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24 JUNE 2026

## **FDA allows AFT's injectable iron project clinical study to proceed**

AFT Pharmaceuticals (NZX: AFT; ASX: AFP) Managing Director Dr Hartley Atkinson is presenting to the 2026 Bio International Convention in San Diego, California, this morning<sup>1</sup>.

The presentation, attached, details the US Food and Drug Administration (FDA) has reviewed AFT's Investigational New Drug (IND) application for its injectable iron research and development project, allowing the company to proceed with its Phase III clinical trial.

AFT and its development partner Hyloris Pharmaceuticals, will now undertake a large global confirmatory study involving 1,366 patients across multiple geographies (planned for New Zealand, China, India, Japan, Armenia, Europe and US).

The project targets an addressable market estimated at US\$7.41 billion<sup>2</sup>.

*Released for, and on behalf of, AFT Pharmaceuticals Limited by Stuart Houlston, Chief Financial Officer.*

### **For more information:**

#### **Investors**

Dr Hartley Atkinson  
Managing Director  
AFT Pharmaceuticals  
Tel: +64 9488 0232

#### **Media**

Richard Inder  
The Project  
Tel: +64 21 645 643

### **About AFT Pharmaceuticals**

AFT is a growing New Zealand based multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over the counter (OTC), prescription and hospital. Our product portfolio comprises both proprietary and in-licensed products, and includes patented, branded, and generic drugs<sup>3</sup>. Our business model is to develop and in-license products for in our markets of Australia, New Zealand, Singapore, Malaysia, Hong Kong, USA, Canada, EU ex Ireland and UK, and to out-license our products to local licensees and distributors to over 125 countries around the world. For more information about the company, visit our website [www.aftpharm.com](http://www.aftpharm.com).

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<sup>1</sup> Tuesday 23 June 2026 3.00pm PDT

<sup>2</sup> <https://www.biospace.com/intravenous-iron-drugs-market-size-to-worth-around-us-7-41-billion-by-2033>