

## A MONOCLONAL ANTIBODY DEFINING LEUKEMIC B-LYMPHOMA CELLS

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A monoclonal antibody anti-Y 29/55 was produced by fusion between a  $1^{-}$  mouse myeloma line and splenocytes of a mouse immunized to PBL of a patient with untreated B-CLL. Characterization of anti-Y 29/55 reactive normal and malignant leukocytes was studied.

The specificity of this complement binding antibody (2a,k) was demonstrated by a modified microcytotoxicity assay, indirect immunofluorescence of immune-electron microscopy. All neoplastic cells spilled over in the blood of patients with CLL of the B-cell type, with leukemic variant of malignant B-lymphoma and HCL carry the protein antigen complementary to anti-Y 29/55 on their cell surface. The same antigen was found on sessile human B-lymphocytes homing in peripheral lymphoid organs like spleen, lymph nodes and tonsils. Approximately 0,5 % of lymphocytes carrying that determinant were found in the peripheral blood of healthy volunteers. It is concluded that this antibody recognizes a leukemia associated antigen. However, it is specific for the entire differentiation spectrum displayed by resting and activate B-lymphocytes in lymphoid tissues and leukemic B-lymphocytes, as demonstrated by immune-electron microscopy after indirect peroxidase labeling and after a monoclonal antibody rosetting method. The antigen does neither appear on leukemic cells of ALL, T-lymphoma, AML or CML nor on B-lymphocytes of patients with reactive lymphocytosis or non-leukemic multiple myeloma.

In follow-up studies this antibody may be very helpful in detection of early leukemic B-cell output.

## THYMOSTIMULIN (TP-1), PHASE I STUDY WITH A NEW IMMUNOMODULATOR

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Thymostimulin (TP-1) is a biologically active calf thymus extract (G. Bergesi and R. Falchetti, 1977). In vitro and in vivo animal studies suggest that TP-1 can confer to precursor or immature T-cells properties of mature T-cells (R. Falchetti and L. Caprino, 1980). TP-1 did not show any significant acute or chronic toxicity in animals (R. Falchetti et al 1977).

24 patients (7 males, 17 females) received TP-1. The median age was 60 years (range: 19 - 74 years). All patients had advanced malignant disease with normal hepatic and renal function. Additionally 12 patients (50 %) had a beginning herpes zoster dermatitis.

Single doses of TP-1 were 1 mg/kg in 20 patients and 2 mg/kg in 4 patients. TP-1 was given i.m. daily during the first 2 weeks of therapy (day 1-5, 8-12), and then once weekly for 5 weeks. The median total dose per patients was 700 mg (range: 100-2340 mg). The following investigations were done once weekly: clinical examination, hemoglobin, leucocyte and thrombocyte counts, differential count, creatinine, bilirubin, SGOT, SGPT and alkaline phosphatase.

Toxicity:

Clinical side effects were observed in 7 patients (29 %). They consisted in (1) pain at the injection site : 4 patients. In 1 patient the pain radiated into the leg. In another patient the injection sites were indurated at the end of therapy (total dose 1170 mg). (2) Temperature between 37,8 - 39° C were observed in 3 patients during the first 3 treatment days. (3) 2 of 3 patients with fever had mild chills. In 1 patient aching of the extremities and flushing of the face occurred 2 hours after the injection. These symptoms vanished spontaneously within 4 hours. In the subsequent course this patient had the same symptoms after i.v. 5-Fluorouracil. It has never been necessary to stop TP-1 treatment because of clinical side effects. There were no hematological changes. Chemical parameters of liver and renal function remained unchanged.

Activity:

There was no evidence of cytostatic activity.

Herpes zoster dermatitis did not progress further under TP-1 in 11 of 12 patients (92 %). It is impossible to judge if TP-1 did change the natural course of this viral infection.