

# 《艾立康》中药制品抗艾特征简介

## Introduction to the Treatment Characteristics of The Chinese Regimen ALK 《艾立康》on HIV/AIDS

### ●一、《艾立康》的研究目的

#### ●1. The Purpose of Research with ALK 《艾立康》on HIV/AIDS

●艾滋病的全称是“获得性免疫缺陷综合症”，英文缩写为 AIDS。该病系由逆转录病毒 HIV (即人类免疫缺陷病毒) 侵犯人类免疫系统,特别是辅助性 T 淋巴细胞 (**CD4<sup>+</sup>**), 造成以细胞免疫缺损为基本特征的病理损害，其临床症状包括各种条件致病菌引发的机会性感染，恶性肿瘤和消耗综合症等。艾滋病毒的英文缩写为 HIV，分 HIV-1 和 HIV-2 两型。

● AIDS is an acronym for "Acquired Immune Deficiency Syndrome ", The cause of AIDS is that the retroviruses HIV ( human immunodeficiency virus) infringe upon the human immune system ,especially invading the T helper lymphocytes (containing CD4+ molecules on their surfaces), This results in the destruction of lymphocytes containing CD4+ molecules, causing pathological damages characterized by human immunodeficiency, The clinical symptoms include the opportunistic infections that are caused by various conditional pathogens , the malignant tumor, and the health consumption syndrome etc 。 The English abbreviations of human immunodeficiency virus is HIV,, including HIV-1 and HIV-2。

●艾滋病被称之为世纪瘟疫，全球每天新增感染者达万人以上。以 2002 年联合国艾滋病规划署公布之全球 HIV 感染者 7300 万，死亡 3100 万为基数，加逐年 HIV 感染新增数推算，截止 2009 年底，全球死于 AIDS 已达 6597 万，仍然存活病人和病毒携带者 3330 万人。

●AIDS is called: "The Century Plague", Worldwide daily increase of newly infected AIDS patients is more than 10,000。 In 2002, UNAIDS announced that there had been 73 million AIDS patients, 31 million of them had died as a base reference, Adding the new HIV infections, the total number of deaths from AIDS has reached 65.97 million in the world by the end of 2009, The virus carrying HIV/AIDS patients who are still alive is about 33.30 million。

●2005 年 1 月，美国纽约及圣地牙哥两市相继发现新变种 “3-DCRHIV”，该病毒不但对多种主要药物具有抗药性，而且大大缩短了感染者的发病时间，最短发病时间只有 2~3 个月，长则不超过 20 个月，而原先已知的艾滋病毒的潜伏期最长可达 15 年之久。

●In January 2005, both New York and San Diego cities have found a new variant strain virus "3-DCRHIV", This new virus is highly resistant to three ART drugs, and the time of progression to AIDS has been greatly shortened, The shortest period of onset to AIDS by this new virus is only 2 ~ 3 months, at most not more than 20 months, We had known that the existing two types of HIV have the longest onset period to AIDS up to 15 years.

●变异新病毒(3-DCRHIV)的流行势必使 AIDS 的死亡以多倍率快速递增，全球抗艾形势更为严峻。国内患者的咨询表明，我国并不排除已经存在病毒变种之可能。

●The epidemic of new variant virus 3-DCRHIV is bound to make the death rate of AIDS rapidly increase, And the global anti-retrovirus problem would be even more difficult, Domestic

patients' consulting record indicates that our country cannot exclude the possibility of already existing variant virus among HIV/AIDS patients.

●2004年底，我国政府公布的病人与病毒携带者为84万人，由于社会歧视等因素，实际潜在者可能远远超过此数。值得严重关注的是，人种基因分析表明：中国人比白人或黑人更易感染HIV。这一潜在威胁使我国在应对AIDS这场世纪瘟疫中，面临着更为严峻的考验。以北京市为例，2005年与上年同期相比，HIV感染者递增了53.2%，足显其不容乐观之征兆。

●At the end of 2004, the government of China announced that HIV/AIDS patients and virus carriers had been 840,000, Due to reasons such as social discrimination, the actual number of HIV/AIDS patients was probably far more than that. Our serious concern is that the ethnic genetic analysis has shown that the Chinese are more vulnerable to become infected by HIV than whites or blacks. This potential threat to the people in our country while we deal with this "Century Plague" in AIDS forces us to face more severe considerations. Using Beijing as an example, in 2005, comparing with 2004, HIV infections had increased by 53.2%, which sadly reminds us that we cannot be optimistic.

●由于HIV在复制过程中能将自身的遗传物质扦入到宿主细胞的染色体中，成为宿主细胞基因的一部分，可随宿主细胞的增殖而不断复制，现代医学无法使HIV从宿主细胞内分离出来，因而认为HIV/AIDS属不可治愈病种。众所周知，全球公认的高效抗逆转录病毒(HAART)疗法即“鸡尾酒”疗法，至多具有控制症状和延缓生命之作用，彻底清除病毒无能为力。

●As HIV injects its genetic coding into the host cell chromosome in the cloning process, it becomes a part of the host cell genes, In the process, the HIV can be repeatedly copied with the host cell's proliferation and replication, Modern medicine cannot separate HIV from the infected host cell so that HIV/AIDS has been regarded as an incurable disease. It is well known in the world that Highly Active Antiretroviral Therapy (HAART) is merely a "cocktail drugs" therapy which could help control the spread of HIV/AIDS and prolong the lives of some of those patients, As for HAART to completely wipe out HIV/AIDS it is still totally helpless.

●由于病毒的耐药性，晚期患者往往面临无药可用境地，而且由于毒副作用过大，致使很多患者无法坚持服药，甚至不因毒副作用而促其死亡者。

●Because of the HIV's resistance to drugs, terminally ill AIDS patients often face the situation of no available medicine due to the strong side effects of these drugs, As a result many HIV/AIDS patients would not keep taking the medication such that the strong side effects often even accelerate the death of AIDS patients.

●由于抗病毒药疗效局限，人们在很大程度上将控制艾滋病的蔓延寄厚望于疫苗。但是，美国VaxGen生物技术公司在2005年2月和11月，先后两次宣告人类第一个和第二个AIDSVAX的大规模艾滋疫苗试验归于失败。2007年9月18日，由美国默克公司、美国国家过敏和传染性疾病研究所、艾滋病病毒疫苗联盟共同实施的称之为“最有希望”的Ad5疫苗试验，再次宣告失败。

● Because of the limited effectiveness in the HAART, people have placed high expectations on vaccines to control the spread of AIDS. But U.S. VaxGen biotechnology company has twice declared that the human's first and second AIDSVAX large-scale AIDS vaccine trials had failed in February and November of 2005, respectively. On September 18, 2007, however, Merck and company, the National Institute of Allergy & Infectious Diseases, and The HIV Vaccine Alliance have also jointly declared that their "Best Hope" Ad5 vaccine trial had failed again.

● 让人不安的是，上述疫苗接种后，人体感染 HIV 的几率反而有所增加。Ad5 希望破灭后，美国《科学》杂志的评论称：“AIDS 疫苗的研究遭到了一次致命的打击”。美国国家过敏和传染病研究所的佩吉·约翰斯顿沮丧地说：“它毁灭了我们的希望”。

● It is extremely unsettling to us that the risk of HIV infection has increased after the vaccine was introduced. After the Ad5 trial failed, the U.S. 《Science》 magazine commented that: "the AIDS vaccine research had experienced a fatal blow". Peggy Johnston who works at the National Institute of Allergy and Infectious Diseases said: "It (Ad5 trial failure) has ruined our hope" .

● 按照孙传正所长理论，HIV 属阴性病毒，其抗体没有抗病毒作用，因而不可能研制出成功疫苗。所以，人类不能期望以疫苗来解决艾滋病问题，必须将根治药物定为主要研究方向！

● According to Dr. Sun Chuan Zheng's\* theory, HIV is a virus with "Yin" characteristics i.e, its antibody does not resist another viral attack so that it is impossible to develop a successful vaccine for HIV. Therefore, we humans cannot expect finding a vaccine to prevent HIV infection, We must make finding the drug or drugs to cure HIV/AIDS as our main research objective!

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Dr. Sun Chuan Zheng, Director of The Institute of Native Herbal Chinese Medicines in Dongyang city, Zhejiang province, China.

## ●二、艾立康的卓越疗效

### ● 2. The Superior Treatment Results Using Chinese Regimen ALK 《艾立康》

● 治疗为了生存，千古不变，对艾滋病类致死性疾病，更是不言而喻！艾立康的保生存疗效，优于任何抗病毒西药。

● It has been true for all times that in order to survive we must find the treatment to any life-threatening disease, and it is the same for HIV/AIDS, So far we have found that the life-saving effect using ALK(Ai Li Kang) or 《艾立康》 has been proven superior to any known Western anti-retroviral regimen of medicines.

● 艾立康胶囊的药品注册受理号为 CXZL0500708 浙。

● The pharmaceutical registration number of ALK 《艾立康》 capsules is CXZL0500708 Zhejiang 。

### ● (一)《艾立康》的保生存疗效

何大一院士在 2006 年清华大学演讲时说：“艾滋病致死率为 99%”。说明抗病毒药并不能缩小死亡率。据国家相关部门公佈数据，截至 2008 年 9 月底，全国累计艾滋病人死

亡数与累计抗病毒治疗数的比例高达 68.17%，其中抗病毒药服用期间五年死亡率就达 45.84%【注 1】，年均死亡率 9.17%。以年均死亡率比对，艾立康的保生存疗效，是未服用者的 5 倍以上。

### ●(1). Life-saving Effectiveness of ALK 《艾立康》

In 2006 ,Dr. He Dayi, member of the elite National Institute of Scientific Research, spoke at Tsinghua University: "AIDS death rate is 99%"。He meant that Western antiviral drugs cannot reduce death rate。According to published data by China National Health Department, by the end of September, 2008, the percentage of National cumulative AIDS deaths of the total number of people receiving ART was as high as 68.17%, The five-year mortality rate of those who had received ART had reached 45.84%【Note 1】，The average annual mortality rate reached 9.17%。Compared with the annual mortality rate of ALK users, however, the survival rate of ALK users is five times higher than Western ART users (Please see the data below)。

#### ●以上蔡县石佛村为例：

①从 2001 年初至 2009 年 12 月底，艾立康在上蔡县石佛等村治疗 165 人，平均用药 4 个月 19 天，八年存活 144 人，其中彻底治愈\*\*10 人；死亡 21 人，死亡率 12.73%，年均死亡率 1.59%。

#### ●Taking Stone Buddha Village in Shang cai xian county, Henan province as example:

①From the first of January, 2001 to the end of December 2009, 165 people took ALK regimen at the Stone Buddha Village etcareas in Shang cai county, Out of these 144 people survived eight years, 10 of them were completely cured\*\*, 21 people died, The death rate was 12.73%, and the average annual mortality rate was 1.59%。

●②比对同时期石佛村服用抗病毒西药而未服用艾立康的 220 人，八年存活 75 人，死亡 145 人。死亡率 65.91%，年均死亡率 8.23%，是艾立康年均死亡率的 5.17 倍。

**【说明】**本资料的“治愈”，是指治疗后 HIV 抗体由阳性转变为阴性者；“临床治愈”，是指临床症状消失后，保持其停药一整年以上不复发者。

●②Compared with the 220 patients in the same time frame who had been treated by HAART and had not taken ALK in Stone Buddha Village in Shang cai county, 75 patients survived the eight years, 145 patients died. The death rate was 65.91%, Average annual mortality rate was 8.23%, which is 5.17 times higher than that of the patients who had been treated by ALK regimen.

