

Level 2, 66 Hunter Street Sydney NSW 2000 Tel: (61-2) 9300 3344

Fax: (61-2) 9221 6333

E-mail: pnightingale@biotron.com.au Website: www.biotron.com.au

26 June 2024

The Manager Companies ASX Limited 20 Bridge Street Sydney NSW 2000

(12 pages by email)

Dear Madam

INVESTORS PRESENTATION AS A WEBINAR

I attach a presentation being presented by Biotron Limited's Managing Director, Dr Michelle Miller, to investors as a Webinar.

This announcement has been approved by the Company's Managing Director.

Yours sincerely

Peter J. Nightingale Company Secretary

pjn12228

Enquiries

Dr Michelle Miller Managing Director Biotron Limited +61-(0)412313329 Rudi Michelson Monsoon Communications +61-3 9620 3333

BIOTRON LIMITED WEBINAR

ASX:BIT

26 June 2024





Forward Looking Statements

This presentation may contain forward-looking statements with respect to the financial condition, results and business achievements/performance of Biotron Limited (ACN 086 399) 144) and certain of the plans and objectives of its management. These statements are statements that are not historical facts. Words such as "should", "expects", "anticipates", "estimates", "believes" or similar expressions, as they relate to Biotron Limited, are intended to identify forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect Biotron's current expectations and assumptions as to future events and circumstances that may not prove accurate. There is no guarantee that the expected events, trends or results will actually occur. Any changes in such assumptions or expectations could cause actual results to differ materially from current expectations

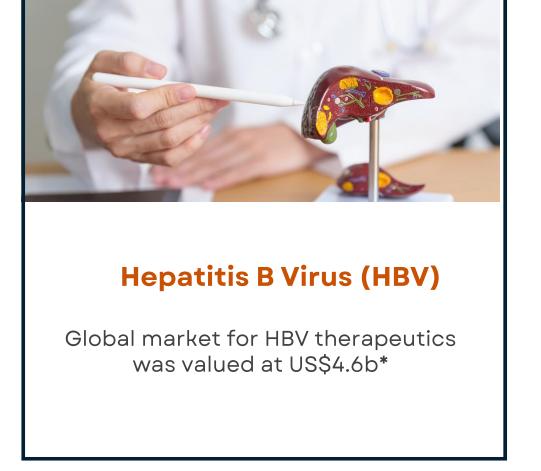


Industry-leading experts focused on transformative viral treatments

- Experienced Board & Management team with pharma, finance and VC backgrounds
- Clinical stage company with portfolio of small molecule drugs targeting viral diseases with major health problems and large international markets







BIT225-010 and -011 Phase 2 HIV Clinical Trials Met Primary End Points

01

Results from these two trials further our understanding of BIT225

02

Unique mechanism that combines immunomodulation combined with direct acting antiviral activity

 Current anti-viral drugs have direct acting antiviral activity i.e. stop viruses replicating, but do not on impact on the effect that viruses have on the immune system.

