



## **Altan Pharma Submits New Drug Application for Acetaminophen Solution for Infusion for Treatment of Pain and Reduction of Fever**

- *NDA filed and Accepted for Review by US FDA*
- *Opportunity to enter \$300m+ US market for intravenous formulations of paracetamol*

**Dublin, February 7, 2019**, Altan Pharma Limited (“Altan”), an Irish specialty pharmaceutical company, today announces that it has submitted a New Drug Application (NDA) for its formulation of acetaminophen solution for infusion to the United States Food and Drug Administration (FDA) and that it has been accepted for review. The NDA was submitted pursuant to section 505(b)(2) of the Food, Drug and Cosmetic Act.

Acetaminophen Solution for Infusion is an analgesic used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population and for the reduction of fever in adult and pediatric patients.

Traditional intravenous formulations of acetaminophen are extremely sensitive to oxygen, requiring them to be deoxygenated in the manufacturing process and to be packaged in glass vials to maintain stability throughout their approved shelf life. Altan has developed a unique, ready-to-use formulation that does not require deoxygenation and that can be packaged in flexible plastic containers, which are preferred by hospitals.

Altan announced last April that the United States Patent and Trademark Office (“USPTO”) had awarded the Company two patents covering its unique formulation of intravenous acetaminophen. These patents will provide protection for Altan’s intravenous formulation of acetaminophen until July 18, 2026. In addition to the US patents, Altan holds patents on its formulation of intravenous acetaminophen in Canada, Japan, Australia, South Africa, France, Germany, Spain, Italy, and the UK as well as most other European countries. Altan has manufactured and sold more than 200 million units of its intravenous acetaminophen formulation in the above non-US markets.

According to IMS, the US market for intravenous acetaminophen is around 10 million units, or \$300 million annually. The US market is currently dominated by one supplier that holds a patent on the process for deoxygenating intravenous formulations. By contrast, Altan’s process for producing Acetaminophen for infusion does not require deoxygenation and therefore offers the potential for an alternative solution in the US market.

**Guillermo Herrera, CEO of Altan said:** “We are delighted that the FDA has accepted our registration package for review. If marketed, our product has the potential to offer a superior, more economically favorable solution for hospitals, patients and payors”.



### **About Altan Pharma Ltd.**

Altan Pharma Ltd. is a privately held, specialty pharmaceutical company that develops, manufactures and commercializes injectable drugs for the hospital and other provider segments. Altan has a broad geographic footprint covering many European, Latin American and Asian markets. The company is highly focused on building its pipeline of injectable drugs and expanding its commercial presence to new markets, including the United States, through both organic and inorganic means. Altan's Lead Investors are Malin Corporation plc (Euronext Dublin: MLC) and Lake Forest Pharma Investments, LLC.

### **Forward Looking Statements**

This press release contains "forward-looking statements" subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict, including the difficulty of predicting FDA approvals, acceptance and demand for pharmaceutical products, the impact of competitive products and pricing, new product development and launch, the regulatory environment, etc. This press release is made only as of the date hereof, and unless otherwise required by applicable securities laws, Altan disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information visit [www.altanpharma.com](http://www.altanpharma.com)

### **Altan Media Relations Contact**

Mark Gorman

Tel: + 353 1 908 1280

Email: [info@altanpharma.com](mailto:info@altanpharma.com)

### **Altan Pharma Ltd.**

2 Harbour Square, Crofton Road

Dun Laoghaire, Co Dublin

Ireland

T: +353 1 908 1280

E: [info@altanpharma.com](mailto:info@altanpharma.com)

[www.altanpharma.com](http://www.altanpharma.com)