WHO WE ARE

ALEXIS International is the only official authorized distributor of GA-40 and other products created by Alexis, Ltd. Our Board of Directors include the founding scientists, of Alexis Ltd., that created GA-40 and other products that heal and enhance the body’s ability to fight Cancer and other viral infictions like Hepatitis C.

ABOUT ALEXIS

ALEXIS Medical & Biological Scientific Research Center, Tbilisi State University Department of Plant Physiology, Phytopathology and National Cancer Center (NCC) in Georgia, focuses on the research and creation of new, biologically active and natural substances from plants known for their medicinal properties and used for centuries in remote European communities.

ALEXIS developed special tests that reveal new, biologically active polypeptides possessing characteristics of cytokines (a class of immuno-regulatory substances that are secreted by cells of the immune system). As a result, we have obtained several new bioactive polypeptides with in-vitro and in-vivo experiments confirming their anti-tumor and immune-modulating activities. The new preparation, GA-40, is one of our patented products derived from this powerful discovery.

GA-40 has passed preclinical and clinical tests in accordance with international GLP and GCP programs in following organizations: Oncological Scientific Center of the Ministry of Public Health of Georgia; Scientific Research Center of Experimental and Clinical Medicine of the Tbilisi State Medical University; Biotechnological Institute of the Ministry of Public Health of Russia; Cellular Technology Institute; Osaka Pharmaceutical Co., Japan; Fuji Memorial Institute of the Preclinical Research, Bivako, Japan; Hanoi Research Center of Cancer Research Laboratories, Hanoi-city, Japan; Japan Immune Research Laboratories, Tokushima, Japan; Therapeutic Application Development Department, Tokyo, Japan; Tokushima institute of New Drug Research and Safety Evaluation, Japan; University of Washington, School of Medicine, Cancer Research laboratory, Department of Pathology, Seattle, USA. We have also published booklets on the results of the preclinical and clinical tests of this preparation.

GA-40 is of natural origin, derived from organic and ecologically pure plant material; a polypeptide complex, containing a chromatographically purified combination of well studied biochemical polypeptides. GA-40 is patented and registered at the Pharmacological Committee Drug and Pharmacy Department Ministry of Health of Georgia, R N2 0003154.

Preclinical and clinical studies showed that GA-40, like some cytokines formed in organisms, (Tumor necrosis factor and Interferon’s) possesses strong immuno-modulating and anti-cancer properties. Like anticancer agents, GA-40 is characterized by direct and specific cytotoxic action on malignant tumor cells without negatively impacting the normal cells of an organism. GA-40 also induces terminal differentiation of the Leukemia cell line HL-60.
GA-40 is an immune system modulator, possessing immunity-correcting properties that actually correct the status of a patient's immune system.

GA-40 normalizes the quantitative and functional characteristics of the T and B immune systems, in particular T-helper, T-cytotoxic, natural killer (NK) cells, macrophages, granulocytes and also normalizes the CD4/CD8 ratio and cytokine production (TNF-x, INF-y). GA-40 treatments show positive effects on clinical, hematological and biochemical indices and does not induce the formation of antibodies against GA-40 in the body of cancer patients. The Toxicity Study of GA-40 on an organism was performed at the Tbilisi State Medical University's Research Institute of Experimental and Clinical Medicine in accordance with the methodical recommendations of the Pharmacological Committee of New Medical Drugs and Medical Equipment Introduction Department of the USSR Ministry of Public Health ("Requirements to the preclinical study of the new pharmacological materials toxic effects") and at the Tokushima Institute of New Drag Research and Safety Evaluation, Japan. The study of GA-40's effect (at 50 times the recommended therapeutic dose) using a wide spectrum of research methods (toxicological, pathomorphological, physiological, biological, histostructural, pathophysiological and immunological ones) and it was established that GA-40 does not induce local irritant or allergic effects, acute or chronic toxicoses, cumulative properties or mutagenic activity. GA-40 does not cause a violation of adipose or alter carbohydrate metabolism, it does not impact or alter the cardiovascular and respiratory systems, or the ability of an organism to produce normal antibodies and does not induce the formation of antibodies against GA-40, the aspect and localization of organs, the histological structure of the heart, lungs, renal, spleen, liver or bowels.

GA-40 is administered through subcutaneous injections with doses of 2 mg/kg of body mass. A single course consists of 21 injections. Injections are carried out once a day before sleep daily during first 14 days, and then every other day during the following 14 days; depending on each case, courses can be repeated. Considering the clinical study results of GA-40 on terminal cancer patients, in the fourth stage of malignant tumors, the following conclusions were made:

1. GA-40 produces no negative side effects and there are no contraindications in relation to age or sex that have been observed or reported; its administration is not connected with problems of any kind and does not negatively alter the emotional stability of patients.

2. Treatment of patients with GA-40 inhibits the process of tumor growth, prevents the formation of new metastases, improves the quality of life and prolongs the survival of the treated patients.

3. GA-40 produces positive results in clinical, hematological, biochemical and immunological indices. It normalizes quantitative and functional characteristics of T and B cellular immune systems, in particular T-total, T-helper, T-suppressor, T-cytotoxic, natural killer (NK) cells, macrophages, granulocytes; normalizes levels of
serum peripheral blood immunoglobulin, cytokines, specific and nonspecific tumor markers and other blood indices.