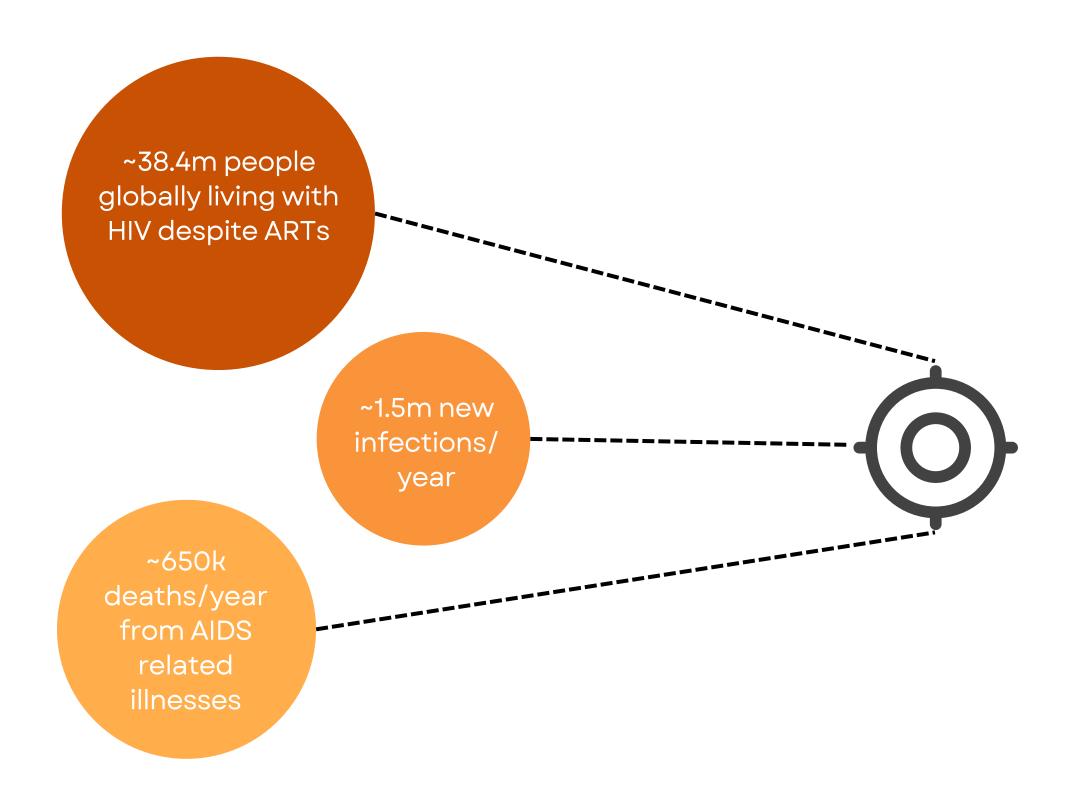
03

Implications go beyond the Company's HIV Program

 The results provide evidence that targeting viroporins, found in a wide range of viruses, has the potential to translate into clinically meaningful outcomes.



Why HIV-1?



The increased prevalence of HIV-1 infections, % of patients on treatment due to improved disease awareness and the need for treatments to improve quality of life are expected to drive market growth to over US\$50b by 2030

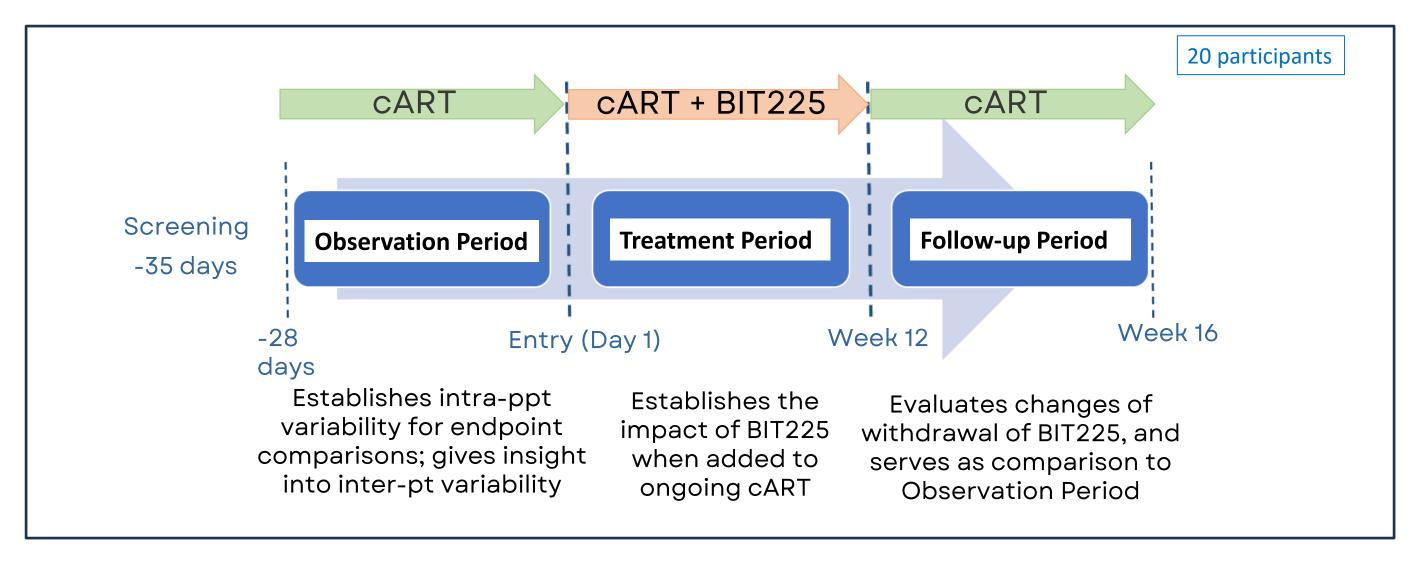
An estimated one third of the ART-treated HIV-infected population achieves only partial immune reconstitution

This population is at increased risk for serious comorbid conditions including neurocognitive, cardiovascular, renal and hepatic disorders that impair quality of life and drive healthcare expenditures.



