

HATTERSLEY LETTER

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Ref: Nich2112

From: Dr A Rejman CA-OPU2

Date: 21 December 1995

Copy: Mr Gallagher PS/SofS  
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### NEW TREATMENTS FOR HEPATITIS C

1. You may be aware that SofS met Roy Hattersley and the Manor House Group on 19 December. This is a group of haemophiliacs who are infected with hepatitis C and are pressing very hard for compensation. They are currently separate from the Haemophilia Society.
2. They were accompanied by Graham Ross, a solicitor from J Keith Park of Liverpool who was involved in the HIV haemophilia litigation and also I believe in the CJD growth hormone litigation. This individual is particularly interested in high profile work and you may well have seen his photograph on occasion in the press.
3. At the meeting Mr Ross handed me a copy of a press release regarding the combined use Thymosin and Alpha Interferon for hepatitis C.
4. I enclose a copy of that press release and would be grateful for any comments you may have on this trial and whether researchers in the UK have been involved.
5. It would be helpful if you could comment as soon as possible after Christmas, so that we can say something about this in SofS' letter to Roy Hattersley.

GRO-C

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May 15, 1995, Monday

Account for G. Rags

19/1/95



# HEADLINE NEW COMBINATION DRUG THERAPY FOR CHRONIC HEPATITIS C DOUBLES SUSTAINED REMISSION OVER THOSE RATES REPORTED WITH STANDARD THERAPY

SciClone Pharmaceuticals, Inc. (Nasdaq: SCLN), today reported that patients suffering from chronic hepatitis C achieved a ~~47% sustained~~ 47% sustained disease remission using a new combination therapy consisting of its patented drug, thymosin alpha 1, with alpha 1 interferon during an 18-month clinical trial conducted in Italy. Currently, alpha interferon alone, the only Food and Drug Administration (FDA) approved drug to treat chronic hepatitis C, has a reported sustained disease remission rate of approximately 10-25%. Results from the trial, which was conducted by Guido Rasi M.D. and colleagues of the University of Rome, were presented yesterday by Dr. Rasi at the annual Digestive Disease Week meeting in San Diego.

"The majority of patients in this trial had hepatitis C virus (HCV) genotype 1b, which accounts for approximately 80% of HCV infections in Southern Italy," said Dr. Rasi. "This is very significant news for the United States as well as Italy, since approximately 50-70% of HCV patients in the U.S. are also infected with HCV 1b genotype." There are more than 3.5 million carriers of hepatitis C in the United States and it is estimated that 150,000 Americans become infected each year. There is currently no preventive vaccine available for hepatitis C.

Dr. Rasi also pointed out that in HCV genotype 1b patients, only about a 6-20% sustained disease remission rate is achieved when treated with conventional doses of alpha interferon alone. A 33% sustained remission in genotype 1b patients was achieved in Dr. Rasi's Italian trial, including patients with active cirrhosis.

Patients in the Italian trial were treated for 12 months and followed-up for an additional six months after treatment. After 12 months of treatment, 11 (73%) of the total 15 patients were negative for HCV RNA, including two patients who had failed previous treatment with alpha interferon. Eight of the 11 responders had normalized ALT liver enzyme levels, with two additional patients having only slightly elevated ALT levels. At 18 months (twelve months treatment and six months of follow-up), seven (47%) of 15, including four patients with active cirrhosis (CHC induced liver scarring), demonstrated a sustained disease remission, being HCV RNA negative with normal or near normal ALT levels.

SciClone Pharmaceuticals, Inc., is an international biopharmaceutical company involved in the acquisition, development and commercialization of pharmaceuticals worldwide. SciClone is developing thymosin alpha 1 under the trade name ZADAXIN(R) and is co-sponsoring a 120-patient U.S. combination therapy trial with ZADAXIN and alpha interferon to treat hepatitis C.

## Hepatitis C

### What is hepatitis C?

\* Viral hepatitis C is a contagious disease caused by infection with an RNA virus. The term "hepatitis" means inflammation of the liver, which can occur when the virus attacks both the immune system and the liver cell; both can cause permanent liver damage. Five types of viral hepatitis have been identified, including hepatitis C. The different types of viral hepatitis display similar clinical features but vary significantly in modes of transmission, prevalence and outcome.

### What is the difference between acute and chronic hepatitis?

\* The initial illness is called acute hepatitis and symptoms range from mild to severe. Chronic hepatitis occurs when the virus continues to attack the liver cells beyond a six-month period. The sequelae of chronic

hepatitis C infection includes chronic liver disease, cirrhosis (scarring of the liver) and liver cancer.

What is hepatitis C and how widespread is the disease?

\* Hepatitis C is considered a serious chronic viral illness. There are more than 3.5 million carriers of hepatitis C in the United States and it is estimated that 150,000 Americans become infected each year.

How is hepatitis C transmitted?

\* Hepatitis C is spread directly from one person to another via blood or other blood fluids, or contaminated needles. In more than 40% of patients, however, the source of infection is unknown. Individuals at risk for hepatitis C include blood recipients, I.V. drug users, health-care workers, dialysis patients and to a lesser degree, the sex partners, household members and newborn babies of infected individuals.

What are the symptoms of hepatitis C?

\* Hepatitis C is often referred to as the "silent disease," because of the lack of obvious clinical symptoms. Many patients don't know they are sick until they are faced with possibly irreversible liver damage since the disease often becomes apparent only months to years after infection.

\* Acute hepatitis C is usually asymptomatic. Some patients may feel fatigued or experience a loss of appetite. It is estimated that the number of persons who recover from acute hepatitis C infection is small; as many as 80% of patients become chronic carriers of the disease. Chronic hepatitis C carriers may not demonstrate symptoms either; however, this patient group is at risk of developing serious liver damage that can progress to cirrhosis and liver cancer.

How is hepatitis C diagnosed?

\* Certain "markers" indicate the presence of HCV and can be identified in HCV carriers by blood tests. These markers include HCV RNA (hepatitis C viral RNA), which may provide evidence of active disease replication and may be found in the liver and/or serum of HCV infected persons. ALT (serum alanine aminotransferase) is an enzyme involved in liver metabolism. ALT levels increase in active liver disease, including hepatitis.

\* Blood tests are used to detect antibodies produced by the immune system specifically in response to the hepatitis C virus (HCV). Additional blood screening tests can detect elevated ALT levels, while a liver biopsy can determine the location and degree of liver injury.

How is hepatitis C treated?

\* The only FDA (Food and Drug Administration) approved treatment available is alpha interferon. This drug, which is administered by injection, has significant side effects and only produces lasting remission rates in 10-25% of patients using standard therapy; the majority of treated patients eventually relapse following withdrawal of therapy. ZADAXIN(R) thymosin alpha 1 (thymalfasin) is currently being studied in combination therapy with alpha interferon to treat hepatitis C in the United States and Italy. In addition to having minimal side effects, ZADAXIN in combination therapy is demonstrating encouraging results in hepatitis C clinical trials.

What is an HCV RNA genotype?

\* A genetic variation of the HCV RNA virus, of which there are multiple species. The significance of genotype differentiation is that some genotypes appear to be more resistant to interferon treatment than a genetic variation of the HCV RNA virus, of which there are multiple species.

For more detailed information on hepatitis C, please call SciClone Pharmaceuticals, Inc. at 1-800-SCI CLONE.

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