4. GA-40 in combination with radiation and chemotherapy treatments greatly reduces and in some cases completely eliminates the harsh side effects caused by those types of treatments. GA-40 allows for an extended treatment of chemotherapy while improving the general condition of the patient. The inclusion of GA-40 in a chemotherapy cycle promotes more efficient and promising results.

Advanced Third + Stage: By means of GA-40 treatment long term inhibition of tumor growth processes with improvement of general conditions of the patients has been achieved. Second and First Stages: GA-40 treatments in most cases lead to the complete regression of tumors or a complete recovery; GA-40 treatments prior and after surgical operations practically eliminate the chances of a relapse. The list of ailments where GA-40 treatments have shown significant results include: fibroma, myoma, mastopathy, pulmonary tuberculosis, liver disorders (cirrhosis, hepatitis-C), allergic diseases (pollinosis, rhinitis, bronchial asthma, etc); trichomonadal prostatitis, chronic banal prostatitis; disorders of sexual function in men and women-menstrual cycle disorders, complicated climaxes, oligospermia and sexual potency improvement in men.

GA-40 treatments have given patients a chance for a life with normal activities free of cancer and other autoimmune ailments.

ABOUT GA-40

GA-40 is an immuno-therapeutic and cancerostatic preparation. It is a well studied combination of standardized biochemical polypeptides extracted from natural plant material. Proven to enhance the body’s response to varying treatments, from chemotherapy to naturopathic regimens, GA-40 is also highly effective as a stand-alone therapy; helping the body combat viral attacks and auto-immune diseases; especially cancer.

WHAT ARE THE ACTIONS OF GA-40?

GA-40 is characterized by its direct & specific cytotoxic action on malignant tumor cells and causes their necrosis. GA-40 has a soft and effective immuno-modulating action.

GA-40 causes the slow down, suppression and regression of tumor growth and metastases in a patient. It normalizes the quantitative and functional characteristics of the T and B immune systems, restores the activity of NK-killers cells and improves other immune indices.

IN WHAT CASES CAN GA-40 BE USED?

To suppress and regress malignant tumors in primary and secondary immunodeficiency cases independently, before and after an operation. In combination with radiation and chemotherapy, to prevent side effects of these therapies, to enhance the defensive reactions of the patient. As a soft and highly effective supplement for the immune system to combat different infectious diseases.
IS GA-40 SAFE FOR THE BODY?

GA-40 has powerful healing properties absent of negative side effects.

By use of toxicological, path-morphological, physiological, biochemical, histostructural, path-physiological, immunological and other methods; GA-40 has been tested at 50 times the standardized therapeutic doses and it was established that GA-40 does not cause local inflammations, allergic reaction, pathological changes in biochemical, immunological or other indices of peripheral blood. GA-40 does not show acute or chronic toxicity, cumulative properties, and mutagenic activities. GA-40 does not alter metabolisms of lipids and carbohydrates; blood and respiratory systems; morphology of outer and inner organs and their blood supply; histological structures of heart, lung, spleen, liver, intestine, pancreas and other tissues; organism's temperature and pressure.

THE TRUSTED HEALING POWER OF GA-40:

Direct and specific action on cancer cells

Restoration of the immune system, normalization of its qualitative and functional indices, and activation of the NK killers in particular

Absence of negative side-effects

Does not affect normal cells

HOW IS GA-40 ADMINISTERED?

GA-40 is taken subcutaneously, as an injection intramuscularly, with doses of 1-2 rng/kg to patient mass. A single course consists of 21 injections, each taken once a day before sleep, during the first 14 days and then every other day during the following 14 days; depending on each case. Courses can be repeated.

ARE THERE ANY RESTRICTIONS IN THE USE OF GA-40?

The only restriction is to halt intake during the period of pregnancy.

ANTI-CANCER PROPERTIES AND ACTIONS OF GA-40

MALIGNANT TUMORS

In experiments carried out in The Oncologic Scientific Center at the Georgian Ministry of Health, the cytotoxic properties of GA-40 were studied on the short term culture suspensions of human lung, mammary gland, uterus and larynx tissues.
Influence of GA-40 on malignant tumors and normal cells:

According to the obtained results the criterion of cytotoxic activity of GA-40 (125-273%) in most cases was higher than the minimum cytotoxic activity criterion (125%), adopted for the appreciation of oncologic preparations in the former USSR and USA.

In order to reveal the nonspecific cytotoxic behavior of GA-40, its influence on the culture suspensions of normal fibroblasts were studied. According to the results, concentrations of GA-40, which are lethal for malignant tumor cells, does not affect the normal fibroblast cells. Thus, GA-40 invokes necrosis in malignant tumor cells, as a result of its direct and specific action on malignant cells. (FIG.2) According to the obtained results, GA-40 belongs to the group of cancerostatic compounds; unlike other cytostatics, GA-40 is characterized not only by cytotoxic (cytocidal) action, but also by its indirect mechanism of enhancing a depressed or inadequate immune system as seen in figure 3 below:

Fig.3
Our hope is that you discover how effective GA-40 can be in enhancing your body’s immune system and fighting cancer.

Start the healing process.

**RESEARCH HIGHLIGHTS**

The following reviews are highlights of studies performed at the University of Washington and at Atsuka Pharmaceutical Co. Ltd. If there’s an interest to review a comprehensive report, please provide your request and complete contact information.