\*\*In this report "cured" refers to the conversion of HIV antibody positive into antibody negative in a patient, "clinical cure" refers to the clinical symptoms which have disappeared, In the mean time, the disease had not relapsed for a full year, Those 10 people had been given an overdose of ALK capsules.

#### ● (二) 两组艾滋病人的死亡率与保生存疗效的统计学结果

#### ● (2) Statistical treatment results on mortality rate as well as on survival rate for the two groups of HIV/AIDS patients in the Stone Buddha Village of Shangcaixian county

●艾立康治疗的八年统计学分析表明，服用艾立康组的艾滋病人 (n=165)，比石佛村服用抗病毒西药而未服用艾立康组病人 (n=220) 的死亡率差异超过 5 倍；艾立康的死亡风险比未服用艾立康组降低了 9 倍；两组存活率差异超过 3 倍。

● Statistical treatment results over eight years for the two groups\* of HIV/AIDS patients in the Stone Buddha Village of Shang caixian county has shown that the annual average

death rate of Group A patients was 5 times lower than those in Group B who took the HAART regimen instead. The death expectancy of those in Group A who had survived after 8 years was 9 times lower than those survivors of Group B while the life expectancy of the survivors of Group A was shown as being more than 3 times longer than the surviving patients in Group B.

- \* ● **Group A consists of 165 patients who took ALK regimen while**
- Group B consists of 220 patients who took the Western medicine HAART regimen treatment**

● 美国自 1996 年始实施高效抗逆转录病毒治疗，美国 CDC 公布的 1981-2009 年间的艾滋病年均死亡率为 53%。相比之下，更显其艾立康疗效的重大突破。

● Since 1996 the physicians in America had started to use the HAART regimen to treat HIV/AIDS patients. But the average annual death rate from 1981 to 2009 as was announced by the CDC in US was as high as 53%. In comparison with the 1.6% average annual death rate of the 165 HIV/AIDS patients who took ALK regimen in 8 years, it has shown that ALK regimen is indeed a major breakthrough in this field.

该组数据详见附件 1：《服用艾立康者与未服用者的保生存统计对照图表》。

【说明】：统计学图表由桂林医学院赵海潞博士负责的团队按原始数据统计制作。

The set of data are listed in Appendix 1: "Surviving ALK users against those who did not take ALK-- Survival statistics and charts".

\*Statistical charts were produced by Dr. Zhao Hailu's team of Guilin Medical College who were responsible for the production of them according to the original raw data.

### ●三、艾立康的药理机制及实验室支持依据

#### ● 3. The Pharmacological Mechanism of ALK and Its Experimental Support Basis

##### ●1、艾滋病的免疫学特征及其成因

人体抗感染免疫分两部分，即细胞免疫与体液免疫。T 细胞产生细胞免疫，B 细胞产生体液免疫。艾滋病的免疫学特征呈现其双极端态势，即细胞免疫低下而体液免疫过剩。细胞免疫低下家喻户晓，体液免疫过剩则多被忽视。

##### ● 3-1 The Immunological Characteristics of AIDS Patients and Their Causes

Human anti-infection immune process consists of two parts, namely cellular immune and humoral immune. T cells produce cellular immune while B cells produce humoral immune, AIDS immunological characteristics present a bipolar extremes situation, namely the cellular immune falls in the cd4 lymphocytes cell count while humoral immune antibodies increase to excess. The cd4 lymphocytes cell count falls upon AIDS infection is well known in the medical community, but humoral immune in the surplus in antibodies have often been ignored.

● 验之于临床，一半以上的相关症状，均由体液免疫过剩引发，属于自身免疫病范畴，如艾立康拟定适应症中的哮喘、疱疹、并发性萎缩性胃炎、慢性活动性肝炎、并发性溶血性贫血、血小板减少性紫癜等等【注 2】。

● According to clinical experience, more than half of the related symptoms are caused by the excess of humoral immunity, It belongs to autoimmune response to many diseases, ALK Intended Treatable Diseases include Asthma、herpes、concurrency atrophy gastritis、chronic active hepatitis、simultaneously occurring hemolytic anemia、thrombocytopenic purpura, etc 【note 2】.

● 艾滋病的双极端免疫缺陷，基于两大成因：

### (1) CD<sub>4</sub> 的 T<sub>H</sub> 细胞亚群比例倒置，导致细胞免疫低下

除 HIV 感染使 CD<sub>4</sub><sup>+</sup> 细胞持续下降，有可能引发调节功能衰退外，导致细胞免疫低下的主要原因，在于 HIV 凭借对人体的特殊亲和力，诱导人体内环境朝着有利于它生存发展的方向转变，使 CD<sub>4</sub> 的 T<sub>H</sub> 细胞亚群发生了比例倒置。正常人体 CD<sub>4</sub> 的 T<sub>H</sub> 细胞亚群以 T<sub>H-1</sub> 为主 T<sub>H-2</sub> 为辅，两个亚群之间借助细胞因子实行免疫功能的相互调节达到相对平衡。

- AIDS bipolar extreme immunodeficiency is based on two causes

#### (1) The ratio of CD4' TH-cell subsets gets inverted upon HIV attack, leading to lowered cellular Immunity

Because of the HIV infection, CD<sub>4</sub><sup>+</sup> cells continue to decline and may lead to the regulating function decline, But the main reason depends on the special HIV infected human environment, HIV has a special affinity to the human body and can induce the human body environment to become conducive to its survival and development. In normal human body, CD4' TH-cells have two subsets。The primary one is TH-1, and the TH-2 subset is complementary, Between the two subsets, the immune function becomes balanced by secreting cytokines in normal humans。

● 倒置后的 T<sub>H</sub> 细胞以 T<sub>H-2</sub> 为主，从而使 T<sub>H-2</sub> 分泌的增强体液免疫的 II 型细胞因子 IL-4 和 IL-10 增高，抑制其 T<sub>H-1</sub> 分泌的增强细胞免疫的 I 型细胞因子 IL-2 与 IFN-γ，由此削弱了 CD<sub>8</sub><sup>+</sup> 细胞对 HIV 的细胞毒作用，细胞免疫功能被同步削弱。同时，过高的 II 型细胞因子产生了高浓度 Ig，使体液免疫发生过剩。

● After the ratio inversion, however, TH-2 subset lymphocytes become the primary cells, TH-2 cells secrete type II cytokines IL-4 and IL-10 that can enhance humoral immune function, but it can inhibit type I cytokines IL-2 and IFN-γ secreted by TH-1 lymphocytes that normally enhance cellular immune function and weaken the cytotoxic effects which CD<sub>8</sub><sup>+</sup> cells normally deal with HIV, Thus, the cellular immune function is simultaneously weakened. The excessive type II cytokine production in high concentration of Ig would then make humoral immune function excessive.

### ● (2) B 细胞多克隆活化，导致体液免疫过剩

B 细胞的主要功能是合成抗体 Ig 而发挥免疫效应。现代免疫学认为，人体感染病毒后，体内病毒的清除主要靠细胞免疫而不是靠体液免疫来实现，体液免疫的作用仅仅限于清除游离的病毒抗原，高 B 高 Ig 是加重 HIV/AIDS 病理损害的主要因素。

#### (2) Excessive cloning of more B lymphocytes leads to higher humoral immune function and lower cellular immune function

The main function of B lymphocytes is the production of antibody Ig and its contribution to humoral immune action. Modern immunology believes that after HIV infection of human body, viral clearance is done by cellular immune function, not by humoral immune function which is limited to the removal of free viral antigens. Thus, more B lymphocytes and higher Ig antibody concentration would indirectly aggravate the pathological damage by HIV/AIDS.

