PROCONT

ANTI-CANCER AGENT

EXECUTIVE SUMMARY

Since the beginning of the active phase of research in 1998, we have isolated the two well-defined groups of the active material.
Both groups are brand new fractions of albuminoids without any reference to date in the medicinal literature. In February 2003, based on the results of animal tests, the company was ready to submit the application for patent to the Hungarian Patents Office.

Dr. András Bertha is the holder of the patent protecting the agent.
Since February 2003, we have completed the NCI international preclinical examinations, based upon which we claim that:

- *Its survival index exceeds many times that of known materials.*
- *It is not cancer-specific, considering the examined types of cancer.*
- *There are no toxic side-effects, even in case of a 50 times overdose.*
- *The discrepancy between therapeutic and toxic dosage is huge.*
- *It is effective even in stages three or four of terminal cancer.*
- *It is produced from a biological system, the basic materials are unlimited.*
- *It is produced cost-efficiently, thus the consumer price is expected to be low compared to that of other cancer treatments common today.*

DESCRIPTION OF THE INVENTION

How the tumor develops

At cell-level, there are four gene-groups we currently know of, gene-groups that can lead to the development of cancer via mutation or deletion.

- *Oncogenes*
- *anti-cancer genes*
- *DNA improving genes*
- *Genes affecting programmed cell deaths.*

In the course of our research,we have isolated from a biological system two fractions of albuminoids, never referred to in medicinal literature as yet, that act as anti-cancer agents at the level of two gene-groups out of the above four groups, - one being the level of DNA improving genes, the other one being the level of genes affecting the programmed death of cells.

Compared to the aforementioned chemotherapy treatments, the anti-cancer agent of our treatment has the following advantages:

- *Based on results of preclinical animal tests, we are in the position to declare that the agent has a general anti-cancer effect.*
- *This effect is reinforced by the fact that the anti-cancer agent affects through the Tumor Suppressor Gene, in the phase of cell division: maintaining the physiological level of the TSG, it recognizes the transcription errors and immediately kills the cells before division.*
- *The TSG has no immunosuppressive effect; figures prove that the status of the immune system is retained.*

The anti-cancer agent is a wide-spectrum therapeutic material:

- *Non-toxic*
- *There are no known harmful side-effects.*
- *It can be produced from a biological system, the basic material is always available.*
- *It is produced cost-effectively, thus the consumer price can be expected to be lower than that of other treatments commonly used.*

Results of the Invention

1. ***S-180 sarcoma*** *in BDF1 male mice*
2. ***MXT breast carcinoma*** *in BDF1 female mice*

The average survival rate for the positive control-group is 100% for all types of cancer.The survival index of the group is compared to following treatment:
Minimum survival index of chemotherapy treatments nowadays must be 125%; the higher the index, the higher the efficiency of the therapy.
According to the present results from animal tests, we can declare the following on biologically avtive materials:

- ***In S-180 sarcoma, the average survival index (280%) was considerably over*** *that of the positive control group (100%).* ***The average number*** *of tumors diminished to 1/3 of the initial one.* ***Due to the treatment with Procont, the frequency of metastases dramatically diminished****, compared to the positive control group. This result is reinforced by histologic and laboratory diagnostic figures, as well as enzymatic tumor markers.*
- ***In MXT breast carcinoma, the survival index is 149%;*** *the average tumor mass diminished to ¼.*

The patent

Dr. András Bertha was the first (on 15th January, 2002) to submit his application to the Hungarian Patents Office for the patent to cover the 'Method to produce anti-cancer material'. The patent of P0200172 was registered on 15th January, 2003 under the international number of PCT/HU0300004.