The following are highlights of the University of Washington study:

**CRDF PROJECT STATUS REPORT**

**AWARD NUMBER: 3313**

**REPORT NUMBER: Quarter Four - Report #4**

**REPORTING PERIOD: June 1, 2004 to August 31, 2004**

I. PROJECT INFORMATION

(1) Overall Status: During the June 1, 2004 to August 31, 2004 reporting period, the project was continued in collaboration with researchers at the University of Washington Department of Pathology. In the forth quarter, the cytotoxic effect of GA-40 was investigated on A-549 non-small lung carcinoma cells and on OKF6/TERT1 normal human oral keratinocytes, two adherent cell lines.

(2) Developments and Accomplishments: A-549 non-small lung carcinoma cells were obtained from the American Type Culture Collection (ATCC) and grown in I-lam’s F12K medium containing 2 mM L-glutamine, 1.5 g/L sodium bicarbonate, 100 units/mL penicillin, 100 µg/mL streptomycin, and 10% fetal bovine serum. Normal human oral keratinocytes, which were immortalized by transfection to express hTERT, a telomerase catalytic subunit, were purchased from the Rheinwald laboratory, Harvard Medical School. OKF6/TERT1 normal human oral keratinocytes were cultured in keratinocyte serum-free medium (Gibco/Invitrogen) supplemented to contain 30 µg/mL bovine pituitary extract, 0.1 ng/mL epidermal growth factor, 0.4 mM CaCl2, 100 units/mL penicillin, and 100 µg/mL streptomycin. All cell lines were grown under aseptic conditions at 37°C in a humid, 5% CO2 environment. Cells were seeded in 96-well microplates (A-549 = 2.5x103 cells/well, OKF6/TERT1 = 1.0x104 cell/well) and grown for 24 h (A-549) or 48 h (OKF6/TERT1). The cytotoxic effect of GA-40 on A-549 non-small lung carcinoma cells and on OKF6/TERT1 normal human oral keratinocytes was determined after 72-h treatment with 100 µg/mL, 50 µg/mL, and 10 µg/mL GA-40 in comparison to untreated controls. Cytotoxicity was evaluated with the DNA stains Hoechst 33342 and propidium iodide. Fluorescence was detected with a SpectraMax M2 microplate reader (Hoechst 33342: ex. 360 nm, em. 465 nm; propidium iodide: ex. 530 nm, em. 645 nm). Experiments were performed in duplicate with OKF6/TERT1 cells and
quadruplicate with A-549 cells. Statistical analysis was performed using Student’s t-test and p-values <0.05 considered significant.

The cytotoxic effect of 100 tg/mL, 50 tg/mL, and 10 jig/mL GA-40 on A-549 non-small lung carcinoma cells and on OKF6/TERT1 normal human oral keratinocytes compared to untreated controls and evaluated with oechst 33342 is displayed in Fig. I. Cytotoxicity was concentration-dependent for both cell types. GA-40 had a significantly (p<0.00 1) less cytotoxic effect at each treatment concentration on OKF6/TERT1 cells compared to these same treatment concentrations on A-549 cells. Similar results were found in experiments evaluated with propidium iodide (Fig. 2). Furthermore, a statistically significant (p<0.001) increase in cell proliferation was seen in OKF6/TERTI cells after 72-h treatment with 10 pg/mL GA-40 (Figs. 1 and 2). These results support the conclusion that GA-40 may serve as an anticancerogenic preparation for treating nonsmall cell lung carcinomas.

The following graphs demonstrate the in-vivo test results of GA-40 on cancerous cells at different concentrations. Note that repetitive testing produced nearly identical results in figures 4 & 5 and in figures 6 & 7:

Figure 4
MEDICO-BIOLOGICAL SCIENTIFIC RESEARCH CENTRE << ALEXIS >>

GA-40 IMMUNOTHERAPEUTIC PREPARATION WITH ANTICANCEROGNIC PROPERTIES CONFIRMED BY THE MINISTRY OF HEALTH OF GEORGIA THE DRUG AND PHARMACY DEPARTMENT REGISTRATION CERTIFICATE MP № 003008 PATENT P 2256

GA-40 a preparation of a polypeptide nature has been obtained from ecologically pure plant material. It includes chromatographically purified, standardized combination of polypeptides and is used as a colorless solution in medicine.

**COMPOSITION**

Vial consists: 10 ml solution for injection or 119 mg lyophilized powder

Acting substances: 2 mg GA-40

Supplement substances: 90 mg sodium chloride, 27 mg mono potassium phosphate pH 7.4

**PHARMACOLOGICAL PROPERTIES**

Preclinical and clinical tests carried out according to international programmes GLP and GCP, show that GA-40, similar to certain cytokines such as the tumor necrosis factor and interferon possesses anticancerogenic as well as immunomodulating properties that determine the wide spectrum of such biological activities as antitumour, immunocorrective, anti-viral, anti-inflammatory, etc. GA-40 has a direct cytotoxic effect on malignant tumor cells, causing necrosis. Unlike chemical preparations, GA-40 does not have a negative effect on the normal cells in an organism. As an immunomodulator, GA-40 has immunocorrective properties, that make a correction of the immune status of the organism and restore the quantitative and functional indicators T and B of immune cellular systems i.e. T-helper cells, T-cytotoxic cells, T-killers (NK-cells), macrophages and granulocytes; it regulates the correlation of T-helper and T-suppressor cells, it also regulates the indicators of immunoglobulins, stimulates the production of cytokines, including the tumor necrosis factor (TNF-a) and interferon's (INF);

