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The Manager Companies  
ASX Limited  
20 Bridge Street  
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(3 pages by email)

Dear Madam

## HEPATITIS C PHASE 2A TRIAL POSITIVE RESULTS

- *Phase 2a trial validates Biotron's novel drug*
  - *First-in-class new, oral drug*
  - *Good results on tolerability and efficacy*
- *Full data to be presented to scientific conference in December*

**Sydney, Australia: 10 October 2011:** Australian drug development company Biotron Limited (ASX:BIT) has released headline results from its landmark Phase 2a trial of its lead drug candidate, BIT225 in Hepatitis C virus (HCV) infected patients.

Preliminary analysis of trial data confirms that BIT225, an orally administered, small molecule drug, has good antiviral activity against HCV. Patients receiving BIT225 in combination with interferon and ribavirin (the current standard of care for treating HCV) had greater reductions in HCV levels than patients receiving standard of care treatment alone.

Patients receiving the 400 mg dose of BIT225 showed the greatest levels of virus reduction, with an improvement of ~1 log (a measure of the amount of reduction of the virus in the blood of patients) over standard of care treatment at the completion of the dosing phase with BIT225. This is a significant improvement over and above the standard of care treatment in this patient group.

Twenty four patients who had passed a stringent screening process were randomly assigned to receive either 400 mg or 200 mg BIT225, or placebo (ratio of 1:1:1), for the first 28 days of their standard treatment with interferon and ribavirin. The trial was undertaken at the Siriraj Hospital, Bangkok, Thailand. All patients were infected with genotype 1 HCV, which is the most common type of HCV and the most resistant to current treatment.

Since the completion of the clinical phase of dosing with BIT225 in August, samples have been analysed and the resultant data has been subject to preliminary review by the independent Data Safety Monitoring Committee.

The Company's Managing Director, Dr Michelle Miller, commented: "This highly encouraging result is the culmination of 10 years of research and development of Biotron's antiviral program. The trial has shown that BIT225 has good activity against HCV, and validates Biotron's approach to treatment of this virus."

BIT225's antiviral activity in this human trial supports the previously reported highly synergistic activity with interferon and ribavirin that was seen in cell culture models of HCV infection.

Robert Murphy, Professor of Medicine at Northwestern University Feinberg School of Medicine in Chicago, commented: "The results from this study provide good evidence that this novel approach to treating HCV infection has significant antiviral activity compared to the standard of care interferon plus ribavirin. Tolerability was reasonable with only one person dropping out of the study because of intolerability."

BIT225 is the first in a new class of direct-acting antiviral drugs for HCV. It specifically targets the p7 protein, a viral protein essential to virus production and replication.

The results of this trial will guide the future development path for this new class of direct-acting anti-HCV drug. BIT225 has the potential to be used with either interferon based therapies or with other direct-acting antiviral drugs in interferon free regimens. The drug is also in development for treatment of HIV, with a Phase 1b/2a trial currently underway. It has the potential to be used in the HCV/HIV co-infected population, which makes up to 30% of all HIV-positive cases.

Dr Miller said that detailed analyses of the data from the trial are ongoing, and it is anticipated that full data will be available when it is presented at an international scientific conference later in 2011.

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Yours faithfully



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### **About Biotron**

Biotron Limited is engaged in the research, development, and commercialisation of drugs targeting significant viral diseases with unmet medical need, with a major focus on HIV and HCV. The Company has BIT225 in clinical development for both HIV and HCV, and also has several earlier stage preclinical and research programs for several other viral infections including influenza, Dengue and Hepatitis B.

### **About BIT225 and HCV**

BIT225 is an investigational, orally-administered, novel antiviral compounds in development by Biotron for treatment of HCV. BIT225 represents a first-in-class drug, targeting the p7 protein of HCV. It is estimated that in the USA alone, some 4 million people have been infected with Hepatitis C with 2.7 million suffering from chronic infection. Worldwide, 170 million people are infected. HCV causes inflammation of the liver, which may lead to fibrosis and cirrhosis, liver cancer and, ultimately, liver failure. Existing drugs for HCV have limited effectiveness and toxicity issues, leaving a significant need for new therapies. The worldwide market is currently almost US\$3.3 billion, but is estimated that this market will expand to over US\$10.0 billion as safe, effective therapies enter the market.