ASX Announcement

AD-214 safe in non-human primates, bulk manufacturing complete

Highlights:

- **AdAlta completes non-human primate study enabling phase I clinical study of AD-214**
- **Study showed AD-214 was safe, well-tolerated with no study mortalities or adverse events**
- **Manufacture of bulk AD-214 for phase I now complete**
- **AD-214 phase I study expected to commence 1Q 2020**

MELBOURNE Australia, 29 October, 2019: AdAlta Limited (ASX: 1AD), the biotechnology company advancing its lead i-body candidate towards clinical development, is pleased to announce the completion of its non-human primate study program necessary to enable the phase I human clinical study of AD-214.

AdAlta has now completed three non-human primate studies of AD-214, evaluating various aspects of safety and pharmacology. Study 1 saw a single dose of AD-214 administered. The other two studies saw three different doses, 10mg/kg, 30mg/kg and 100mg/kg administered multiple times over a four-week period. The studies evaluated a comprehensive range of safety, toxicology and pharmacology measures. The most recent toxicology study, reported here, was completed under Good Laboratory Practice (GLP) conditions, a standard required for regulatory submissions to the Therapeutic Goods Administration in Australia or the US Food and Drug Administration in the US.

Top-line audited safety results of the most recent toxicology study show that AD-214 was well tolerated and did not result in any signs of overt toxicity when administered intravenously up to a dose level of 100mg/kg. There were no deaths and no AD-214 related adverse events, nor any changes in body weight, respiratory, neurology, cardiovascular and ophthalmology tests that were performed as part of the safety assessment. Transient increases in white blood cell counts returned to baseline and/or control values by 24 hours after infusion of AD-214. Slight decreases in blood protein and albumin levels observed in some animals at the highest AD-214 doses were completely reversible. These results are

consistent with those seen in the previous non-human primate studies of AD-214.

AdAlta's contract manufacturing organisation has also completed the manufacturing of bulk AD-214 for the phase I human study under Good Manufacturing Practice (GMP) conditions. AdAlta is now making final preparations for the phase I clinical study that is expected to commence in first quarter 2020.

Managing Director & CEO, Tim Oldham, commented "We are pleased to reach both the toxicology and GMP drug substance manufacturing milestones on schedule and with expected results, enabling us to progress AD-214 into safety studies in humans as an important next step in bringing a much-needed new therapeutic option to fibrosis patients and in demonstrating the safety of the i-body as a platform. We also look forward to additional pharmacokinetic and pharmacodynamic information from this study in the near future."

Notes to Editors
About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors and ion channels that are implicated in many serious diseases.

AdAlta is currently preparing for its phase 1 clinical studies for its lead i-body candidate, AD214. The clinical program is expected to commence in early 2020 following completion of the current toxicity study, clinical trial design finalisation and manufacture of clinical product. AD214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need. The Company is also in collaborative partnerships to advance the development of its i-body platform. It has recently announced an agreement with UK-based research organisation, Excellerate Bioscience to collaborate on an undisclosed

target of commercial interest and an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta plans to continue further drug discovery and development directed towards other drug targets and diseases.

Further information can be found at: www.adalta.com.au.

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