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The Manager Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000 (3 pages by email)

Dear Madam,

INTERIM DATA FROM BIT225-008 STUDY
IN SUBJECTS WITH HEPATITIS C VIRUS GENOTYPE 3

Biotron Limited ('Biotron' or the 'Company') provides the following interim data from a Phase 2, three-month dosing study of its lead drug BIT225 in subjects infected with Hepatitis C virus ('HCV') genotypes 1 or 3 ('G1' or 'G3').

- BIT225-008 - a double-blinded, placebo controlled, multi-site, 60 subject Phase 2 trial in Thailand.
- Trial objectives:
  - Primary - Assessment of the safety and tolerability of a three-month repeat dose regime of BIT225.
  - Secondary - Assessment of the pharmacokinetic and antiviral efficacy of BIT225.
- Trial outcomes:
  - The new BIT225 capsule formulation was found to be a more efficient delivery regimen than the powder formulation used in previous trials.
  - Important information has been generated that will inform future dosing regimens and levels for BIT225 in future trials.
  - BIT225 showed no serious safety issues using the new capsule formulation over a three-month repeat dose regime.
  - There was a very high overall SVR12 response rate in the G3 cohort (prediction of permanent clearance of HCV), regardless of treatment type. The BIT225/IFN/RBV cohort had 88% SVR12 compared to the placebo/IFN/RBV treatment group's 90% SVR12. These SVR12 rates were higher than reported historically (68%) in the HCV G3 population in Thailand.
  - The BIT225 G1 cohort SVR12 response is expected in late 1Q16.
- Results support the submission of a comprehensive data package on BIT225 to the USA FDA for an IND application and for discussions with potential commercial partners.

Under the protocol of this double-blind, placebo controlled study (BIT225-008), undertaken at several sites in Thailand, 60 patients infected with HCV G1 (n=30) or G3 (n=30) were treated for 12 weeks with either BIT225 (200 mg twice daily) or placebo (ratio of 2:1), in combination with pegylated interferon alfa-2b and ribavirin (IFN/RBV). At the conclusion of this 12 week period, HCV G3 patients continued to receive IFN/RBV for an addition 12 weeks (i.e. to week 24 of the trial). HCV G1 patients continued to receive IFN/RBV for an additional 36 weeks (i.e. to week 48 of the trial). These IFN/RBV treatment times are as per standard treatment guidelines.

The HCV G3 cohort has now reached week 36 of the study. All G3 patients have been off all drugs for 12 weeks and hence at the SVR12 time point. The last patients in the HCV G1 cohort continue with IFN/RBV treatment until late 1Q16 and will be reported on at that time.

The primary objectives of the trial were to gather important safety and tolerability data that will be central to determining dosing regimens and levels in future studies with BIT225. Secondary objectives of assessment were to study the pharmacokinetics and antiviral efficacy.

The trial was the first evaluation of repeat dosing of the BIT225 capsule formulation. The delivery of BIT225 was found to be greater on a mg/kg basis than in the previous single dose bioequivalence trial, leading to higher than expected accumulation over repeated doses. This data provides Biotron with important information on the dose and dosing frequency selection for future trials, indicating that a lower dose and less dose frequency may be achievable without compromising the efficacy of BIT225. There is potential for once a day dosing which would be a major economic and efficacy advantage in many of the target populations.

There was a higher withdrawal rate for the BIT225/IFN/RBV HCV G3 cohort compared to the placebo/IFN/RBV cohort. There were no discontinuations in the placebo/IFN/RBV group.

A total of 12 of 20 patients in the BIT225/IFN/RBV group discontinued the study. Three patients withdrew their consent, for personal reasons, during the first week of the study. An additional three patients withdrew due to side effects including ataxia, exfoliated dermatitis, urticarial and angioedema. It is not possible to assign causality for these adverse events as similar side effects have been reported to be associated with IFN/RBV treatment.

