THE ISICR NEWSLETTER

VOLUME I   NUMBER 1

We are happy to launch the ISICR newsletter. We anticipate publishing 4 times/year and providing useful information to the ISICR membership. There are a number of categories in which we would welcome input from the membership. These include:

1. Listing of active clinical trials utilizing interferons/cytokines
2. Recent approvals of interferons/cytokines for clinical use or diagnostic testing
3. Teaching articles: For example, an article on in situ staining of interferons/cytokines, with a list of antibodies that work in the procedure, would be most welcome.
4. Positions open/Positions wanted
5. Request for reagents/request for help- Having trouble finding a cDNA clone or an antibody or having problems with a procedure? We will list your request with your phone/fax/e-mail address.
6. Business briefs- bullet summaries of recent business actions which relate to the interferon/cytokine field.
7. Meeting announcements
8. ISICR member notes (Promotions, position changes, awards, etc)
9. Humor

We welcome your ideas and suggestions for this newsletter. Please contact us with your thoughts. Information for the next newsletter should be sent to either editor by November 1, 1994.

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For the first newsletter, here is some information for the above categories.

Clinical Trials:

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<tr>
<th>ID #</th>
<th>Location/Description</th>
<th>Investigators</th>
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<tr>
<td>CM-27783-01 (B93-0008)</td>
<td>Phase Ib Trial of Autologous Tumor Cell Vaccine Plus Combination Interferon (α plus γ) in Renal Cell Cancer</td>
<td>Ernstoff</td>
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<tr>
<td>CM-87289 (B91-0006)</td>
<td>The Treatment of Patients with Metastatic Renal Cell Carcinoma Using a Combination of In Vivo Primed Tumor Infiltrating Lymphocytes, Recombinant Alpha-IFN and Recombinant Interleukin-2</td>
<td>Figlin/Slamon</td>
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<tr>
<td>CM-87290 (B90-0009)</td>
<td>Augmentation of Interferon-Induced Proteins in Adenocarcinomas After Exogenous IFN Therapy</td>
<td>Mahvi/Sondel</td>
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<tr>
<td>CM-97611 (B93-0012)</td>
<td>Phase II Study of Interferon Enhanced Dual ^131^I-Labeled Monoclonal Antibody Therapy in Patients with Metastatic Colon Cancer</td>
<td>Meredith/LoBuglio</td>
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<tr>
<td>CM-97610 (T92-0104)</td>
<td>Phase II Study of ^131^I-CC49 Monoclonal Antibody Plus Recombinant Alpha Interferon in Patients with Refractory Metastatic Breast Carcinoma</td>
<td>Murray</td>
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Recent approvals/filings:

Ares-Serono recombinant IFN-ß has been approved in Italy for several viral (hepatitis B, C, genital herpes) and cancer indications (hairy cell leukaemia, adjuvant therapy for breast and uterine cancers)........Otsuka received approval in
Japan for IFN-α for Hepatitis B. Genentech’s IFN-γ recommended for US approval for Chronic Granulomatous Disease. Immunex files GM-CSF for use in white blood cell recovery following chemotherapy in acute nonlymphoblastic leukemia.

...of interest:

In the May 13 issue of *Science*, scientists at Immunex reported on a new cytokine, designated IL-15. The studies demonstrated that IL-15, like IL-2, stimulated the proliferation of T-lymphocytes; IL-15 uses components of the IL-2 receptor, and has activity in the absence of IL-2.

- Results of a Phase I/II clinical study of Pixykine (GM-CSF and IL-3) were published in the April issue of the *Journal of Clinical Oncology*. In this study patients undergoing chemotherapy for sarcomas were treated with the drug before chemotherapy and again after the 2nd cycle of chemotherapy. Results indicated that Pixykine significantly reduced the depth and duration of low white cell count and reduced cumulative thrombocytopenia.

- Results of a 3-year interferon-alpha-2a trial conducted by the WHO melanoma program were published in *The Lancet* (April 9). The preliminary analysis of the study showed that the interferon increased survival of patients with malignant melanoma when given after surgery to remove lymph node metastases.

- Bioject, a company in Portland, Oregon that develops jet injection systems, has entered into an agreement with Schering AG for development of a delivery system for Interferon-beta. The delivery system will be a needle-free injection device for multiple sclerosis patients to deliver Betaseron (recombinant beta-interferon).

- Imclone Systems, Inc. filed an Investigational New Drug Application (IND) for Interleukin-6 Mutein (IL-6m) for the treatment of thrombocytopenia associated with chemotherapy. IL-6m is a non-glycosylated variant of native IL-6 and contains a 22-amino acid deletion. The proposed U.S. study will involve patients with breast and lung cancer and IL-6m will be given only after patients receive chemotherapy.

- Genentech has initiated Actimmune (Interferon-gamma-1b) Phase I/II clinical studies for treatment of drug-resistant tuberculosis and non-tubercular mycobacterial infections such as Mycobacterium avium intracellulare. The studies will be conducted at the National Jewish Center for Immunology and Respiratory Medicine (Denver, Colorado) in collaboration with the NIH.
• In April, 1994, Immunex filed a supplemental PLA for Leukine [Granulocyte macrophage colony stimulating factor (GM-CSF)] for acceleration of white cell recovery following chemotherapy for patients with acute non-lymphoblastic leukemia. Leukine is currently approved for stimulating white blood cell activity following autologous bone marrow transplantation and as a treatment for cancer patients whose bone marrow transplants have failed.

• The National Institute of Neurological Disorders and Stroke has initiated a Phase I study with Betakine (recombinant transforming growth factor beta-2 produced by Celtrix) for the treatment of multiple sclerosis (MS). The trial will enroll patients with actively progressing chronic MS. Celtrix is also developing Betakine as a treatment of ophthalmic diseases and dermal wounds.

• Celgene began Phase II trials with thalidomide (Synovir) for the treatment of cachexia in AIDS patients at the Rockefeller University in New York and Thomas Jefferson University in Philadelphia. Celgene is also collaborating with NIAID on a multicenter, double-blind placebo-controlled trial to measure viral load and immunological markers in HIV-positive patients. Thalidomide has been shown selectively to inhibit the synthesis of Tumor neurosis factor-alpha (TNF-α), a cytokine believed to be a potent activator of HIV replication and has been implicated in the weight loss associated with a number of diseases, including AIDS.