Summary

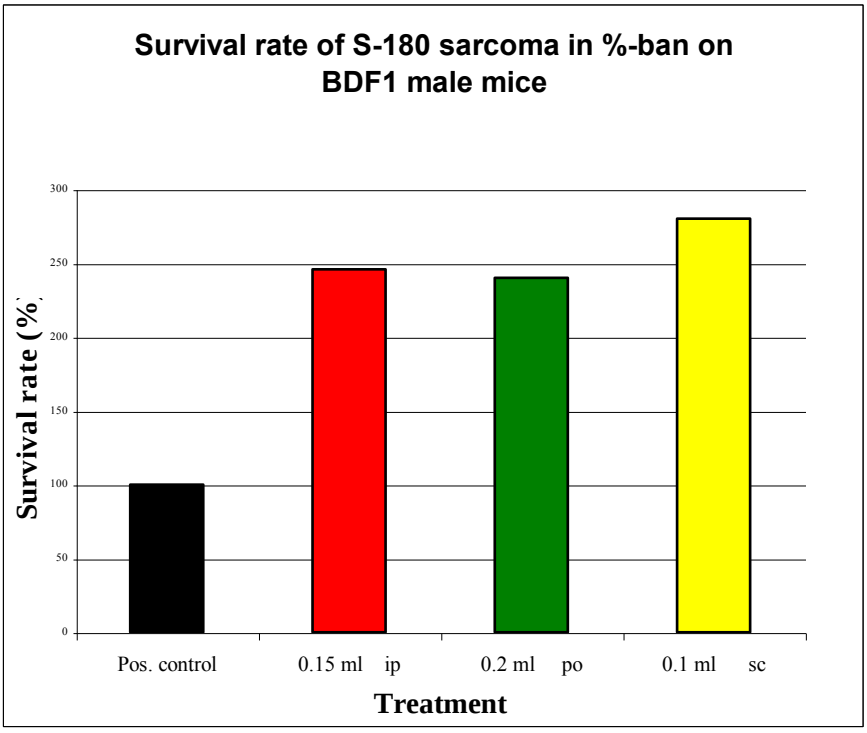
- *During different model experiments, the enzymatic tumor-marker activity figures have the same tendency, but different levels.*
- *The enzyme-activity figures measured in serum and tumor tissues correlate to the treatment applied and the schedule of treatment.*
- *The most significant changes were detected on day 8 for positive control animals, and day 16 for other methods of treatment. The methods of treatment applied extend to the pre-moribund period.*
- *Comparing figures measured in serum to those in tissues, concerning promising therapeutic effects, activity levels in serum and tissues are the same in terms of quantity and quality.*
- *During various model experiments, the applied enzymatic tumor-markers show different levels of sensitivity. It is a general feature that metabolic disorders are identifiable in every experiment.*
- *The anti-cancer effect of the Tumor Suppressor Gene is the obvious and provable reason for the compensation of metabolic disorders and the therapeutic effect.*
- *Out of the applied methods of treatment, the 0.2 ml Per os dosage proved the most effective, a dosage that is supposed to maintain an extended 'retarded' impact. Explanation for a '+ retarded' effect may lie in slower assimilation and metabolism, as well as existence of fragments, that can have therapeutic effect of their own.*

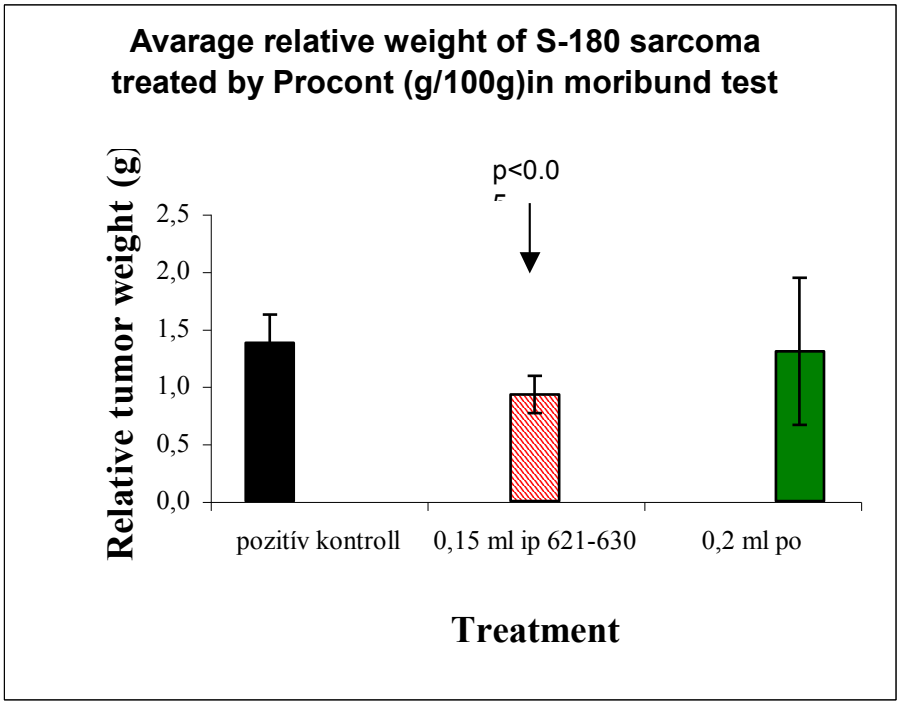
The agent affects its anti-cancer influence by controlling the enzyme P53 of the Tumor Suppressor Gene.