● 因为大量病毒（包括 HIV）、细菌均可诱导非特异性的多克隆 B 细胞活化而产生高浓度 Ig，这种高浓度 Ig 不但对病毒无杀伤功能，反而会导致自身免疫病【注 3】。

● Because a large number of viruses (including HIV)、and bacteria can induce non-specific polyclonal B cell activation and produce high concentration of Ig, antibody which not only cannot

kill the HIV virus in the already invaded lymphocytes, but may lead to autoimmune disease【Note 3】。

● **AIDS** 病人除大量的 **HIV** 外，往往还混合感染有 **EBV、CMV**（人巨细胞病毒）和多种机会性菌群，多元性地诱导着 **B** 细胞多克隆活化及自身抗体的产生【注 4】，从而造成体液免疫过剩引发自身免疫病，加剧了疾病的恶性循环。免疫学检查发现，艾滋病血液系统损害，在诊断标准具备之前就已出现，根源就在于多克隆 **B** 细胞活化使 Ig 增高【注 5】。

● In addition to a large amount of HIV, AIDS patients have often been infected by a combination of viruses such as EBV, CMV (HCMV) and a variety of opportunistic bacteria. This would induce an excessive cloning of B lymphocytes and Ig antibody production 【Note 4】，This in turn would cause surplus humoral immune, and trigger autoimmune disease, aggravating unnecessary cycle of HIV infection.Immunological studies have found that the blood system of AIDS' patients had already been damaged before diagnostic criteria were formed, The root cause was due to excessive cloning of B lymphocytes and high Ig antibody production 【Note 5】。

● 艾滋病属阴病，中医学定位是“寒疫湿毒逆向传变”，病机特点阴盛阳衰。细胞免疫属阳而体液免疫属阴，故免疫双极端现象与中医学病机完全吻合。

● AIDS is a “Yin” (passive) disease, The diagnosis by Chinese traditional medicine is "reverse conversion caused by cold plague and damp poisons", More specifically, “Yin grew while Yang declined”。Cellular immunity has been classified as “Yang” and humoral immunity has been classified as “Yin”， So the bipolar extremes immunology phenomenon and the Chinese traditional medical pathogenesis seem to perfectly agree with each other。

● 艾滋疫苗因何屡试屡败？就在于背离了疾病客观规律——只宜于阳病而不宜于阴病。疫苗属体液免疫，其性属阴。艾滋病的疫苗接种无异于以阴治阴，只会适得其反，故美国 VaxGen 生物技术公司与默克公司的疫苗，都使志愿者的 HIV 感染率上升，医学术语称之为“免疫促进”。

● Why did the HIV vaccine trials repeatedly fail? Because it has deviated from the objective laws in the treatment of HIV——The vaccine treatment would work on “Yang” disease but not on “Yin” disease。HIV vaccines promote humoral immunity whose nature is “Yin”。But HIV/AIDS is also “Yin” such that it is “Yin” fighting against “Yin”。So the result would have been counterproductive according to Chinese traditional medicine, The US biotechnology company VaxGen and Merck' company used vaccines on the volunteers and caused higher HIV/AIDS infection rate, The medical term for this is called “immune to promote” illness。

## ● 2、免疫双向调控，艾滋病治疗的最佳方案

尽管现代免疫学至今仍未明了 HIV 导致免疫功能衰退并最终发病之机理【注 6】，但艾滋病免疫缺陷的双极端现象已被越来越多的人们所认识。针对该一病机，免疫双向调控才是最佳方案。所谓免疫双向调控，就是治疗药物必须具备既能提高细胞免疫又能抑制体液免疫的双重功效。

### ● 3-2 Bipolar Yin-Yang Immune functions regulation is the Best Solution for HIV/AIDS

Although modern immunology has not been able to understand the mechanism under which HIV causes lymphocytic immune function decline and its final cause of AIDS and death 【Note6】，but the bipolar extremes in the immune functions phenomenon in HIV patients has been

recognized by more and more people. According to the Yin and Yang pathogenesis. bipolar immune functions regulation is the best solution. The drug used for this purpose must possess dual ability to increase cellular immune function while it suppresses the efficiency of humoral immune function.

- 极端免疫缺陷的成因，有着两个连锁的“源”“流”关系，它们的关系式是：

上源：HIV 等病毒+机会性菌群+II型细胞因子  $\xrightarrow{\text{流}}$  中源：细胞免疫低下+体液免疫过剩（高浓度 Ig） $\xrightarrow{\text{流}}$  下源：机会性感染+自身免疫病。

该关系式中，“细胞免疫低下+体液免疫过剩”处于中间位置，按照“上下同病取其中”的中医学治则，实施中间环节的免疫双向调控——提高细胞免疫+抑制体液免疫，必将导致下述预期效果：

● The origin of the bipolar immunodeficiency consists of two interlocking “source” and “flow” relationship. They are related as follows: (flow:  $\rightarrow$ ) **Top Source:** HIV+ other viruses + opportunistic bacterial groups + type II Cytokines  $\rightarrow$  **Middle Source:** cellular immune function low + humoral immune function (high concentrations of Ig)  $\rightarrow$  **Bottom Source:** opportunistic infection +autoimmune disease.

In this formula, “cellular immune low + humoral immune surplus” is in the middle. According to traditional Chinese medicine theory: “if the same disease is in the top source as well as in the bottom source, we take the middle source” So if we used bipolar immune regulation in the middle source—improving cellular immune function+ inhibiting humoral immune function, it would inevitably lead to the expected result:

- ① 下源，“机会性感染+自身免疫病”被有效控制或消除—源清则流洁。  
② 上源，“HIV 等病毒+机会性菌群+高浓度 Ig”被有效抑制或清除—流洁源必清。
- ① Bottom Source, effectively control or eliminate “opportunistic infections + autoimmune disease” — clear source leads to clean flow.  
② Top source, “HIV and other opportunistic viral + bacterial + high concentration Ig” is effectively control or eliminated—clean flow comes from clear source.

● 重温免疫缺陷的两大成因，“体液免疫过剩”分别以主次因由重复出现，足说明该要素在疾病归转中之举足轻重地位。急则治标，缓则治本；有余为急，不足为缓。

● Let us review the two major causes of HIV immune deficiency: lowered cd4 lymphocytes being the primary cause and Humoral immune surplus being the secondary cause. Therefore, bipolar extremes immune functions are a necessary and sufficient element in HIV disease cycle. According to the Chinese pathogenesis, treating the acute disease first only takes care of the symptoms. But treating the chronic disease would take care of the root cause of the disease. Acute disease is due to surplus while chronic disease is due to shortage.

● 中医治病，泻有余而补不足；洪水汪洋，疏筑河道导源归海方为上策。所以我们认为，中药治疗艾滋病，只有使体液免疫指数下降，才具根本性意义。单纯提高细胞免疫的中药，之所以难以保证体质稳定和病毒载量之下降，原因就在于缺乏抑制体液免疫之功效！

● The principle of Chinese medicine is based upon reducing the abundant; and supplying the shortage, It is much like preventing floods in the rivers and waterways by constructing passages

which would lead the flood water to the ocean instead of blocking it。Therefore, we believe that a traditional Chinese medicine that can reduce the humoral immunity indices would be of fundamental significance。If only to improve cellular immunity alone, as is true with HAART regimen, the effort is wasted。The reason that it is difficult for HAART to ensure physical stability and the decline in viral load lies in its lack of inhibitory power over humoral immunity indices！

### ●3、免疫双向调控的实验室支持依据

由中国中医科学院基础理论研究所于 2005 年 6 月完成的“艾立康胶囊环孢素 A 所致免疫抑制小鼠免疫功能影响实验 (CsA)”，揭示了该药所以能使 HIV 抗体转阴的药理机制。实验结果见列表：

●(3).Experimental Support for Bidirectional Regulation of Bipolar Immune Functions Completed by the Institute of Theoretical Research, China National Academy of Traditional Chinese Medicines in June 2005, the “Experiments(CsA) Using ALK Capsules Containing Cyclosporine A on the Suppression of Humoral Immune Functions in Mice” has revealed the pharmacological mechanism of conversion from HIV positive antibody into HIV negative。The results are listed in the table below:

●艾立康对免疫受抑小鼠淋巴细胞亚群影响 (  $\bar{x} \pm S$ , % )

组 别	例数(n)	$CD_3^+$	$CD_4^+$	$CD_8^+$	$CD_4^+ / CD_8^+$	$CD_{19}^+$
正常对照组	20	65.24±7.10	48.94±6.01	17.59±6.01	2.96±0.77	23.05±5.38
CsA 模型组	20	56.79±8.85 <sup>△△</sup>	38.17±6.29 <sup>△△</sup>	16.45±5.33	2.49±0.74	18.02±8.90 <sup>△</sup>
贞芪扶正组	20	61.77±12.05	41.98±10.74	18.20±4.23	2.33±0.87 <sup>△</sup>	23.06±7.41
艾立康高剂量组	20	61.60±7.52	44.35±7.61 <sup>**</sup>	16.26±2.88	2.82±0.77	14.23±5.66 <sup>△△</sup>
艾立康中剂量组	20	65.40±14.71 <sup>*</sup>	47.13±13.20 <sup>**</sup>	17.29±4.41	2.78±0.78	17.68±7.50 <sup>△</sup>
艾立康低剂量组	20	61.99±13.16	43.25±12.26	18.65±5.04	2.49±1.04	16.94±5.48 <sup>△△</sup>

●ALK application increases lymphocyte cell immune function while suppresses humoral Immune function in mice at the same time

Group	例数(n)	$CD_3^+$	$CD_4^+$	$CD_8^+$	$CD_4^+ / CD_8^+$	$CD_{19}^+$
Control	20	65.24±7.10	48.94±6.01	17.59±6.01	2.96±0.77	23.05±5.38
CSA model group	20	56.79±8.85 <sup>△△</sup>	38.17±6.29 <sup>△△</sup>	16.45±5.33	2.49±0.74	18.02±8.90 <sup>△</sup>
Tonic group	20	61.77±12.05	41.98±10.74	18.20±4.23	2.33±0.87 <sup>△</sup>	23.06±7.41
Aili Kang high dose group	20	61.60±7.52	44.35±7.61 <sup>**</sup>	16.26±2.88	2.82±0.77	14.23±5.66 <sup>△△</sup>
Aili Kang in the dose group	20	65.40±14.71 <sup>*</sup>	47.13±13.20 <sup>**</sup>	17.29±4.41	2.78±0.78	17.68±7.50 <sup>△</sup>
Aili Kang low dose group	20	61.99±13.16	43.25±12.26	18.65±5.04	2.49±1.04	16.94±5.48 <sup>△△</sup>

● $CD_{19}^+$ 和 $CD_{20}^+$ ，是表达于外周血B淋巴细胞表面的重叠标记。**B**细胞的主要功能是合成抗体Ig而发挥体液免疫效应，所以 $CD_{19}^+$ 表达的是体液免疫。药后 $CD_{19}^+$ 降低，表明体液免疫已受到抑制。上述图表清晰地表达了该药免疫双向调控功能：

● $CD_{19}^+$  and  $CD_{20}^+$ , are overlapping markers displayed on the surface of B cell lymphocytes. The primary function of B cell is to produce Ig antibody, so as to yield humoral immune function. Since the value of  $CD_{19}^+$  has been decreased after ALK treatment, it indicates that humoral immunity has been suppressed. The above chart clearly implies the bidirectional regulation of the bipolar immune functions in HIV patients by ALK.