BIT225-011: Phase 2 Trial in Treatment-Experienced Immune Non-Responders – TRIAL DESIGN

First time BIT225 has been trialed in this at-risk HIV population. Trial was run at sites in Sydney, Australia



Parameters measured throughout:

- Safety & tolerability
- Plasma viral loads
- Broad range of immune cell subtypes, cytokines, inflammation markers, cell activation and exhaustion markers to assess potential immunomodulatory effects of BIT225



BIT225-011: Phase 2 Trial in Treatment-Experienced Immune Non-Responders – OUTCOMES vs OBJECTIVES

PRIMARY OBJECTIVES

1. Safety and tolerability

- 2. Viral markers
- 3. Change of immune cells, immune markers, etc

OUTCOMES

Safe and generally well tolerated No deaths or drug-related SAEs AEs were similar to those seen in previous trials

All participants maintained viral suppression throughout study

Statistically significant changes were observed for several immune subpopulations/markers/cytokines during the Treatment period compared to the initial Observation period.

CONCLUSIONS

The changes seen when BIT225 is added indicate that the drug has induced statistically significant changes in specific immune cell populations, markers, and cytokines.

This HIV population is not well served with current cART; new mode of action drugs are needed to improve numbers and activity of immune cells and markers, leading to clinical benefits.



BIT225-010: Phase 2 Trial in Naïve, Acutely Infected HIV Population - OVERVIEW

BIT225 or placebo added to cART in HIV-positive individuals commencing cART treatment (n=27, randomised 2:1)

BIT225/cART or placebo/cART dosing continued for 24 weeks. At conclusion, everyone continued on cART

Parameters measured throughout:

- Safety and tolerability
- Viral loads
- Immune cells, markers, cytokines etc to assess potential immunomodulatory activity of BIT225

Trial was run at several sites in Thailand



BIT225-010: Phase 2 Trial in Naïve, Acutely Infected HIV Population - OUTCOMES vs OBJECTIVES

PRIMARY OBJECTIVES

1. Safety and tolerability

2. Impact on virus levels

3. Change of immune cells, immune markers, etc

OUTCOMES

Safe and generally well tolerated No deaths or drug-related SAEs AEs were similar to those seen in previous trials

BIT225/cART cohort had a faster decline in virus levels than those on placebo/cART.

Statistically significant differences were observed between the two cohorts for several immune cell subpopulations/ markers/ cytokines

CONCLUSIONS

The changes seen when BIT225 is added indicate that the drug has induced statistically significant changes in specific immune cell populations, markers, and cytokines.

The immune results are consistent with those seen in earlier trials and suggest a possible immune modifying effect of BIT225 when used with cART.

The blood (plasma) viral load data suggests that BIT225 is having an impact on a critical phase of viral decay when latent reservoirs are established.

SUMMARY

- Preliminary analyses indicate that both HIV trials achieved their primary objectives
- BIT225 uniquely combines direct-acting antiviral and immunomodulatory activities
- The challenge for HIV therapies is demonstrating clinical benefit over and above current cART
 - Regulatory agencies e.g. FDA have been focused to date on direct-acting antiviral drugs
 - Pathways for immunomodulatory agents for viruses have lagged
 - BIT225-010 and BIT225-011 are important steps in the path to development of viroporin inhibitors as a new drug class
- The results from BIT225 have important implications for Biotron's other antiviral programs targeting other viruses as they support the druggability of this new class of drugs
- Biotron's core expertise is in designing and developing this new class of drug (viroporin inhibitors)
- New classes of antiviral drugs are needed across a broad therapeutic field
- Current focus is now on sharing and discussing the latest data from Biotron's trials with pharma/industry



BIOTRON LIMITED (ASX:BIT)

Michelle Miller Managing Director

mmiller@biotron.com.au www.biotron.com.au +61 412313329

