

17 August 2026

The Manager Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000

Dear Madam,

HBV TREATMENT TO PROGRESS TOWARDS HUMAN TRIALS

- New studies performed at The Scripps Research Institute, San Diego, confirm and extend the antiviral activity of Biotron's lead candidate BIT-HBV001 against HBV and associated HDV infections.
- Combination studies demonstrated significant synergistic antiviral activity when BIT-HBV001 was used with Myrcludex-B, an approved treatment for chronic hepatitis delta infection in people co-infected with HBV and HDV.
- HBV/HDV co-infection is associated with the most severe form of viral hepatitis and remains an area of significant unmet medical need.
- Biotron plans to progress BIT-HBV001 through formal GLP preclinical studies and manufacture of GMP-grade drug product, with the aim of commencing first-in-human studies in the second half of 2027.

Biotron Limited (ASX: BIT; Biotron or the Company) is pleased to provide an update on its Hepatitis B Virus (HBV) program.

Biotron has previously advised that its lead HBV candidate, BIT-HBV001, has demonstrated strong antiviral activity against HBV in a range of cell-based assays, reducing key HBV replication markers HBV DNA, HBsAg, HBeAg, pregenomic RNA, as well cccDNA, a marker of the persistent viral reservoir that underpins chronic hepatitis infection.

In November 2025 Biotron reported that BIT-HBV001 demonstrated antiviral activity in two different animal models of hepatitis liver disease and infection.

In March 2026 the Company reported that BIT-HBV001 is also active against Hepatitis Delta Virus (HDV). HDV is a satellite virus of HBV that infects people with an existing HBV infection. Co-infection with HBV and HDV is associated with the most severe form of viral

hepatitis, often leading to rapid progression to cirrhosis, liver failure or hepatocellular carcinoma.

Now, new cell-based studies performed at The Scripps Research Institute, San Diego, provide additional key data on BIT-HBV001 against HBV and HDV.

In the first study, the activity of BIT-HBV001 was directly compared with that of Myrcludex-B (Myr-B), a recently approved drug, marketed as Hepcludex, for the treatment of chronic hepatitis delta infection in people co-infected with HBV and HDV.

Cells infected with HBV and HDV were treated with either BIT-HBV001 or Myr-B at a range of concentrations. After incubation for several days, the levels of virus-specific markers were measured to determine how well the drugs had worked against the viruses. Both drugs showed strong antiviral activity against both viruses.

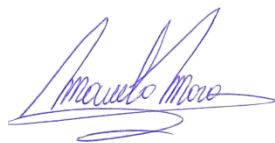
The reduction of key viral markers were: HBsAg 98.1% vs 93.8%, HBV-DNA 99.7% vs 93.0%, HDAg 81.0% vs 94.8 percent respectively for BIT-HBV001 vs Myr-B.

In a second study, BIT-HBV001 and Myr-B were tested in combination with each other in cells infected with HBV and HDV. This study was performed to determine if the two drugs are synergistic with each other i.e. if the drugs would work better in combination than each on their own. Synergism scores were calculated in R-statistical software using four different statistical models. The scores indicated significant antiviral synergy for the BIT-HBV001 and Myr-B combination across three HBV and HDV replication endpoints. This indicates that lower amounts of each drug may be used in combination to achieve the same level of HBV/HDV inhibition.

Biotron's Managing Director Dr Michelle Miller said, *"The ongoing positive results from Biotron's Hepatitis B program support the progression of BIT-HBV001 to human clinical trials. Over two billion people worldwide have been infected with HBV, and the World Health Organization estimates that more than 250 million people are chronically infected. A functional cure for chronic HBV infection remains one of the most important unmet needs in antiviral medicine. These latest results underline the broad potential of BIT-HBV001, including in treatment of high-risk HBV/HDV coinfections."*

In coming months, the Company plans to progress BIT-HBV001 through formal GLP preclinical studies and manufacture of GMP-grade drug product, with the aim of commencing first-in-human studies in the second half of 2027.

Yours sincerely



Marcelo Mora
Company Secretary

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This announcement has been approved by the Company's Board of Directors.

Enquiries

Dr Michelle Miller

Managing Director

Biotron Limited

+61-2-9300 3344

mmiller@biotron.com.au

Rudi Michelson

Monsoon Communications

+61-3 9620 3333