**GA-40**

Fig.1. Schematic diagram of the interactions between malignant tumor, some diseases, immunocompetent cells and blocking by GA-40 their mutual negative influence.

it restores the functional activity of stem haemopoietic cells, too normalizing the content of leukocytes, erythrocytes, neutrophils, thrombocytes, lymphocytes and other blood forming elements; GA-40 provides for a normalization of the blood biochemical indicators-total protein, albumin, globulin, urea nitrogen, creatinine, bilirubin, glucose, as well as certain enzymes such as alanine-aminotransferase (ALT), aspartate-aminotransferase (AST), ?-glutamine-transpeptidase (?-GP), alkaline phosphatase. The preparation renders a positive influence on the dynamic contents in the bloodstream of
carcinoembryonic antigens (CEA), alpha-fetoprotein (AFP), prostate-specific antigen (PSA), as well as the blood contents in mineral compounds of sodium, calcium, potassium and others.

INDICATIONS

GA-40 is applied to:

Malignant tumors

GA-40 treatment opens the following therapeutic possibilities: Treatment of cancer of all types and all stages offering a considerable chance of recovery even for patients in advanced stages who have exhausted all standard treatments. GA-40 reduces and decreases the rate of growth of the tumor cells, and results in the regression of tumor and metastases, considerably lessens the pain and increases the activity and life span of the patients.

It can be applied before and after surgical intervention in the preparation of planned surgical operations (the decrease of immunological indications is a direct contra-indication of surgical intervention), for rapid post-surgical recovering processes and for decreasing the risk of the initiation of progressive growth of hidden metastases mostly caused by the surgical removal of the initial tumor of the main localization and also for the inhibition of the processes of the arising and spreading of new metastases. Preparatory long-term GA-40 monotherapy or combined with radio or chemotherapy in patients with a rapidly growing tumor to render inoperable tumors operable.

Application of GA-40 during and after radiation and/or chemotherapy increases the effect of contra-tumor treatment of oncological patients, considerably increasing the anti-carcinogenic effects, and what is most essential, the combined treatment decreases the toxic influence of chemical and radial therapy on the organism, which for its part causes serious complications and the necessity of interruption of treatment of oncological patients.

It may also be used:

· for leucosis as an adjuvant therapy. GA-40 has a marked affect on the maturation and differentiation of the myeloblast and megakarioblast cells and causes it turning into normal ones.

· for the treatment of during benign tumors (fibroid, mioma, adenoma, cystose, etc.).

· during infection-inflammatory processes (pneumonia lobularis, bronchopneumonia, pulmonary tuberculosis, cholangitis, liver disorders (cyrosis, hepatit-C), trichomonadal prostatitis, chronic banal prostatitis etc.)

· for allergy diseases.

· nontoxic preventive treatment for patients at risk (genetic predisposition coupled with environmental challenges), and those with precancerous lesions.
for prophylaxis. It is recommended for persons above 40-50 age to carry out a course of treatment twice a year, to allow us to get rid of senile non-specific diseases, to reduce the risk of oncological diseases, to create a state of the organism in which susceptibility to virus and other infectious diseases, reduced to a minimum.

Fig. 1. Assessment of therapeutic effects (therapy of terminal cancer patients)

**DOSAGE**

Each vial contains 10 ml GA-40 solution for Injection. Use only clear and colorless solution. GA-40 is injected intramuscularly or subcutaneously. The dosage is one injection of 2 microgram per kilogram of weight (0.01 ml/kg of body weight). One course of treatment consists of 21 injections. Injections are made after 6 o’clock in the evening, when tumour cells are more sensitive to anti-carcinogenic agents. Treatment duration should last until full remission of an existing tumour or other diseases. It should be consist of no less 7 courses with time interval 10 -14 days. After long-term therapy for prophylaxis standard course of of therapy may be given at intervals of 2-4 months.

**CONTRA-INDICATIONS**

The usage of GA-40 is contraindiicted for pregnant women.

**SIDE EFFECTS**

Adverse reactions or some other side effects have not been reported.

**FORM OF PRODUCTION**

GA-40 manufactured in the form of a lyophilized powder or 0.025 solution. A box contains 5 vials of GA-40. Each vial contains 1 mg GA-40.

**CONDITIONS OF STORAGE**

It should be stored in a place protected from light at a temperature from 4 to 10°C. The shelf life of GA-40 as powder for no longer than 12 months and as an injection solution for maximum of 2 month.

The author of GA-40  Professor Giorgi Alexidze

**THE BREAKTHROUGH OF GA-40**

GA-40 is a breakthrough product that has been accredited in winning the war on cancer in Eastern Europe for over a decade. GA-40 was created in the mid 1990’s by world renowned scientists Dr George Alexidze and Aleksidze Nugzar, Ph.D., and extensively studied by some of the most respected research institutions in the world. GA-40 is a natural agent developed to correct and enhance the body’s immune system functions to control, overcome and prevent inflictions of cancer. GA-40 is now available in the USA to treat cancer and other viral auto-immune inflictions.
No prescription needed, GA-40 is of natural origin and considered a natural supplement. However, we are pursuing extensive studies for FDA approval and hope to have this product available as a prescription, which will help patients by increasing its availability and reducing its cost.

GA-40 heals the body with over a 90% success rate. There are no negative side effects associated with this treatment whatsoever:

Proven to enhance the body's response to Chemotherapy and naturopathic regimens, GA-40 is also highly effective as a stand-alone treatment in strengthening and correcting the immune system; helping the body fight viral attacks and auto-immune diseases like cancer more effectively.