●①ALK能有效提高小鼠细胞免疫的 $CD_8^+$ 、 $CD_4^+$ 、 $CD_3^+$ 指数。高低剂量组与贞芪扶正组相当，中剂量组不亚于正常对照组，这是十分理想的效果。

②ALK能显著降低 $CD_{19}^+$ 指数。其中中低剂量组明显低于贞芪扶正组与正常对照组，较之该二对照组的平均值低了5.74，降低率为24.89%；高剂量组则降低8.82，降低率为38.27%。说明艾立康胶囊高中低剂量都能有效抑制体液免疫效应，都能使诸多病毒、机会性菌群和高浓度Ig得到清除，机会性感染与自身免疫病得以控制。

●①ALK can effectively enhance the cell immune index of mice lymphocytes  $CD_8^+$ ,  $CD_4^+$ , and  $CD_3^+$ . The immune index for the median dose group is no less than the normal control group, which is an ideal result.

②ALK can significantly reduce  $CD_{19}^+$  index. Compared with the average of the two control groups, it was lowered by 5.74, reduction rate 24.89%; The high-dosage group mice humoral immune index was lowered by 8.82, reduction rate 38.27%. It implies that the ALK capsules at (all) high, median, and low dosages can effectively suppress the humoral immune index, and can clean up many viruses, opportunistic bacteria and reduce high Ig concentration, Opportunistic infection and autoimmune diseases are also under control.

●实践是检验的唯一标准。本所提供的上蔡县165人中144人的8年保生存疗效，无疑是对该实验数据的最现实解读。尤其是高剂量组 $CD_{19}^+$ 的大幅下降，为上蔡部分超剂量服用艾立康者的抗体转阴提供了药理依据。因为HIV抗体转阴的先决条件，必须是体液免疫得到有效抑制。

●Successful clinical trial is the only standard for testing a medical theory. The 144 out of 165 HIV patients who had survived after 8 years in Shangcai county undoubtedly gave us the most realistic interpretation of the above experimental data. Especially in the high-dosage group mice, the value of  $CD_{19}^+$  dramatically declined. It has given us with the pharmacological basis for the 10 HIV patients in Shangcai county who took the overdose of ALK that their HIV positive antibody had become negative. For the preliminary condition of HIV positive antibody turning negative relies upon the suppression of humoral immune function in a HIV patient.

●13-35岁是体液免疫最旺盛阶段。统计学多因素分析表明：上蔡县艾滋病患者中13-35岁年龄组的死亡风险，是<13岁年龄组的4.5倍，是>35岁年龄组的2.1倍。说明艾滋病的“体液免疫过剩”对预后有着重大影响。

●The age group of 13-35 is in the most productive phase of humoral immunity. Multivariate statistical analysis has shown us that: Among Shang cai county AIDS patients, 13-35 age group's risk of death was 4.5 times higher than that of 13 years or younger age group. At the same time, it

was 2.1 times higher than 35 years or above age group. This explains that humoral immune surplus has a significant influence on the risk of death prognosis.

数据详见附件 1：《艾立康与未服用者的保生存统计对照图表》。

Data in appendix 1: “The HIV Survival Statistical Chart for the ALK Users vs. Non-users”.

●据 2010 年 12 月报导，德国杰若·许特尔(Gero Hutter)博士在 2006 年通过含有突变基因“CCR5-Delta32”的骨髓移植于“柏林病人”提摩太·布郎，同时治愈了白血病和艾滋病的事实，再次证明了孙传正关于艾滋病的免疫学特征是“细胞免疫低下体液免疫过剩”的正确性。因为骨髓移植者必须实施抗排斥治疗，进行抗体抑制。抗体属体液免疫。

●According to the report in December 2010, the bone marrow transplant of mutation genes "CCR5-Delta32" that had been performed by Dr. Gero Hutter in 2006 on a leukemia and AIDS patient Timothy Ray Brown was completely successful. It proved the theory by Dr. Sun Chuan Zheng once again that HIV's bipolar immune characteristics are due to "low cellular immune function and the surplus of humoral immune function". Because in a bone marrow transplant, anti-rejection treatment must be implemented at the same time. The Anti-rejection antibodies must be suppressed. But these anti-rejection antibodies belong to humoral immune secretions from B cell lymphocytes.

●科学是多元的，中西医是两个不同的理论体系，中医药的愈病机理，并非完全能被现代医学所能阐释。譬若人类向大自然取火，可以有很多种方法，不管哪种方法，取到火就是目的。总之，重要的是结果而不是过程。

●Science is multi-faceted, The theory of Western medicine and Chinese traditional medicine are based on two very different systems. The mechanism of Chinese traditional medicine cannot be fully explained by modern Western medicine. For example, there are many ways you can do to make fire from nature. But no matter what method you take, making fire is the goal. In short, the important thing is the result rather than the process.

#### ●四、艾立康的重大理论跨越

##### 1、艾滋病的中医学定位与调整内环境之关系

任何学科的发展都离不开理论的支撑。一种新病种的出现，没有新的医药理论创立，决不可能在治疗上获得实质性的突破。《艾立康》的成功是重大理论跨越的结果。孙所长经长期临床认定：艾滋病在八纲分类上属阴属寒，在致病因子上则属寒属湿，艾滋病的中医学定位属“寒疫湿毒”；其传变规律为营血气卫“逆向传变”。

##### ● 4. Important Crossing of the Theoretical Canyon by ALK Regimen

4.(1), The development of any scientific research is inseparable from sound theoretical support. Upon the emergence of a new disease, one cannot reach a substantial breakthrough for cure without a new medical theory. The success of ALK is based on an important crossing of the theoretical "canyon". Through long-term recognized clinical research, Dr. Sun saw that the classification of HIV/AIDS is "Yin" and "Cold" from the "Eight Elements of Chinese traditional medicine". Then when it is considered on pathogenic factors, HIV/AIDS Is "cold" and "wet". So the interpretation by Chinese doctors is: "HIV is due to epidemic dampness and cold poison". The progression rule followed by HIV is from Ying→Xue→Qi→Wei, The progression of this disease is reverse progression.

● 中医学强调“治病求本”，一是本于阴阳，二是本于病源，HIV 就是艾滋病之本源所在。由于 HIV 与人体基因结合在一起，因而治愈艾滋病的必备前提，就是要让其从人体宿主细胞内分离出来。调整人体内环境，是中医药清除人体 HIV 的可靠途径，是通过调控整体生命状态而愈病的基本疗法。这种整体生命状态，是以多系统多指标的生理病理综合评价体系“证”来表述的。

● Chinese traditional medicine emphasizes finding the origin of the disease in order to find its cure. The first origin is Yin and Yang and the second origin is the Source of the disease. HIV is the origin and the source of AIDS. Because HIV and human genome are combined with each other, so that the necessary pre-condition of a cure for AIDS is to isolate HIV from the host cells. So adjusting the internal environment of the infected human body is a reliable way of clearing human HIV. Through regulation of the state of the whole life, people can become healthy. This whole life state is interpreted through multiple system and multiple goals in the physiological and pathological comprehensive evaluation process called “Zheng”.

● 中医学的“辩证论治”，辩的就是整体生命状态，揭开它的黑箱就是机体内环境综合情势在四诊上的表达，其人体生态学意义是“辩内环境论治”，其中阴、阳、表、里、寒、热、虚、实“八纲辩证”【注 7】是其总纲；燥、湿、痰、瘀、水、郁、气【说明】、火、风、暑【注 8】之类是其条目。总之，不论是致病因子，生理病理产物，生理病理形态与体质机能状况等等，都属机体内环境范畴。

● In Traditional Chinese medicine, dialectical theory is used in treatment. The whole life state is like a black box. The comprehensive situation as is interpreted by the four diagnostic methods (Look, Listen, Inquiry, and taking the Pulse) opens the black box. Its human ecology significance is that "we must debate the internal environment to discuss treatment". In which Yin, Yang, Exterior, Interior, Cold, Heat, Imaginary, Real are the "eight elements for disease debate" 【note 7】 Dryness, Dampness, Phlegm, Haemostatic, Water, Melancholy, Qi 【Interpretation】 , Fire, Wind, and Sun 【note 8】 are subordinate items. To summarize, whether we consider pathogenic factors, physiological and pathological products, physiology and pathology conditions and physical health status, etc, they all are within the human body environmental domain.

**【说明】：**“气”，是中国传统文化对构成天地万物之本源物质，及存在形式与能量之综合概括。中医学上的“气”，主要指人体先后天生命运动中肉眼不可见，但又无处不在、无处不达之功能物质与功能概念之总和。既可是生理性，也可是病理性。

**【Interpretation】** “Qi” was assumed to be the original source substance which had formed the heaven, the earth, and everything in the universe according to traditional Chinese culture, including physical matters and energy therein. “Qi” in the Chinese traditional medicine primarily describes the sum of everything inside a person unseen but yet present throughout his being that can provide energy for him. Thus, “Qi” is both physiological and pathological state in a person.

● 由于中医治理的是机体内环境，强调辩证论治（即辩内环境论治）而不是辩病论治，所以同病可以异治，异病亦可以同治。中医古籍虽不乏辩“病”治疗内容，但同样以辩证论治为基础。

● Chinese traditional medicine treats and cares for the human body internal environment, emphasizing dialectical theory in the treatment rather than debating for treating the disease before

considering the internal body environment condition. Therefore, the same disease can be treated by different methods while different diseases can be treated by using the same method.(The case of the “Berlin Patient” being successfully treated by Dr. Gero Hutter in the special bone marrow transplant of 2006 is a good example of the latter.) Although there are many recorded cases in ancient Chinese medicine books where debating to treat the disease prior to consideration of the patient’s internal body environment, those doctors still took “dialectical theory” in their treatment of patients as basis.

● 辩内环境论治与辩证论治的主要区别，在于前者具有主动性，后者失之被动。因为辩证论治要证候出现才能实施治疗。辩内环境论治，既不失辩证论治，又属“治未病”范围。

● Debating internal body environment for treatment differs from using “dialectical theory” to treat a disease because the former method is active while the latter one is passive. This is due to the fact that the latter requires the appearance of a disease before the dialectical discussion begins. The former method does not lack the dialectical debate but in the mean time it belongs to the domain of “curing without disease” while caring for the internal body environment first.

● 中医学的辩内环境论治这一特殊性，决定了对传染病的治疗完全可以不问病原体是什么，只要按机体内环境综合情势的信息表达予以实施，即可达其治疗之目的。

● The special nature of caring for internal body environment as practitioners of Chinese traditional medicine have learned, has decided that while considering the method for treating infectious diseases one can completely ignore the pathogens. One can choose a method according to the information found in comprehensive internal body environmental conditions in the patient.