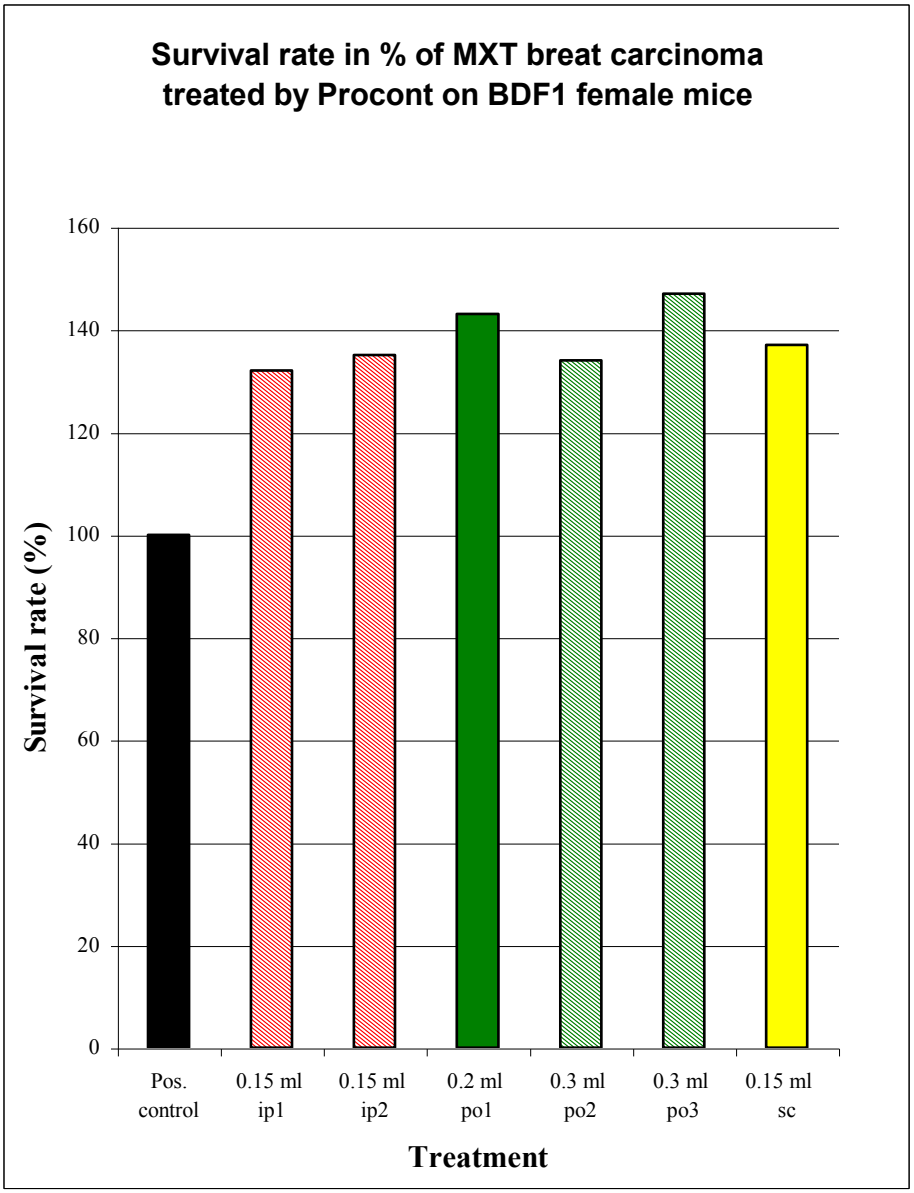
Following animal tests, we carried out histology examinations, in line with GLP and OECD guidelines.