We strongly recommend that you do not discontinue or alter any undergoing treatments prescribed by your existing medical care provider. GA-40 is proven to enhance the body's immune system to withstand extended treatments of radiation and chemotherapy as an immuno-enhancer and immuno-modulator producing no contraindications in conjunction with any other treatments.

HOPE IS HERE
**Epicrisis 1**

Patient: Jujunashvili L, 58, female.

Diagnosis: acute myelomonoblastic leukemia. The diagnosis was established at the Research Institute for Hematology and Blood Transfusion in Tbilisi. The patient was treated in the same Institute. Several courses of chemotherapy gave no remission. The patients position worsened considerably. Strong general weakness, loss of weight, loss of appetite, can not stand on feet.

Physician 'forecast: no perspective.

The patient refused chemotherapy and asked for a treatment with GA-40. The treatment started on 04.04.97.

GA-40 therapy: single course of treatment with only GA-40:

04.03.97 - 04.10.97 (2mg/kg) 8 injections

04.10.97 - 04.23.97 (2mg/kg) 5 injections


General condition improved, activity and life energy increased, weight gain, appetite improved, began to walk. At the time is out of hospital and continues treatment only with GA-40.

Patients report: I feel an interest to live again.

**Epicrisis 2**

Patient: Katamadze L.L., 50, female.

Diagnosis: Right mammary gland cancer. In February 1994 radical resection by means of radio surgery was carried out. In April 1996 progression of the disease was revealed: numerous metastases in liver; cancer cell complexes in lymphatic vessels; hyperplasia in lymphatic nodes. Examination and treatment were carried out in the Oncological Center at RAMS (Moscow) by the use of computer tomography, ultrasonic investigation and angiography.

05.12.96 - ultrasonic investigations: oval zone of the size 4.4x3.6x5.2 cm was found out in segment IV of liver.

05.29.96 - computer tomography: oval zone of the size 3.0x4.9 cm was found out in segment IV of liver.

07.12.96 - liver angiography: oval growth in the form of two decantating nodes of the sizes 6x7 and 3x2.8 cm, and near above - a node 1.8 cm in diameter in the central sections of the right part of liver.
Treatment: 07.16.96 to 10.29.96 - six courses of polychemotherapy according to the scheme SAF: doxorubicin 50 mg/m², 5-fluoracile - 500 mg/m², cyclophosphane 500 mg/m². GA-40 therapy: started on 08.24.96 and is being continued up to present time.

Dosage:

2mg/kg. One course of the treatment included 8 injections (one injection a day) during the first 8 days and 7 injections (one injection every other day) afterwards. Time interval between the courses was 14 days.

Physicians report: After 6 courses of chemotherapy and 3 courses of GA-40 treatment on 12.03.96 computer tomography was carried out: in the 4th segment of liver a zone of size 2x1.8 cm was observed. In other segments of liver no pathology observed.

On 04.21.97 after 8 courses of GA-40 treatment computer tomography, angiography and ultrasonic investigations were carried out: peripheral lymphatic nodes not enlarged, in the right mammary gland after-operational scar without any signs of relapses, complete regression of the tumor in liver, no metastases observed.

The patient is feeling well. She is asking for continuation of GA-40 treatment for prophylactic purposes.

**Epicrisis 3**


An operation - urine bladder partial resection with left side urethrocystostomy - had been carried out. After the operation prophylactic chemotherapy was planned, but the patient refused categorically.

In 1994 a relapse of the process occurred, which was testified by computer tomography (#831, 1994). There was observed filling defect on the left lateral wall of urine bladder - soft tissue neoplasm of size 3x2 cm, with uneven and indistinct contours. On the right side wall there was also observed 1x1 cm tissue neoplasm.

The patient underwent a Turi operation, during which the above neoplasm were cauterized. Chemotherapy was also conducted using paraplatine, adriablastine, metatrexsate and vincristine.

In summer 1996 new complaints started: pains in the urine bladder projection region, blood and pieces of ragged formations in urine. Ultrasonic investigations of abdominal cavity, ailed urine bladder (July 2, 1996) showed: spherically shaped urine bladder with uneven contours; 3.6x3.9 cm voluminous neoplasm fixed on the left side wall, which was penetrating all the layers of urine bladder. The patient refused chemotherapy and treatment in specialized medical establishments and asked for the GA-40 treatment.
GA-40 therapy: 8 courses of GA-40 treatment were conducted on the patient (administered doses were 2mg/kg):

I 08.04.96-09.26.96 - 15 injections
II 09.03.96-09.25.96 - 15 injections
III 10.02.96-10.25.96 - 15 injections
IV 11.22.96-12.13.96 - 15 injections
V 12.20.96-01.10.97 - 15 injections
VI 01.20.97-02.10.97 - 15 injections
VII 02.21.97-03.14.97 - 15 injections
VIII 03.25.97-04.16.97 - 15 injections

Physicians report: The patient's condition changed significantly: he feels much better, became more active, pains in the urine bladder projection region disappeared, urine became normal without blood and ragged formations; ultrasonic urine bladder investigations (January 14, 1997) showed significant shrinking of the neoplasm: 3.2x2.0 cm.

04.20.97 - computer tomography and ultrasonic investigations showed no pathologies.