● 中医学的这种人体内环境治疗理念，决定其愈病机理与西医西药截然不同，对传染病的治疗，不是依靠药物直接杀灭病原体，而是通过调整和营造不利于病原体生存的内在环境，提高机体代谢功能和自我修复能力而愈病。

● The concept of caring and debating for the internal body environment of a patient by traditional Chinese medicine practitioners has manifested in their practice that it is entirely different from Western medical doctors and their use of Western medicines. The treatment of infectious diseases by Chinese medicine practitioners does not rely on finding the medicine that kills pathogens directly, but it is done through adjusting and constructing an internal body environment that is not conducive to pathogenic survival. It improves the metabolism function and the self-repairing ability in a patient for the natural cure of diseases.

● 众所周知，生态环境改变导致生物链的解体并非必然是化学物质杀灭了某些物种，主要是变迁了的环境不再利于这些物种的继续生存，中医愈病机理亦然。《素问·阴阳应象大论》曰：“阴阳者，天地之道也，万物之纲纪，变化之父母，生杀之本始，神明之府也，治病必求于本”。该“本”者本于阴阳，此乃逐邪祛病、生杀病原体之“本始”所在。故而艾滋病的中医药治疗必须以协调阴阳为第一要点。

● As is known to all, the disintegration in the chain of living organisms is not necessarily due to killing of certain species by chemicals, but the ecological environment is no longer favorable for the continued survival of these species. The same is true to the theory and practice

of traditional Chinese medicine. 《Basic Inquiry-The Big Debate in Response to Yin and Yang Observations》 says: "Yin and Yang is the way of heaven and earth; it is the rule of all things; it is origin to all changes in the universe;. it governs the life and death of all things; it is the home of all spirits; we must find the Root before treating any disease." The "Root" is also based in Yin and Yang which can eliminate all evils and pathogens because that is where the "Original Root" is found. So the correct method in traditional Chinese medicine for the treatment of HIV/AIDS must first coordinate the balance of Yin and Yang in a patient as its primary point of consideration.

- 艾滋病既属“寒疫湿毒”，中医药就可通过逆转“寒疫湿毒”内环境（包括细胞内环境）使其不利于病毒之生存，HIV 从人体宿主细胞内被分离出来则可水到渠成！譬若房子诚非杀人之具，然则断其粮食、水电或空气之供给，不再具备基本生存条件，入住者如不搬迁，就只有死亡。艾立康胶囊清除 HIV 的药理机制，即是运用了调整人体内环境法，其特点是：症状控制快，体质恢复快，病毒清除快，无耐药反跳现象。

- HIV/AIDS belongs to “cold epidemic and damp poison”. Chinese traditional medicine can convert through the internal environment(including intracellular environment) to build something that is not conducive to survival for pathogens. When HIV in host cells are separated and leave the host cells, the disease would be naturally cured. Although a house itself cannot kill, if its food, water or air supply gets cut, the occupants in it must leave the house, otherwise they would die. The method with which ALK can help clean out HIV from the lymphocyte cells is exactly the same. By building the right internal body environment not conducive for HIV, the virus is naturally cleaned out of the patient. The special features after the use of ALK are: Fast removal of the symptoms, fast recovery for the patient, fast cleaning of the HIV virus, and no side effects by the patient because the ALK capsules are not toxic.

## ● 2、艾滋病的治疗原则，生存第一病毒第二

艾滋病治疗的有效性评价，必须以国际公认的艾滋病定义为基础，国际公认的艾滋病定义是—“获得性免疫缺陷综合症”。“综合症”三字，是该定义的本质所在，它是对 HIV 感染晚期出现的一组复杂疾病的总称，主要包括各种机会性感染、恶性肿瘤和消耗综合症等。

### ● (2).The principle for AIDS treatment: survival comes first, killing the virus second.

The valid evaluation for AIDS treatment, must be based on the definition recognized internationally as the standard. The internationally recognized definition for AIDS is "acquired immune deficiency combined syndrome", where "combined Syndrome" is the essence of this definition. AIDS is a group of complex diseases appearing at later period of this disease. The combination Includes various opportunistic infection by bacteria, malignant tumor, and complex health consumption syndrome, etc.

- 值得提示的是，判定 HIV 感染是否已经发展到“综合症”阶段，并非由 HIV 载量大小来标定，而是以诸多相关症状为标志。艾滋病的致死原因，并非是 HIV 感染之本身，而正是那些恶性相关综合症。恶性相关综合症，源于 HIV 感染的免疫缺陷和并发性高 B 高 Ig 诱导的自身免疫病。

- Whether HIV infection has developed to "combined syndrome" stage, cannot be determined by the HIV load, but by many related symptoms. The cause of death is not due to HIV infection itself, but is due to those related bad syndrome caused by opportunistic bacteria

infection, malignant tumors, and is from immunodeficiency and concurrent high B high Ig induced autoimmune diseases.

●毛泽东指出：“不同质的矛盾，只有用不同质的方法才能解决”。HIV 感染的全过程分感染期、HIV 携带期（潜伏期）与艾滋病期三个阶段。前二阶段不影响患者正常生存，HIV 是主要矛盾方面；然而一旦发展到艾滋病阶段，患者的自然生存期已相当短暂，消除症状保证生存已上升为主要矛盾方面。

● Former chairman Mao had once pointed out that:“Contradiction of different quality can only be resolved by using methods of different quality”。The progress of HIV/AIDS can be divided into three stages: infection stage, incubation stage, and AIDS stage. In the first two stages the patient's normal life is not affected, and HIV is the primary contradiction. However, once it is developed into the AIDS stage, the natural life expectancy of the patient is quite short. In this stage, eliminating symptoms to preserve the patient's life has been promoted to the primary contradiction.

●现代医学中，疾病性质发生重大变化的病种并不少见，例如乙肝病毒长期感染会引发肝硬化或肝癌，幽门螺旋菌感染会引发胃癌等。当癌症发生时，抗菌抗病毒治疗早已时过境迁，只有代之以解决新矛盾的抗癌疗法，才是“治病求本”。HIV 感染一旦发展到艾滋病阶段，疾病已发生了质的变化，保证生存已上升为矛盾的主要方面。

● In modern medicine, viruses which could cause major qualitative changes in diseases are not uncommon, For example, chronic infection by Hepatitis B virus (HBV) can cause liver cirrhosis or liver cancer, *Helicobacter pylori* (bacteria) infection can cause stomach cancer etc. When cancer is confirmed, antibacterial or antiviral treatment would be too late, In order to “cure the life- threatening disease from the root” we must find a new anti-cancer therapy to resolve the new contradiction. Once HIV infection has reached the AIDS stage, the disease has made a major qualitative change in the patient, To ensure survival has become the dominant factor of the contradiction.

●治疗的目的为了生存，千古不变。所以，艾滋病治疗必须以控制症状保证生存为前提，坚持生存第一病毒第二的原则。假定某种药物（不管是中药还是西药）能使所有症状得以消除，生命状态得以恢复，那么按照国际公认的艾滋病定义，不管 HIV 载量是否还存在，就已不再是“艾滋病”，定义这样的药物为抗艾滋病药物才顺理成章而合乎逻辑。

● The goal of treatment for a life-threatening disease is for survival. This is forever true. Therefore, the goal of treatment for AIDS must guarantee survival and remove symptoms. insisting on the principle that patient survival comes first and killing HIV second, Assuming that there is a certain drug (It doesn't matter if it is Chinese or Western medicine) which could eliminate all symptoms of AIDS and restore normal life conditions in the patient, then according to the internationally recognized definition of AIDS, no matter how much HIV load still exists, it is no longer AIDS. Under such a recognized definition if we named it as an “anti-AIDS drug” we are being logical and reasonable.

●纯粹降低 HIV 载量的药物，只能用于 HIV 携带者而并不适用于艾滋病，正如拉米呋啶只能用于乙肝治疗而不能用于后期的肝硬化肝癌一样。

● The drug that can only reduce HIV load, can only be used for the HIV carriers but not for AIDS patients, Just as lamivudine can only be used for Hepatitis B treatment and cannot be used

for cirrhosis in the liver or liver cancer.

## ●五、艾立康的临床应用特点

### 1、安全性大，基本无毒

《艾立康》的药物设计，旨在调整人体内环境，排除了以毒攻毒类药物，加之工艺设计合理，成品基本无毒。重金属及砷含量均符合国家标准。

#### ● 5. Characteristics of ALK in clinical application

##### (1). ALK is non-toxic with high safety factor

Rejecting the faulty concept of “fighting poison with poison”, the design goal of ALK Is to balance the internal environment of the human body. The drug is non-toxic, and the design of the manufacture engineering process is reasonable. Heavy metals and arsenic levels in the ALK all conform to the national standard. There are neither known side effects nor narcotic drug dependency in the patient after use of ALK.

●急长毒试验结果显示，分别给予小鼠、大鼠相当于成人临床剂量 611.7 倍和 122.3 倍的生药量饲喂（**长毒试验 6 个月**），动物未见明显不良反应，而且体重增长正常，对血液系统，肝肾功能及糖脂代谢无明显不良影响，各脏器未见由中毒导致的变质性病理变化及中毒炎性反应，免疫系统形态学正常。说明艾立康毒性极低，按拟定临床剂量服用可以确保安全。试点治疗中**列入统计的 165 人**，没有一例发生过不良反应。

● In the acute and chronic poisoning tests of ALK, mice and rats were given crude drug at 611.7 times and 122.3 times of the dose equivalent that is used in adult dose in clinical trials (The experiment lasted for six months in chronic poison tests), The animals had no observable bad reaction. And the weight gains were normal, The blood system, function of liver and kidney and glucolipid metabolism all had no adverse impact by the use of ALK, Every internal organ of these animals did not show any pathological damage caused by drug poisoning or any inflammatory reaction. The immune system morphology was normal. It demonstrated that the toxicity of ALK Is extremely low, Therefore, if we evaluate it according to clinical dose, it can ensure complete safety. Out of the 165 patients in the Shangcai county clinical trial for 8 years there was not a single case of adverse reaction caused by the use of ALK.