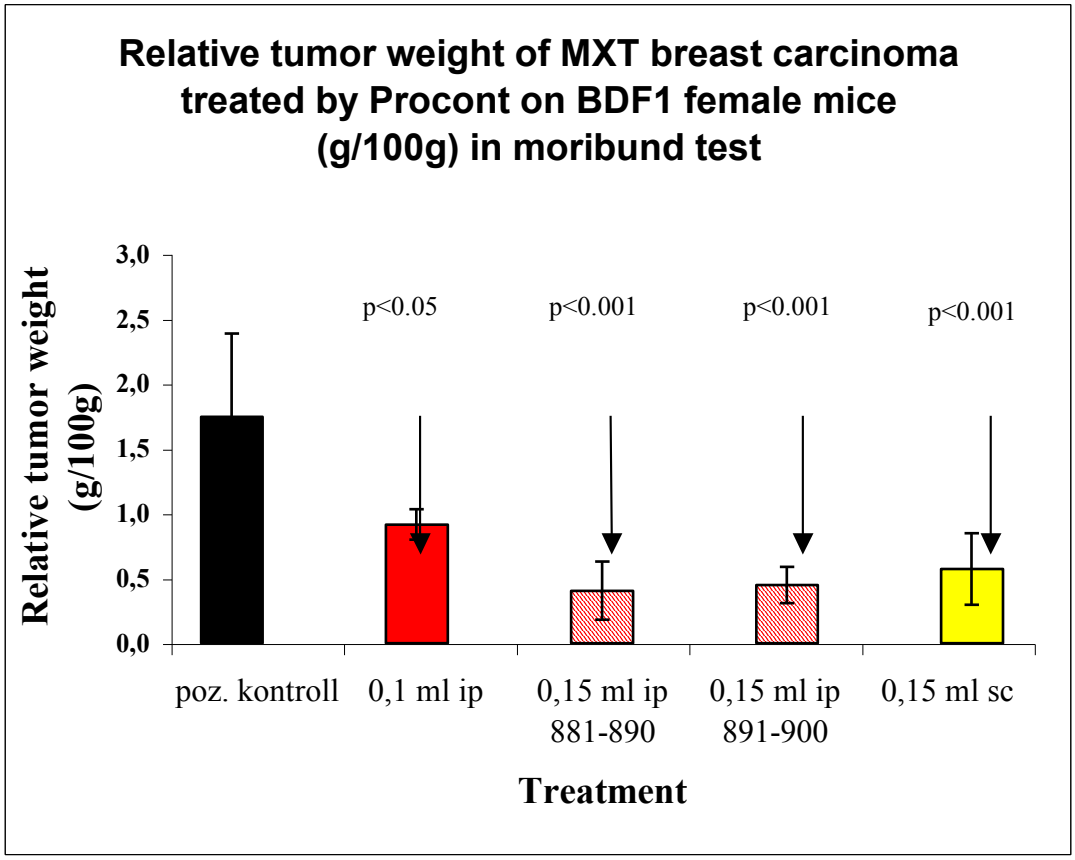
Macroscopic and enzymatic tumor-marker figures are confirmed and reinforced by histology analyses for all the types of cancer examined.

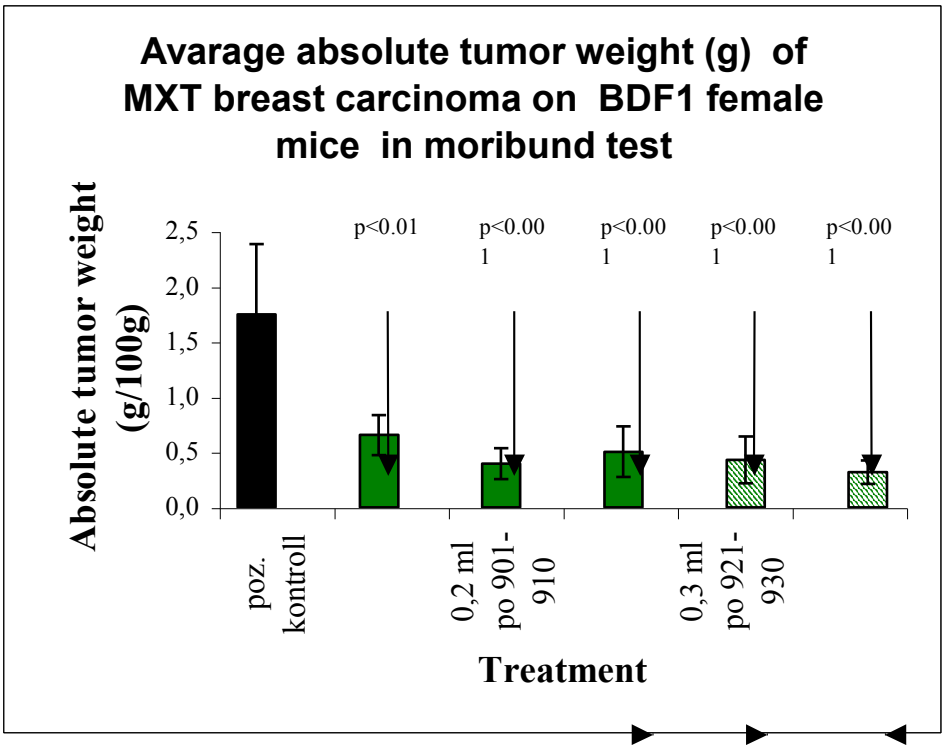
Till this day, there is no other anti-cancer material the survival index of which would equal the material of ours and that has no toxic side-effect.