Conclusion - full regression of the tumor.

Patient’s report: I am feeling well; I want to use GA-40 life long.

Additional Patient Summaries (patent names are abbreviated to maintain privacy and all patients featured below have consented to share their story):

**opinions of our clients**

1. PATIENT Dz.S.D., 3 YEARS OLD (FEMALE).

DIAGNOSIS: Acute megakaryoblastic leukemia - M7 (FAB). It was carried out repeated courses of chemotherapy by scheme: BFM-ALL-90, block MNL-BFM-90AA, but full and stable remission was not reached. Physicians conclusion: state of child’s health is very serious, diagnosis has no prospect, necessity of marrow transplantation. Analysis of marrow puncture: undifferentiated blasts — 44.75%, neutrophils — 10%, lymphocytes - 8%, platelets — single in number.

GA-40-THERAPY: Single course of treatment with GA-40 given alone.

PHYSICIAN’S REPORT: At the beginning of treatment the child was in coma. After the course of treatment the child came out from hopeless state, began to walk and play with other children. Partial remission was reached. Analysis of marrow puncture after the
treatment: undifferentiated blasts 0.00%, neutrophils — 68%, lymphocytes - 5.25%, platelets — 40.0%.

PARENTS' REPORT: The child feels well.

2. PATIENT V.T.V., 12 YEARS OLD (FEMALE)

DIAGNOSIS: Acute myelomonoblastic leukemia. It was carried out repeated chemotherapy, but full and stable remission was not reached. Child's health became very serious, no appetite, asthenia. Parents flatly refused additional chemotherapy. Physicians recommended marrow transplantation. Analysis of marrow puncture:

undifferentiated blasts — 80%, neutrophils — 7%, lymphocytes - 5 , platelets - single in number.


PARENTS' REPORT: The child feels well.

3. PATIENT M.G.N., 13 YEARS OLD (MALE)

DIAGNOSIS: Acute lymphoblastic leukemia. Philadelphia chromosome Ph. It was not reached full and stable remission after chemotherapy by scheme: EFM-90, block R1M1, block R2M. Child had strong general weakness, pain, loss of weight, increased liver and spleen. Parents were strongly against additional chemotherapy and radiation. Physicians recommended marrow transplantation. Analysis of marrow puncture:

undifferentiated blasts - 89.6%, neutrophils — 6.8°C, lymphocytes —3.2 , platelets — single in number.


PARENTS' REPORT: We did not have an optimistic outlook on the child’s condition before the treatment and after administering GA-40, there's great hope of a full recovery.

4. PATIENT , 39 YEARS OLD (FEMALE)
DIAGNOSIS: Mammary gland cancer (adenocarcinoma) with metastases in lungs. It was conducted mastectomy surgery at Moscow Oncological Center in 1989 and were realized 6 courses of chemotherapy and then 48 courses of radiotherapy. The patient began to cough in 1994 and lost her voice. At present there are new metastases on second breast and in neck region, swelling hardness and hyperaemia in umbilicus region, strong pain in stomach region, sickness, general weakness, depressive mood, no appetite, The patient categorically refused additional chemotherapy and radiotherapy.

GA-4 0-THERAPY: Two courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN’S REPORT: Positive dynamics of general haematological indices. Decrease of general weakness; sickness, vomiting and cough became considerably rare; voice began to reestablish; no pain; neck lymph nodes became normal.

PATIENT’S REPORT: I feel better.

5. PATIENT L.M.G., 43 YEARS OLD (FEMALE)


GA-4 0-THERAPY: Two courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN’S REPORT: General hematological indices completely normalized, swelling of lymph nodes disappeared. Thermogram of the breast showed that the tumor there resolved. No pain. Recovery from stomach ulcer. Patient feels excellently and carries on active mode of life.

PATIENT’S REPORT: I am delighted and wish to receive more GA-40, even purchase it as a prophylactic.

6. PATIENT I.Ts.T., 56 YEARS OLD (FEMALE)

DIAGNOSIS: Mammary gland cancer (adenocarcinoma). Pain in tumor region, general weakness, strong depressive mood. Patient ceased work and keeps confinement to bed. She had been proposed an operation which she flatly refused.

GA-4 0-THERAPY: Eight courses of treatment with GA-40 given alone for 14 month with 2 two-month intervals. The treatment continues.

PHYSICIAN’S REPORT: After single course of treatment general biochemical and immunological blood indices normalized, tumor became soft. According to the X-ray examination there was decrease in tumor dimensions after three courses of treatment. At present the tumor feels with difficulty. Pain and depressive mood disappeared,
patient returned to her duty and normal mode of life. GA—40 will be repeated when the patient feels change for worse.

PATIENT'S REPORT: I am well and full of energy. Besides, I recovered from the stomach ulcer and cystitis.

8. PATIENT Dj.N.L., 35 YEARS OLD (FEMALE).

DIAGNOSIS: Keratinizing, squamous cell cancer of uterine cervix with multiple metastases in pelvis region, thigh and lymph nodes. Strong pain in pelvis and thigh regions, general complaint, uterus bleeding, high ESR(70), vomiting. Patient takes sedative drugs.

GA-4 0-THERAPY: Four courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN' S REPORT: Positive dynamics of general haematological indices, ESP normalized, uterus bleeding ceased, lymph nodes recovered their normal dimensions after two courses of treatment, pain ceased, no sedative drugs, appetite improved, mood improved. No side effects, well tolerated.