### ●(2)、症状控制快，体质恢复快

服用《艾立康》10 天左右，HIV/AIDS 症状可明显改善。对于长期高热、腹泻、乏力、口腔念珠菌感染、消耗综合症等棘手症状，《艾立康》可收立竿见影之效。例如：文楼村 HIV/AIDS 患者程建中，头晕乏力，全身痒疹，长期低热，易感冒发烧，骑自行车去城里一趟（约 5 华里），就发高烧得挂几天吊针。服用《艾立康》二个月后，所有症状全部消失，体质增强，开三轮摩托赚钱，风雨无阻，冬天冷水洗头也不再感冒。

●(2) With the Use of ALK, HIV/AIDS symptoms are quickly removed and the physical conditions of the patients are quickly recovered

After taking ALK for 10 days, the HIV/AIDS symptoms are obviously improved Thorny symptoms such as long-term high fever, diarrhea, fatigue, oral Candida infection, health consumption syndrome, etc. can be immediately improved after ALK treatment for a short time. Mr. Cheng Jianzhong who was a HIV/AIDS patient in WenLouCun village of Shangcai county had symptoms of dizziness & fatigue, itchy rash, long-term low grain fever, frequent colds. Riding a bicycle once to the city (about 5 li, or 2.5 Km) would result in a high fever which required

intravenous feed of medicines for a few days. But after taking the ALK for two months, all his symptoms disappeared. His physical conditions were improved to the extent that he started driving a side-car motorcycle to make money, rain or shine. In the winter when he shampoos his head he no longer catches a cold.

● 凡服用《艾立康》的病人，体重都有大幅增加。例如石佛村的万新才增加了 11 公斤，郑凤莲（女）增加了 17.5 公斤；文楼村的程金东增加了 15 公斤；刘庄村的林新军增加了 22 公斤，林新卫增加了 16 公斤。

● Every patient who took the ALK had experienced a substantial weight gain. For example, Wan Xincai of the Stone Buddha village gained 11 Kg, Zheng Fenglian (female) added 17.5 kg, Cheng Jindong of Wenlou village added 15 kg; Lin Xinjun of Liuzhuang village gained 22 Kg, and Lin Xinwei gained 16 Kg.

### •(3)、临床治愈时间短，《艾立康》停药不反跳

所谓临床治愈，是指所有症状消失后，保持其停药一整年以上主要症状不予复发。《艾立康》在河南上蔡的无偿试点治疗，多数患者仅服药 3~6 个月，平均停药 6 年来，患者们都重新参加了劳作或外出打工赚钱，促进了社会的稳定和谐。HIV/AIDS 只要能切切实实地达到临床治愈，就说明已经突破了病毒耐药，重复治疗可以继续有效。

●(3) Time duration for cure of HIV/AIDS is short with ALK, and the Symptoms do not recur in one year or more after stopping the ALK regimen treatment

The so-called “clinical cure” refers to the disappearance of all symptoms and no recurrence after the treatment is stopped for one year or more. At ALK’s free clinical trials treatment in ShangCai county, most patients took the medicine only 3 to 6 months, In six years of the average drug stoppage, patients have gone back to labor or gone out to work to earn money. This promoted social stability and harmony. As long as we can achieve the clinical cure of HIV/AIDS, the drug ALK has shown a breakthrough in the virus resistance to drugs. Repeat treatment can continue to be effective.

### ●4、能达彻底治愈效果

艾滋病的彻底治愈必须具备两个条件：一是将 HIV 从宿主细胞中分离出来，二是抗体转阴。只有抗体转阴，才能说明已经没有隐匿病毒。

● (4) Using ALK on HIV/AIDS Can help patients reach the thoroughly cured effect

To thoroughly cure AIDS we must fulfill two conditions: Firstly, we must get HIV to leave the host cells. And secondly, we must help to get the HIV positive antibody to turn negative. Only when HIV positive antibody turns negative can we say that there is no more hidden HIV virus in the patient.

● 艾立康的 HIV 载量下降，呈现其 S 形图标曲线。服用 25 天至 1 个月，病毒载量可下降 40% 左右。1 个月后，血液病毒载量开始升高，因为细胞内病毒已被分离出来。

● The Cellular HIV load in a patient would decline with an S-shaped curve by taking ALK. After taking ALK in 25 days to 1 month, the cellular HIV load would decline by about 40%. One months later, however, the blood serum HIV load begins to rise because the HIV virus has already left the lymphocyte cells.

● 病毒载量上升的越高，说明从细胞内分离出的病毒越多。当上升到一个至高点后，由于细胞内病毒已处于低值，血液病毒载量则持续下降，直至被完全清除或检测不到。

● The higher the blood serum HIV load increases, the more HIV virus has left the lymphocyte cells. When the blood serum HIV load rises to a maximum, because the cellular HIV load has declined to a low value, the blood serum HIV load would then continue to decline until all of it is removed by humoral immune cytokine.

● 例如湖北李xx（男），2009-03-19 日病毒载量 213000cp/mL，服药三个月，病毒分离后的最高值达 3870000cp/mL，至 2010-01-11 降至<500cp/mL（地标表示检测不到）。

● Example: Mr. li (male) in Hubei province, His blood serum HIV load on March 19, 2009 was 213Kcp/mL. After taking ALK medicine for three months, his HIV virus went from lymphocyte cells into the blood serum, and the peak of his blood serum HIV load was 3,870Kcp/mL, On January 11, 2010 it dropped to < 500cp / mL (Low mark shows that it could not be detected), We believe that his blood serum HIV was removed by his humoral immune cytokine.

#### ● 数据详见附件 2：《艾立康治疗 HIV/AIDS 病检测登记表》。

● Data in Appendix 2: “Detection Registration Form of ALK treated HIV/AIDS Patients”。

● 学界将 AIDS 定为不可治愈病种，是基于“抗体终身携带论”。“抗体终身携带”论，大约来源于某些疾病之后的终身免疫。不同传染病病后免疫状态并不一致，免疫期有长有短，短的仅能持续数日或数年不等，有的甚至不产生保护性免疫。终身免疫仅限于麻疹、天花、水痘、乙脑等少数病种。其实，终身免疫与抗体终身携带并不等同。

● In academic circles AIDS is regarded as “an incurable disease”, This maybe based on “Lifelong Carrying Antibodies Theory”, Yet, “Lifelong Carrying Antibodies Theory” probably came from the observed life-long immunity after suffering from certain diseases. Different infectious disease have a different immune status after illness, The immune period could be long or short. The shorter ones may only last a few days or several years. Sometimes they even do not produce protective immunity. Life-long immunity is limited to measles, smallpox, chicken pox, etc. Actually, life-long immunity is not the same as lifelong carrying of antibodies.

● 2007年9月，中国军事医学科学院生物安全国家重点实验室公布了对“SARS恢复期病人保护性抗体消失”的研究结果：**3年后约1/4病人的特异抗体消失**。此足证明，在疾病痊愈后的一定时间段内，抗体可以自然消失。

● In September 2007, The National Key Laboratory of Biological Safety, Institute of China Military Academy of Medical Sciences released research results about “The Disappearance of SARS Patient’s Protective Antibodies”: Three years after SARS attack, about 25% of the patients have lost their distinctive protective antibodies. This is proof that within a certain period of time after recovery from a certain disease, the antibodies in a patient can naturally disappear.

● 因为抗原消亡后，原有抗体不可能背离世界万物共同遵循的从生到灭这一自然规

律而永恒存在。HIV 抗体并无免疫保护作用，痊愈后的消失也就更快。艾立康的 CsA 实验已充分阐明了 10 例抗体转阴的药理机制。

● Because after the disappearance of the antigens, the original antibodies cannot possibly deviate from the world natural law from birth to death and have eternal existence. HIV antibodies have no Immune protection effect. They disappear faster after recovery of the patient. The CsA experiment of those 10 patients taking ALK overdose has already fully illustrated the pharmacological mechanism of turning HIV positive antibodies into HIV negative.

### ●5、能迅速提升免疫功能

①**CD<sub>8</sub>指数** 从现代免疫学角度，CD<sub>8</sub><sup>+</sup>细胞的抗病毒应答是控制HIV复制的主要因素，所以艾滋病治疗的免疫评价，应以维持和提升该细胞的高表达状态为主。细胞免疫的抗病毒机制，是CD<sub>8</sub><sup>+</sup>细胞和自然杀伤细胞释放穿孔蛋白等细胞因子，破坏并溶解被感染的靶细胞（HIV/AIDS的靶细胞，主要是带毒CD<sub>4</sub><sup>+</sup>），使病毒失去增殖场所，切断感染周期。但在抗病毒过程中，CD<sub>8</sub><sup>+</sup>会被消耗性降低，所以促进CD<sub>8</sub><sup>+</sup>的提升或保持其高表达状态，是抗艾药物必备的重要条件。

● (5). ALK could rapidly promote HIV immune function in an AIDS patient

①**CD<sub>8</sub> index** ...From the perspective of modern immunology, the antiviral response of CD<sub>8</sub><sup>+</sup>cells is the main factor in controlling HIV's replication. So the AIDS treatment evaluation of immune function should primarily sustain and promote the high antiviral response. The Cellular immune antiviral mechanism is due to the secretion of perforation protein and other cytokines by CD<sub>8</sub><sup>+</sup> cells and other natural killer cells which destroy and dissolve infected target cells. (HIV/AIDS's target cells are mainly virus adhered CD4+ cells). Thus, they can cut off infection cycle and remove the HIV proliferation environment. But in the antiviral process, CD<sub>8</sub><sup>+</sup>cells are consumed. So to maintain or promote the antiviral response of CD<sub>8</sub><sup>+</sup>cells is the most important and essential condition in anti-AIDS drugs.

●所谓 CD<sub>8</sub> 的高表达，是指相对于 CD<sub>4</sub><sup>+</sup>大幅度低于正常标准底线而言，使 CD<sub>8</sub><sup>+</sup>始终保持着≥美国标准正常低限的 323/ $\mu$ l 状态。所有服用艾立康的患者，都能始终保持其 CD<sub>8</sub><sup>+</sup>的高表达状态。例如张巧（女），服药一个月 CD<sub>8</sub><sup>+</sup>增长 276 cells/ $\mu$ l；苏永红（女），服药一个月 CD<sub>8</sub><sup>+</sup>增长 112 cells/ $\mu$ l；何平（男），服药 38 天，CD<sub>8</sub><sup>+</sup>增长 667 cells/ $\mu$ l；付xx（男），服药二个月，CD<sub>8</sub><sup>+</sup>增长 361 cells/ $\mu$ l。

●The so-called CD<sub>8</sub><sup>+</sup>cells high response refers to the value relative to the CD<sub>4</sub><sup>+</sup>cells greatly lower than normal bottom line standard. We need to maintain CD<sub>8</sub><sup>+</sup>cells at ≥323cells/ $\mu$ l level which is the normal low limit by US standard. All patients using ALK can maintain his/her CD<sub>8</sub><sup>+</sup>cells at high response state. Examples such as Zhang Qiao(female)had her CD<sub>8</sub><sup>+</sup> cells increased by 276cells/ $\mu$ l after taking ALK for a month. Su Yonghong (female)had her CD<sub>8</sub><sup>+</sup> cells increased by 112 cells/ $\mu$ l after taking ALK for a month. He Ping (male)had his CD<sub>8</sub><sup>+</sup>cells increased by 667cells/ $\mu$ l after taking ALK for 38 days. Mr. FU had his CD<sub>8</sub><sup>+</sup> cells increased by 361 cells/ $\mu$ l after taking ALK for two months.

