biota

Biota Holdings Limited
ACN 006 479 081
10/585 Blackburn Road
Notting Hill VIC 3168
Australia
T +61 3 9915 3700
F +61 3 9915 3702
E info@biota.com.au
W www.biota.com.au

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HRV phase IIa study achieves clinical proof-of-concept

Biota Holdings Limited (ASX:BTA) announced today that its Phase IIa challenge study of BTA798, an orally active inhibitor of human rhinovirus (HRV), was successful in demonstrating proof-of-concept in humans and was shown to reduce the incidence and severity of HRV infection.

Proof-of-concept studies are early clinical trials undertaken to establish preliminary evidence of efficacy in a small number of subjects. Rhinovirus infection is usually transient and mild in otherwise healthy individuals, but is frequently associated with potentially serious complications in people with asthma, cystic fibrosis, chronic obstructive pulmonary disease or those with a compromised immune function, such as transplant patients.

Dr Jane Ryan, Vice President of Product Development commented, "That efficacy was shown so convincingly in such a small cohort is surprising, but the most exciting aspect of the trial is that it brings us closer to realising our plans for an effective HRV treatment in high risk patients".

Study design and conduct

The clinical trial was a double-blind challenge study designed to evaluate BTA798 for the prevention of HRV infection in healthy male subjects who had no evidence of immunity to the HRV study virus.

Prior to being exposed to an experimental rhinovirus infection, volunteers were administered either placebo or one of three dose levels of BTA798. The study used the incidence of confirmed HRV infection and the incidence of upper respiratory illness in the four groups as the primary endpoints, with measures of viral count, symptom improvement, safety and pharmacokinetics as secondary endpoints.

The study was designed to enrol up to 4 groups of volunteers, each with approximately 60 subjects. Sufficient groups were to be recruited to confidently demonstrate proof-of-concept. Analysis of the first group of 41 subjects provided positive efficacy data and adequately confirmed proof-of concept.

The ultimate small study size was limited by the availability of volunteers without prior immunity to HRV and costs were reduced to approximately $4.0 million in F2009, significantly less than budgeted.

Efficacy

BTA798 was shown to reduce the incidence and severity of HRV infection when compared to placebo and these benefits were dose proportional.

Compared with subjects who received placebo, subjects who received the highest dose of BTA798 demonstrated a statistically significant:

- Lower peak viral level (0.605 vs 2.07 $\log_{10}$ $TCID_{50}$/mL, p=0.0311) equivalent to a 97% difference between the groups
- Lower total amount of virus (1.42 vs 6.50 $\log_{10}$ $TCID_{50}$ .days/mL, p=0.0170) which is equivalent to a greater than 99% difference between the groups.

Safety and pharmacokinetics

Generally, BTA798 was well tolerated. Adverse events were observed in both placebo and drug groups although due to the small sample size, no conclusive difference between the groups could be established. However, enhanced safety monitoring will be incorporated in the design of future studies.

Analysis of pharmacokinetic data from the planned subgroup of volunteers indicated that mean plasma levels of BTA798 increased predictably across the three doses, similar to the observations from the previous Phase I studies. Further pharmacokinetic analysis is ongoing.

Future Plans

Biota has informed the UK Medicines and Healthcare Products Regulatory Agency of its intention to conclude the study.

Future studies will now be developed to confirm efficacy and safety in target patient groups with naturally acquired HRV infection, where appropriate risk/benefits can be established. Clinical plans will be discussed in detail with regulatory agencies before the end of 2009.

Biota has confirmed its intention to license the global rights to the HRV program and is actively seeking commercial partners.

About Biota

Biota is a leading anti-infective drug development company based in Melbourne Australia, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, subsequently marketed by GlaxoSmithKline as Relenza. Biota research breakthroughs have included a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease, licensed to AstraZeneca and novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems. In addition, Biota has a key partnership with Daiichi Sankyo for the development of second generation influenza anti-virals.

Further information available at www.biota.com.au

Investor / Analyst Enquiries
Biota Holdings Limited
Peter Cook
T: +61 3 9915 3720
Damian Lismore
T: +61 3 9915 3721

Media Enquiries
Jo Lynch
Hinton & Associates
T: +61 3 9600 1979
M: +61 411 208 101