Another six patients were withdrawn from the study as a precaution by the clinical trial site under the electrocardiogram QTc stopping rule. Subsequent to the withdrawal of these patients, the electrocardiograms from these individuals were sent to a USA-based expert cardiology company for independent and detailed review and investigation. This company's expert cardiologist concluded that none of the six patients demonstrated a clear cardiac safety issue. This indicates that the precautionary withdrawal of these individuals was premature and unnecessary.

Biotron was not aware of issues associated with the withdrawals until the trial was fully recruited, dosing completed, and data was unblinded and made available to the Company. Unfortunately, once a trial is underway, additional subjects cannot be recruited to replace those lost to the study.

The absence of serious toxicity at the higher than anticipated blood levels of the drug provides confidence that BIT225 is acceptably safe and tolerable.

The endpoint of HCV treatment is a sustained virologic response ('SVR'). Sustained virologic response at week 12 ('SVR12') is defined as an undetectable HCV RNA level 12 weeks after completion of all treatment. It is considered to be a prediction of permanent clearance of the virus.

Both treatment groups, BIT225/IFN/SBV and placebo/IFN/RBV, achieved a very high rate of clearance of virus. Only one patient in each group did not achieve SVR12. The reported historical average of HCV G3 patients achieving SVR12 treated with IFN/RBV in Thailand is 68%.

The BIT225/IFN/RBV cohort had 88% (7/8) SVR12 compared to the placebo/IFN/RBV treatment group's 90% (9/10) SVR12 in a per protocol evaluation. There was no statistically significant difference between the treatment arms.

Biotron Managing Director, Dr Michelle Miller, commented that "The higher than expected rate of 90% SVR12 in the IFN/RBV group means that no significant improvement in SVR12 can be shown with the addition of BIT225 in the HCV G3 population in this study. It is unfortunate that six patients were unnecessarily lost to the study under the stopping rule. However, whilst no significant improvement in SVR12 can be shown with the addition of BIT225 in the HCV G3 population in this study, the 88% SVR12 rate is significantly better than the 68% historical reported average."

Dr Miller continued, "This trial has generated positive key safety and pharmacokinetic data, which will be central to determining dose and frequency of dosing in future trials with BIT225."

Data from this study, in combination with data from the other seven clinical trials undertaken with BIT225 in healthy volunteers as well as in HIV, HCV and HIV/HCV co-infected populations, is currently undergoing detailed analyses with expert groups in the USA. These investigations include exposure/adverse event analyses, and pharmacokinetic/pharmacodynamic modelling.

The results of these analyses, along with the clinical study reports, extensive non-clinical toxicology reports and a detailed report on Chemistry, Manufacturing and Control ('CMC') of the compound will form the core of a comprehensive data package on BIT225. Biotron expects to submit this data package to the USA FDA in the form of an IND application in late 2015. Importantly, the data package will also be central to discussions with potential commercial partners for the next stage of clinical development of BIT225.

A review of preliminary data from the trial by an independent Data Safety Management Committee ('DSMC') recommended that future trials with BIT225 be done in combination with other direct acting antiviral drugs ('DAAs'), and focus on HCV G3. Current DAA therapies for this group involve treatment for up to 24 weeks duration and response rates with G3 infections are lower than for other HCV genotypes. The DSMC also noted that more patients than expected are failing treatment with the new DAAs and that this population, which has very limited choices, may be an area of interest for BIT225 given its different anti-viral mechanism of action.

Dr Miller commented further, "The BIT225-008 trial was a complex trial and has provided Biotron with essential data which will support an IND application and discussions with potential commercial partners for the next stage of clinical development of BIT225. Despite recent advances in the field, as confirmed by the DSMC, treatment gaps remain and there is a need for additional new classes of drugs such as BIT225."

Enquiries

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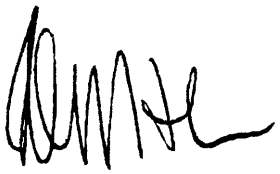
Yours sincerely



Peter J. Nightingale
Company Secretary

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