●②**CD<sub>4</sub>指数** 细胞免疫过程是个 CD<sub>8</sub><sup>+</sup>细胞与自然杀伤细胞破坏并溶解被感染靶细胞过程，假如在病毒载量大幅下降的同时出现 CD<sub>4</sub><sup>+</sup>一时性降低，乃属药效学正常现象，

因为带毒 CD<sub>4</sub><sup>+</sup>正是细胞免疫的靶细胞。

●②The CD<sub>4</sub><sup>+</sup> index cellular immune process is a process in which CD<sub>8</sub><sup>+</sup> cells and natural killer cells destroy and dissolve infected target cells, If the cell HIV load had a big drop at the same time the number of CD<sub>4</sub><sup>+</sup> cells were reduced, it is a normal phenomenon in pharmacology because the HIV adhered CD<sub>4</sub><sup>+</sup> cells are the target cells in the cellular immune process.

●治疗过程中的 CD<sub>4</sub><sup>+</sup>细胞，并不与病毒载量的下降或分离正相关。例如山东宋x(男)，2009-06-12 日的病毒载量 176000cp/mL, CD<sub>4</sub><sup>+</sup>仅 25cells/μl, 并严重感染了卡氏肺囊虫肺炎。6月 25 日服用艾立康，至次年 6 月 10 日，病毒载量降至<LDL (检测不到)，但 CD<sub>4</sub><sup>+</sup>仅 20cells/μl, CD<sub>8</sub><sup>+</sup>则从不到 400 上升至 719cells/μl。

●The number of CD<sub>4</sub><sup>+</sup> cells in the course of the cellular immune process, is not proportional to HIV load's decrease or HIV separation from CD<sub>4</sub><sup>+</sup> cells. Example: Mr. Song (male) in Shandong province whose HIV virus load was 176Kcp/mL on 12-June-2009. His CD<sub>4</sub><sup>+</sup> cells were only 25cells/μl, and had a serious infection of pneumocystis pneumonia. Then on June 25, 2009 he took the ALK regimen. By June 10 next year his virus load was reduced to less than LDL (Can't detect). Although his CD<sub>4</sub><sup>+</sup>cells were still only 20cells/μl, his CD<sub>8</sub><sup>+</sup> cells were increased from 400 cells/μl to 719cells/μl, A Phenomenal success for ALK!

●数据详见附件 2:《艾立康治疗 HIV/AIDS 病检测登记表》。

● Data in Appendix 2: "Detection Registration Form of ALK treated HIV/AIDS Patients".

●《艾立康》对 CD<sub>4</sub><sup>+</sup>的提升效果，远远优于拉米夫定参与的高效抗逆转录病毒(HAART) 疗法即“鸡尾酒”疗法。

●ALK improvement on CD<sub>4</sub><sup>+</sup>cells index is far superior to High Action Antiretroviral Therapy (HAART) in which lamivudine was one of the three antiretroviral drugs used in the first line treatment of, namely "cocktail" therapy.

●根据无国界医生组织对 12058 名运用有拉米夫定参与的一线药物治疗,HAART,的跟踪观察，接受半年治疗后的 CD<sub>4</sub><sup>+</sup>细胞指数平均值为 101cells/μl, 两年后为 208 cells/μl, 即治疗半年的平均增长量不足 36cells/μl。而《艾立康》治疗 1~4 月，其增长量即可远远超过该幅度。

● According to tracking observation about 12058 AIDS patients in which the Medicine Sans Frontieres participated, the patients used lamivudine as first-line treatment. After six months treatment ,the CD<sub>4</sub><sup>+</sup> cells index average was 101cells/μl. Two years later it was 208 cells/μl. The average growth rate in half a year was less than 36cells/μl. If they'd taken ALK for 1 ~ 4 months, however, the average growth rate would have been far more than this magnitude.

●例如张巧 (女)，服药一个月 CD<sub>4</sub><sup>+</sup>升高 77 cells/μl; 苏永红 (女)，一个月 CD<sub>4</sub><sup>+</sup>升高 50 cells/μl; 何平 (男), 38 天 CD<sub>4</sub><sup>+</sup>升高 119 cells/μl; 杜xx (男), 一个月 CD<sub>4</sub><sup>+</sup>升高 160 cells/μl; 付xx (男), 二个月 CD<sub>4</sub><sup>+</sup>升高 180 cells/μl; 邢xx (男), 二个半月 CD<sub>4</sub><sup>+</sup>升高 418 cells/μl。上述 CD8、CD4 数据，详见附件 2:《艾立康治疗 HIV/AIDS 病检测登记表》。

● Such as Zhang .Q (female),after taking ALK a month , CD<sub>4</sub><sup>+</sup> cells index rose by 77

cells/ $\mu$ l; Su.Y.G (female), CD<sub>4</sub><sup>+</sup> cells rose by 50 cells/ $\mu$ l in a month; He.P (male), CD<sub>4</sub><sup>+</sup> cells rose by 119 cells/ $\mu$ l in 38 days; D x (male), CD<sub>4</sub><sup>+</sup> cells rose by 160 cells/ $\mu$ l in a month; Fu x (male), CD<sub>4</sub><sup>+</sup> cells rose by 180 cells/ $\mu$ l in two months; Xing x (male), CD<sub>4</sub><sup>+</sup> cells index rose by 418 cells/ $\mu$ l in two and half months. All of them took ALK.

## ●六、艾立康的拟定适应症与疗效评价标准

### ● 6. The Intended Treatable Diseases by ALK and Evaluation Standard of Its Effectiveness

#### ●1、拟定适应症范围

##### ● (1). Intended Range of Treatable Diseases by ALK

●艾立康胶囊系根据艾滋病属“寒疫湿毒逆向传变”这一中医学定位，按照“治病求本”、“标本兼治”原则设计，经实践验证对控制常见的“非特异性”并发症，清除HIV，提高CD<sub>8</sub>、CD<sub>4</sub>免疫指数有其显著效果。对照2007年9月17日国家局发布的《中药注册管理补充规定》公开征求意见稿，符合第六条（三）款“主治为病症结合的中药复方制剂”的规定，临床定位是“病症结合”的艾滋病治疗中药，其适应症是HIV抗体阳性兼有下述症状者：

● The design of ALK capsule is based on AIDS being: "epidemic cold and damp poison in reverse transfer conversion" of Chinese medicine concept. The design is done according to the principle of "search for the root of disease in treatment" and "treating both symptoms and root of disease". In actual treatment practice it was proven effective in the control of many common "undistinctive" simultaneous infections as well as the removal of HIV load in the AIDS patient while improving both the CD<sub>8</sub> and CD<sub>4</sub> immune function indexes. Referring to the draft document released by the China Bureau of Traditional Chinese Medicines on September 17, 2007: 《Supplementary Regulations for Traditional Chinese Medicine Registration & Management》 requesting for public opinions, ALK capsule design conforms to the regulation in article 6 (3): "A Complex Regimen of Traditional Chinese Medicine for the Primary Treatment of Integrated Symptoms and Diseases". The clinical treatability of ALK capsules is "symptoms and disease integrated" traditional Chinese medicine for AIDS treatment, and its Intended Treatable Disease is HIV positive antibodies along with the following symptoms:

- ①口腔白膜，口腔白斑病，口腔溃疡；
- ②腹胀，腹泻，肛口溃疡；
- ③困倦，乏力，消瘦；
- ④慢性皮疹，疱疹，淋巴结肿大；
- ⑤长期低热或咳嗽；
- ⑥并发性胃炎（胃痛）、慢性活动性肝炎；
- ⑦并发性神经性头痛，头晕，耳鸣，视蒙；
- ⑧其它非特异性症状。

- ①oral albuginea, oral leukoplakia, oral ulcers;
- ②abdominal distension, diarrhea, anal mouth ulcers;
- ③drowsiness, fatigue, weight loss;
- ④chronic skin rashes, herpes, swollen lymph nodes;

- ⑤long-term fever or coughing;
- ⑥concurrent gastritis (stomach pain), chronic active hepatitis;
- ⑦complicated nervous headache, dizziness, ringing in the ears, as the Mongolia;
- ⑧other non-specific symptoms.

### ●(2)、纳入标准

#### ● (2) Entering into ALK Standard

●根据中医学防病于治的原则，凡 HIV 抗体阳性，兼上述一种或一种以上症状并具备下述条件者：

- ①年龄≥18岁，≤60岁，男女均可；
- ②符合成人 HIV 感染诊断标准；
- ③病毒载量>1 Kcp /ml, <100K cp /ml;
- ④CD4<sup>+</sup> 细胞数异常，但不低于 200 者；
- ⑤自愿接受本药物治疗的患者。

● According to the principle of prevention of disease by its treatment in traditional Chinese medicine, when the patient has HIV positive antibodies and has one or more of the symptoms listed above with the following conditions:

- ① 18 years ≤ Patient age ≤ 60 years old, either man or woman;
- ② diagnostic criteria consistent with adult HIV infection;
- ③HIV viral load > 1 Kcp / ml, <100 Kcp/ml;
- ④ CD4 + cell count unusual, but not less than 200 cells/ $\mu$ l;
- ⑤patients who voluntarily accept the ALK treatment.