Survival rate of S-180 sarcoma in %-ban on BDF1 male mice
Survival rate (%)
300
250
200
150
100
50
0
Pos. control
0.15 ml ip
0.2 ml po
0.1 ml sc
Treatment


Avarage relative weight of S-180 sarcoma treated by Procont (g/100g)in moribund test
Relative tumor weight (g)
p<0.0
2,5
2,0
1,5
1,0
0,5
0,0
pozitív kontroll
0,15 ml ip 621-630
0,2 ml po
Treatment


Survival rate in % of MXT breat carcinoma treated by Procont on BDF1 female mice
Survival rate (%)
160
140
120
100
80
60
40
20
0
Pos. control
0.15 ml ip1
0.15 ml ip2
0.2 ml po1
0.3 ml po2
0.3 ml po3
0.15 ml sc
Treatment


Relative tumor weight of MXT breast carcinoma treated by Procont on BDF1 female mice (g/100g) in moribund test
Relative tumor weight (g/100g)
3,0
2,5
2,0
1,5
1,0
0,5
0,0
p<0.05
p<0.001
p<0.001
p<0.001
poz. kontroll
0,1 ml ip
0,15 ml ip 881-890
0,15 ml ip 891-900
0,15 ml sc
Treatment


Avarage absolute tumor weight (g) of MXT breast carcinoma on BDF1 female mice in moribund test
Absolute tumor weight (g/100g)
2,5
2,0
1,5
1,0
0,5
0,0
p<0.01
p<0.001
p<0.001
p<0.001
p<0.001
poz. kontroll
0,2 ml po 901-910
0,3 ml po 921-930
Treatment

Curriculum Vitae of prof.Dr. András Bertha

STUDIES

1985	***Semmelweis Medical University***
	Degree in International Experimental Toxicology
1984	***Semmelweis Medical University***
	Degree in Pharmaceutics and Toxicology
1980	***Medical University of Szeged***
	Doctorate in Pharmaceutics *Ph. D. in pharmaceutical chemistry, toxicology.*
1978	***Medical University of Szeged***
	Degree in Pharmaceutics

WORK EXPERIENCE

2001-	***Pro-B Biotechnology LLC.***
	Continued independent research work under the patronage of the Company.
1998-	***Independent research into agents.***
1998-	***AMT Hungarian – American Ltd.***
	Toxicological advisor *Pharmacological and toxicological research into an anti-cancer medicine and preclinical documentation.*
1994-	***Research Centre for Toxicology, Veszprém***
	Head of Dep't for Reproduction and Embrio-toxicology *Complete preclinical documentation for two new medicine molecules*
1990-	***Freelance toxicological advisor***
1987-	***Medical University of Debrecen***
	Pharmacologist *Complete preclinical toxicology of a new medicine molecule.*
1980-	***Laboratory of Toxicology, Ministry of Agriculture and Food, Keszthely***
	Head of Dep't for Toxicology

RESEARCH WORK AND PATENTS

2002	*Epoxy-bonded natural oil solutions with high oxygen content, primarily for medicinal materials*
2001	*Medicinal material to facilitate recovery of burns*
2000	*Medicinal material to primarily cure and diagnose cancer, and a new method to produce lipid-free fraction of blood plasm*
2000	*Enzimatic tumor-marker micro-method to assess 5 nucleotidaze to diagnose and follow up cancer metastases*
2000	*Transforming fat-soluble vitamins into water-solubles used in drinking water for animals*
1997	*Environment-friendly method for the incineration of naphta distillation residues*
1986	*Teratological assessment of embrios in Wilson-section – automation*
1984	*Method to assess the relative mass of experimental animals' organs related to the mass of their brain*