PATIENT'S REPORT: I feel well; wish an increase in the dose of GA-40.


GA-4 0-THERAPY: Two courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN' S REPORT: General haematological indices including ESR normalized, tumor resolved, swelling of the extremities ceased. The patient began to move more actively. Well tolerated, no side effects.

PATIENT'S REPORT: I feel well and wish to go on the treatment with GA-40.

10. PATIENT Ch.T.V., 52 YEARS OLD (FEMALE)

DIAGNOSIS: Ovary adenocarcinoma of vestige with multiple metastases in stomach region and pleura cavity. It was carried out uterine extirpation with adnexa in Moscow Oncological Center. After chemotherapy patient's condition sharply got worse, general complaints, symptoms of intoxication, pain, confinement to bed.

GA-4 0-THERAPY: Three courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN'S REPORT: General haematological indices became normal, no pain, mood improved, moves without outside assistance and walks every day. Well tolerated, no side effects.
PATIENT'S REPORT: I feel very well.

11. PATIENT T.G.I., 58 YEARS OLD (MALE)

DIAGNOSIS: Weakly—differentiated cancer of left lung with metastases in supraciavicular. Diagnosis was confirmed by morphological and X-ray examinations. Loss of voice, general weakness, fever, coughs, rapid breathing.

GA-4 0-THERAPY: Nine courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN'S REPORT: Biochemical and immunological blood indices normalized after the first course of treatment. General condition became stable after the second course and after the third it started to improve. At present metastases disappeared and X-ray examination shows decrease in the intensity and size of the shadow in the lung. No fever, no cough; breathing is normal; voice is recovered. No side effects.

PATIENT'S REPORT: I feel much better and ask to continue the treatment.

12. PATIENT Dj.T.Sh., 52 YEARS OLD (MALE).

DIAGNOSIS: Pulmonary apical cancer of the left lung (carcinoma) with metastases in the same lung, in lymph nodes of bronchi furcation and in 2-3 lumbar vertebrae. Cough, blood-spitting, strong general weakness, pain in breast region, high ESR. Diagnosis was confirmed by morphological, endoscopical, X-ray and tomographic analyses.

GA-4 0-THERAPY: Single course of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN'S REPORT: Biochemical and immunological blood indices normalized after the first course of treatment. No cough; general weakness disappeared, no sedative drugs. X-ray examination shows better condition. No side effects.

PATIENT'S REPORT: I feel well and ask to continue the treatment.

13. PATIENT T.G.G., 55 YEARS OLD (MALE)

DIAGNOSIS: Primary liver cancer with metastases in lungs. Pain in region of liver, general weakness, strong depressive mood. Radiation and chemotherapy were ineffective. Biochemical analysis of blood showed high content of embryocarcinogenes and increasing activity of the following enzymes: ALT, LDG, LST, gamma-GT, alkaline phosphates. Patient is a citizen of Germany and by conclusion of German physicians is not operable.

GA-4 0-THERAPY: Four courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN'S REPORT: Positive dynamics of general biochemical and immunological indices of blood. For example, after three courses of treatment, the activity of
gammaglutamiltansferase decreased from 158 to 67 (standard 18-28), asparagineaminotransferase - from 19 to 16 (standard 15-18) and alkaline phosphates - from 212 to 167 (standard 60-180). Pain, general weakness and depressive mood disappeared, capacity for work and life activity restored. The patient has hope of full recovery. Well tolerated.

PATIENT'S REPORT: I feel very well and wish to take the GA-40 treatment all my life.

14. PATIENT M.N.M., 10 YEARS OLD (FEMALE)

DIAGNOSIS: Primary liver cancer. Very grave and passive condition, enlarged liver, fever, pain in stomach region. The patient can lie on his back. Diagnosis made on the basis of morphological and tomographical researches. It was proposed chemotherapy, which the parents of the child categorically refused.

GA-40 THERAPY: Three course of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN'S REPORT: Biochemical and immunological indices of blood normalized after the first course of treatment. General condition improved, pain in stomach region ceased. The patient can lie in any position. Temperature is normal. Mood and appetite are well. No side effects.

PATIENT'S REPORT: I feel well, this treatment should be continued.

15. PATIENT D.A.V., 39 YEARS OLD (MALE)

DIAGNOSIS: Spleen lymphoma. Strong pain in all body and especially in joints, fever, perspire, strong depression, lies without moving loss of 20 kg weight.

GA-40 THERAPY: Three courses of treatment with GA-40 given alone. The treatment is completed.


PATIENT'S REPORT: I feel well; quality of life and vitality improved.

16. PATIENT Kh.A.M., 41 YEARS OLD (MALE)

DIAGNOSIS: Schmincke's tumor of urinary bladder, disposed in sub-mucus region. Resection of the urinary bladder with transplantation of the right ureter, metastasis in the region of post-surgical paunch. The metastasis had been removed and chemotherapy was conducted. The patient began to complain on pain in the left leg and groin region. It appeared to be edema of the left buttock and the left thigh. The association of the enlarged lymph nodes along the left iliac vascular, hyperaemia of the bladder wall in the region of transplanted right ureter.
GA-4 0-THERAPY: Seven course of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN'S REPORT: Positive dynamics of general haematological and immunological indices. Pain and edema of the left lower extremity ceased. Histological analysis showed absence of tumor in the bladder wall. Mood and general conditions are fine. The patient returned to an active life. Well tolerated, no side effects.