### ●3、疗效评价标准

#### ● 3. Evaluation Standard of the Effectiveness in ALK Treatment

●根据生存第一病毒第二的原则，艾滋病的疗效评价必须以控制症状保证生存为前提。只有在保证生存的前提下，HIV 载量的下降和免疫指数的上升才有意义。我们拟订的标准，参照国家中医药管理局《11 省中医药治疗艾滋病项目临床技术方案》标准，并高于该标准。服药周期 10 个月。

●According to the principle of survival comes first, killing virus second, the assessment of the effectiveness in the treatment of AIDS must focus on symptoms control and guaranteed survival as the goal. Only under survival guarantee, the decline of HIV load and the increase of immune function index can be meaningful. We drafted our ALK standard which refers to the standard released by China Bureau of Traditional Chinese Medicine: 《Clinical Technique Plan of TCM Therapy for AIDS Project in 11 Provinces》 and is higher than that standard. Our prescribed ALK medication cycle is 10 months.

● (1) 治愈：体症消失，HIV 抗体转阴。

● (1) Clinical Cure criteria: Body symptoms disappear, HIV positive antibodies become negative.

● (2) 显效：①体症消失，体力增强，能从事正常劳作而不显疲惫；

②消瘦者体重增加 3 千克以上；

- ③HIV 拷贝数下降 1 log(十倍)以上;
- ④CD<sub>8</sub><sup>+</sup>维持在高表达状态 (高于美国标准正常低限 323/ $\mu$ l );
- ⑤CD<sub>4</sub><sup>+</sup>升高≥30%或 50/ $\mu$ l , 或 CD<sub>8</sub><sup>+</sup>升高大于 CD<sub>4</sub><sup>+</sup>的降低值。

● (2) Distinct Effectiveness:

- ① body symptoms disappear, enhanced physical wellness, can engage in normal labor or work without fatigue;
- ②Lost weight patient's weight gain more than 3 kg;
- ③ HIV copy number drops more than 1 log(10 times less than before);
- ④ CD8 + remained at high response status (higher than the lower limit of the normal U.S. standards 323/ $\mu$ l );
- ⑤ CD4 + ≥ 30% increase or 50/ $\mu$ l, or CD4 + CD8 + higher than the lower value.

● (3) 有效:

- ①体症消失，体力增强，能参加普通劳作;
- ②消瘦者体重增加 2 千克以上;
- ③HIV 拷贝数下降 0.5 log(五倍)以上;
- ④CD<sub>8</sub><sup>+</sup>维持在高表达状态 (高于美国标准正常低限 323/ $\mu$ l );
- ⑤CD<sub>4</sub><sup>+</sup>升高≥30%或 50/ $\mu$ l , 或 CD<sub>8</sub><sup>+</sup>升高数不低于 CD<sub>4</sub><sup>+</sup>的降低值。

●(3) Effectness:

- ① body symptoms disappear, enhanced physical wellness, can engage in normal labor or work without fatigue;
- ② weight loss patient have more than 2 kg weight gain;
- ③ HIV cp/ml decreases more than 0.5 log(five times);
- ④CD<sub>8</sub><sup>+</sup> remained at high response status (higher than the lower limit of the normal U.S. standards 323/ $\mu$ l );
- ⑤CD<sub>4</sub><sup>+</sup> ≥ 30% increase or 50/ $\mu$ l, or the number of CD<sub>8</sub><sup>+</sup> increased the reduction of not less than the value of CD<sub>4</sub><sup>+</sup>。

● (4) 稳定:

- ①体症有所消失但未完全消失;
- ②消瘦者体重增减不足 2 千克;
- ③HIV 拷贝数升降不足 0.5 log(五倍);
- ④CD<sub>8</sub>、CD<sub>4</sub>总量无升高，或下降<30%或 50/ $\mu$ l 。

●(4) Stabilized Conditions:

- ①Certain symptoms disappeared but not completely gone;
- ②weight loss person gained less than 2 kg;
- ③ HIV cp drops to less than 0.5 log(five times) of previous number;
- ④ CD8, CD4 total cell numbers did not increase or decrease by more than "30% or 50/ $\mu$ l。

● (5) 无效:

- ①体症未完全控制或有所加重;
- ②体重减轻 2 千克以上;

③HIV 拷贝数升高，或下降不足 0.5 log(五倍);

●(5) Ineffective Treatment:

① body symptoms are not under control or got worse;

② more than 2 kg weight loss;

③ HIV cp increases or decreases by less than 0.5 log(five times).

●结束语：

我们所提供的材料都是事实，经得起任何查证。或许有人疑虑：现代科技那么发达，为何解决不了这一医药难题？须知现代医学以微观为强项，其主要缺陷，在于从理论到实践，容易受机械唯物论的影响。宇宙万物的对立统一规律和物质的无限可分性，决定其微观医学永远存在未知领域！

● Concluding Remarks:

The information we have provided is based on facts. It can withstand any inspection. Some people may wonder: modern technology is so advanced, why have they not solved this medical problem? Note that the strength of modern medicine relies upon micro scale approach. Its main flaw is that, from theory to practice it was heavily influenced by mechanical materialism. The law of unity of opposites and the infinite divisibility of all substances has made the micro-medical science forever existing in an unknown region of the universe!

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●【注解】：

【注 1】2008 年 12 月 2 日健康报头版《近两成患者退出抗艾治疗—中国将启动二线抗病毒方案》一文，中国疾病预防控制中心张福杰研究员解释说：“死亡和停药是患者退出治疗的两大主因，其中大约有 45.84% 的人在服药期间死亡”。

●【Note1】On the front page of Health News, December 2<sup>nd</sup>, 2008, in the article《Nearly 20% of AIDS patients have withdrawn from the HAART program—China shall launch her second line plan for Anti-HIV treatment》, senior research scientist Mr. Zhang Fujie of China Center of Prevention and Control of Epidemic Diseases explained it saying: “Massive Death and Stoppage in HAART treatment are the main reasons for the withdrawal because about 45.84% of those who died were right in the middle of the HAART program”.

●【注 2】《现代医学免疫学》：①第 189-190 页第十五章《自身免疫与自身免疫病》第二节《自身免疫病的基本特征与分类》；②第 194 页第十五章第五节《自身免疫应答产物造成病理损伤的机制》。

●【Note2】From 《Modern Medical Immunology》 : ①Chapter 15, pp 189-190 《Autoimmune and Autoimmune Diseases》 Section ; ②p194 《The Basic Characteristics and Classification of Autoimmune Diseases》。

●【注 3】《现代医学免疫学》，刘恭植主编，江苏科学技术出版社出版，2000 年 2 月第 1 版第 197 页《B 细胞多克隆活化》。

●【Note 3】《Modern Medical Immunology》 Mr. Liu Gongzhi, Chief Editor, February, 2000, Section 1, p 197: 《Multiple Cloning of B Lymphocytes》。

●【注 4】《现代医学免疫学》，第 209 页第十六章《免疫缺陷病》第二节《免疫缺陷病的分类和临床表现》。

●【Note 4】《Modern Medical Immunology》 Chapter 16, p.209: 《Immunodeficiency Disease》 Section 2 《Classification and Clinical Symptoms of Immunodeficiency Disease》。

●【注 5】《传染病辨病专方治疗》，王崇国主编，人民卫生出版社出版，2000 年 5 月第 1 版第 497 页。

●【Note 5】《Treatment by Disease Recognition Specialized Regimen for Contagious Diseases》 Mr. Wang Congguo, Chief Editor, May, 2000, Section 1, p.497, Published by People's Sanitation Publishers.

●【注 6】《传染病辨病专方治疗》，王崇国主编，人民卫生出版社出版，2000 年 5 月第 1 版第 494 页。

●【Note 6】《Treatment by Disease Recognition Specialized Regimen for Contagious Diseases》 Mr. Wang Congguo, Chief Editor, May, 2000, Section 1, p.494, Published by People's Sanitation Publishers.

●【注 7】**八纲辨证**：是以阴、阳、表、里、寒、热、虚、实为主线，对疾病之阴阳属性、内外病因、脏腑病位、病势浅深、邪正虚实进行辨析之系统诊法。

●【Note 7】“Eight Elements for Disease Debate”: uses Yin, Yang, Exterior, Interior, Cold, Heat, Imaginary or Real as the central line, to engage in recognition and analysis of systematic diagnosis for the Yin-Yang nature, exterior-interior causes of illness, disease location in which internal organ(s), the degree of seriousness in the illness, imaginary or realistic situation of the disease under investigation.

●①**阴-阳**：是中国古代哲学对自然万物本身或相互关联事物和现象的对立统一属性之高度概括。中医学将其用于解释人体的生理、病理属性及诊疗指导。

●①**Yin-Yang**: Ancient Chinese philosophical theory for the opposite yet unified advanced universal phenomena of everything and every observation in nature which are interrelated. Doctors of traditional Chinese medicine use this to explain the physiological and pathological characteristics of their patients and to guide them in their treatment of the diseases.

●②**表里**：是辨别病因病位之基本纲领。表指表证，病在肌表；里指里证，病在脏腑气血。

●②**Exterior-Interior**: Basic elements for distinguishing and recognizing the causes and location of a disease or diseases. Exterior means surface characteristics, disease on the skins; interior means internal characteristics,disease on the internal organs.

●③**寒热**：是中医辨别疾病阴阳属性之基本纲领。寒属阴，热属阳。

●③**Cold-Heat**: Doctors of traditional Chinese medicine use these elements to distinguish between Yin and Yang characteristics in a disease. Cold or coldness is Yin; Heat or Hotness is Yang.

●④虚实：是中医辨别病势与邪正盛衰之基本纲领。虚指正气虚，实指邪气实。

●④ Imaginary or Real: Doctors of traditional Chinese medicine use these basic elements to distinguish between evil and righteous, weak and strong in a patient's disease characteristics or potential. Imaginary element indicates emptiness in the righteous "Qi" in a patient while Real element indicates the evil "Qi" in a patient.

●【注8】燥湿痰瘀水郁气火风暑：九者中，风、火、暑、湿、燥，是中医外感病致病因子“六淫”中的五淫。郁者，怫郁症致病因子。痰、瘀、水，系病理产物。“淫”者，过度也，溢也。

●【Note8】Dryness, Dampness, Phlegm, Haemostatic, Water, Melancholy, Fire, Wind, and Sun: Among these nine subordinate items to the eight elements, Wind, Fire, Sun, Dampness, and Dryness are five of the six nature items which cannot be over exposed, whereas melancholy being the main cause for mental depression, phlegm,haemostatic, and water belong to products of physiological illnesses in a patient. "Yin" (sound only) here means overflowing, or over exposure, too much.