytic product and a microbial agent for the manufacturing of a medicine for treatment or prevention of cancerous diseases, HIV/AIDS, chronic inflammations, certain autoimmune diseases, and secondary conditions of such primary diseases, such as bacterial, viral and fungous infections, inflammations, and pain, said treating or preventing comprising administering to a human a composition comprising the catalytic product in an amount from 0.01 to 10 mg per day and the microbial agent in an amount from 0.5 to 10 g per day.

10. The use of the composition according to claim 9, wherein the composition comprises the catalytic product in an amount from 0.1 to 1 mg per day and the microbial agent in an amount from 2 to 4 g.

11. The use of the composition according to claim 9 or 10, wherein the treatment or prevention comprises concurrent
administration of the catalytic product and the microbial agent.

12. The use the composition according to claim 9 or 10, wherein the treatment or prevention comprises non-concurrent administration of the catalytic product and the microbial agent.

13. Use of a composition comprising a chemical agent, named Mesodine, a catalytic product, named Mecosome, a microbial agent, and a herbal component, named Phumpat, for the manufacturing of a medicine for treatment or prevention of cancerous diseases, HIV/AIDS, chronic inflammations, certain autoimmune diseases, and secondary conditions of such primary diseases, such as bacterial, viral and fungous infections, inflammations, diarrhoea, dehydration, and pain, said treating or preventing, comprising administering to a human a composition comprising the chemical agent in an amount from 0.1 to 10 g per day; the catalytic product in an amount from 0.01 to 10 mg per day; the microbial agent in an amount from 0.5 to 10 g per day and the herbal component in an amount from 0.1 to 10 g per day.

14. The use of the composition according to claim 13, wherein the composition comprises the chemical agent in an amount from 0.5 to 4 g per day; the catalytic product in an amount from 0.1 to 1 mg per day; the microbial agent in an amount from 2 to 4 g; and the herbal component in an amount from 0.5 to 5 gram per day.

15. The use of the composition according to claim 13, wherein the treatment or prevention comprises concurrent administration of the chemical agent, the catalytic product, the microbial agent, and the herbal component.
16. The use the composition according to claim 13, wherein the treatment or prevention comprises non-concurrent administration of the chemical agent, the catalytic product, the microbial agent, and the herbal component.

17. Product in the form of dietary supplement, additive, food supplement, functional food, homeopathic and natural medicine, nutraceutical and health product comprising the pharmaceutical composition according to claim 1 or 4.
INTERNATIONAL SEARCH REPORT

International application No. PCT/SE2007/000970

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, TXTK, BIOSIS, EMBASE, MEDLINE, CHEM.ABS DATA, CHEMCATS, STN INDEX, XPICOM, XPIMISC, TCM, XPTK

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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<td>Y</td>
<td>WO 9729645 A1 (BIOFEED (THAILAND) CO., LTD.), 21 August 1997 (21.08.1997), page 3, line 16 - line 30; page 4, line 10; page 5, line 9, claims 1-3,8,11,12-23</td>
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<td>P,X</td>
<td>Salutary Care Ltd. &quot;Salutary Care Ltd. develops and markets new products that support the basic a healthy body&quot; (Online) 18 December 2006 (retrieved on 2007-04-25). Retrieved from the Internet: &lt;URL: <a href="http://www.salutarycare.com/%3E">http://www.salutarycare.com/&gt;</a></td>
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Further documents are listed in the continuation of Box C

See patent family annex.

Date of the actual completion of the international search: 5 February 2008

Date of mailing of the international search report: 08-02-2008

Name and mailing address of the ISA/Swedish Patent Office
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Authorized officer
Caro Una Pål mcrantz/ELY
Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (April 2007)
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<td>WO 9514489 A1 (PHAIRSON MEDICAL INC.), 1 June 1995 (01.06.1995), page 4, paragraphs 5-6; page 11, paragraph 2, claim 7</td>
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<td>A</td>
<td>VON ELERT, ERIC ET AL, &quot;Protease activity in gut of Daphnia magna: evidence for trypsin and chymotrypsin enzymes&quot;, Comparative Biochemistry and Physiology Part B, 2004, vol. 137, page 287 - page 296; page 292, right column, lines 3-5; page 293, right column, lines 8-10</td>
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International patent classification (IPC)

A61K 38/48 (2006.01)
A61K 31/375 (2006.01)
A61K 31/555 (2006.01)
A61K 35/60 (2006.01)
A61K 35/66 (2006.01)
A61K 35/74 (2006.01)
A61K 36/00 (2006.01)
A61K 38/06 (2006.01)

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Use the application number as username.
The password is JSHRLW1QQU.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.
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