PATIENT'S REPORT: Fine, I have hope in this treatment only.

17. PATIENT G.N.N., 19 YEARS OLD (FEMALE)

DIAGNOSIS: Mixed cellular granulomatosis. Increased lymph nodes in both supraciavicular, pain, labored breathing, strong depression.

GA-4 0-THERAPY: Four courses of treatment with GA-40 in combination with chemotherapy. At present the treatment continues with the GA-40 only.

PHYSICIAN’S REPORT: After seven injections of the Ga-40 the depression ceased, breathing got normal. After the third course of treatment the increased lymph nodes normalized, the patient began an active mode of life. It should be emphasized that chemotherapy, conducted in combination with the Ga-40, had no side effects according to the laboratory, as well as clinical findings. Well tolerated, no side effects.

PATIENT'S REPORT: I feel very well.

18. PATIENT D.E.E., 55 YEARS OLD (FEMALE)

DIAGNOSIS: Lymphomatoid granulomatosis. Fever, cough, asthenia, perspiration, depression, pain, expressed cystitis. The lower part of increased lymph nodes forms a common conglomeration of nodable tissue on the furcation of bronchi. Conclusion of the computer tomography: a tumor in the region of furcation of bronchi. Six courses of chemotherapy has been conducted.

GA-4 0-THERAPY: Three courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN’S REPORT: Positive dynamics of general biochemical and immunological indices after the first course of treatment. General condition improved, pain and fever ceased; bursts of energy and activity, no subjective phenomena of cystitis. According to X-ray examination the full recovery from tumor took place after the third course of treatment. Well tolerated, no side effects.

PATIENT’S REPORT: I feel well.

19. PATIENT R.G.A., 68 YEARS OLD (MALE)

DIAGNOSIS: Myeloma. Destructive changes in the region of chest vertebrae. Chemotherapy and radiation gave only a temporary improvement. A course of Katrex
treatment had no positive effect. Strong pain, sedative drugs did not help; no appetite; considerable loss of weight; constantly keeps his bed, permanent registration of Bens-Jonse protein in urine.

GA-4 0-THERAPY: Two courses of treatment with GA-40 given alone. The treatment continues.

PHYSICIAN’S REPORT: Positive dynamics of general haematological indices. ERS decreased from 75 to 45. Bens-Jonse protein has not been found since the beginning of treatment. The patient gave up sedative drugs after the second course of treatment. He was bed—ridden during last year, but he can move without help for a long time now. The patient has good appetite and life energy. Well tolerated, no side effects.

PATIENT’S REPORT: I feel well.

20. PATIENT S.N.D., 62 YEARS OLD (MALE)

DIAGNOSIS: NMR-tomography showed a tumor in the parietal lobe of brain (glioblastoma). It was carried out the surgical ablation of tumor and was realized a course of gamma radiation by Arapov. The post-surgical relapse in the same regions with pronounced perifocal edema. Marked brain displacement in right position on 6 mm. Strong pain, loss of speech and extremities moving ability, frequent hiccup; loss of ability getting into contact.

GA-4 0-THERAPY: Ten courses of treatment with GA-40 given alone for 8 months. The treatment continues.

PHYSICIAN’S REPORT: During all courses of treatment blood and urine analyses showed no pathologic changes. Patient’s condition improved, headache ceased, moving ability and speech on the whole restored. Tomography shows no edema. Tumor dimensions decreased and brain moved into normal position. Well tolerated, no side effects.

PATIENT’S REPORT: I feel much better.

21. PATIENT Ts.E.T., 70 YEARS OLD (FEMALE)

DIAGNOSIS: Carcinoma in the left part of liver with metastases in the right part T4 N3 M+; very serious condition. Not operable (after laparotomy period). Strong general weakness, pain in the region of liver, depressive condition, severe constipation, vomiting.

GA-4 0-THERAPY: Two courses of treatment with GA-40 given alone.
PHYSICIAN’S REPORT: Positive dynamics of general biochemical and immunological indices of blood. No side effects observed. Pain considerably abated, patient became active, capacity for work increased, vomiting ceased, face skin color normalized.

PATIENT'S REPORT: I want the treatment with GA-40 to be continued.

22. PATIENT N.O.Sh., 72 YEARS OLD (MALE).

DIAGNOSIS: Tumor of duodenum with metastases in liver. Serious condition with severe pain. The face skin color gets more and more yellow. Severe constipation, vomiting.

GA-40-THERAPY: Single course of treatment with GA-40 given alone.

PHYSICIAN’S REPORT: Positive dynamics of general biochemical and immunological indices of blood. No side effects observed. Vomiting considerably abated, pain relieved, face skin color stabilized, intestines' work normalized.

PATIENT'S REPORT: I feel better.

23. PATIENT S.J.B., 56 YEARS OLD (MALE)

DIAGNOSIS: Stomach cancer with metastases in liver. Serious condition, hardening in the region of epigastrium, the liver is enlarged, color of the face yellow, frequent vomiting, severe constipation. The relatives strongly refused the continuation of chemotherapy.


PHYSICIAN’S REPORT: Positive dynamics of general biochemical and immunological indices of blood. No side effects observed. No pain, softening in the region of epigastrium, vomiting ceased (occasional feelings of nausea remains), face skin color normalized. Intestines' work normalized; desired of variety in diet.

PATIENT'S REPORT: I feel well. Have the hope of recovery.