CSL Commits to New Phase I Clinical Trials in Australia

Melbourne Australia: CSL has today announced that it has progressed three new therapies into first-in-human studies in Australia. In keeping with the Company's objective to expand its research and development pipeline and pursue a diverse portfolio, all three products are new generation, high-tech medicines based on targeted monoclonal antibody technologies.

"Translating basic medical research to a therapy ready for the marketplace can be a real challenge for our scientific community. To move one product from the early concept stage into a Phase I clinical trial is an important milestone. We are very pleased to move three projects into clinical trials over a 12 month period, all of which will be conducted in Australia. This decision speaks to the dedication of our scientists and the commitment CSL has to bringing new products to patients with unmet medical needs," said CSL Chief Scientific Officer, Dr Andrew Cuthbertson.

CSL's decision to undertake Phase I, first-in-human clinical trials in Australia is supported by a local network of world-class clinical researchers who have the skills to collaborate on early-stage trials. In addition, Australia has a regulatory environment that is supportive of early stage clinical development programs, and accessible Phase I clinical trial infrastructure.

Three New Monoclonal Antibodies

All three therapies are monoclonal antibodies with novel mechanisms of action. Each addresses important areas of unmet medical need and has the potential for multiple indications. The Phase I clinical trials will focus on proof of biological concept with a view to unlocking the full potential of these research assets.

- CSL324 is an anti-GCSFR monoclonal antibody, which could be used to treat rare inflammatory diseases caused by overactive neutrophil (white blood cell) activity. CSL324 works by regulating white blood cell activity in autoimmune disease to prevent over-active neutrophils from destroying healthy tissue. The therapy may present a new treatment option for inflammatory diseases involving, for example, skin, joints and lungs. Inflammatory diseases can be debilitating and have serious quality-of-life consequences for the individuals affected. The trial will explore proof of biological concept with particular focus on identifying effective therapeutic dosing.
- CSL312 is an anti-factor XIIa monoclonal antibody that is being studied for multiple indications, including Hereditary Angioedema (HAE) – a disorder that causes episodic, sometimes life-threatening attacks of swelling that can affect the face, extremities, gastrointestinal tract and upper airways. For these patients, CSL312 could reduce the frequency of dosing, with the possibility of subcutaneous administration once every two to three weeks instead of bi-weekly dosing.

Other potential applications being investigated are the prevention of thrombosis – the process of blood clot formation - particularly on artificial surfaces such as cardiac implants.

- CSL346 is an anti-VEGF-B monoclonal antibody that could be used to control glucose absorption in insulin-resistant patients with Type 2 diabetes, by targeting fatty acid metabolism. Type 2 diabetes is one of the fastest growing chronic diseases, affecting more than 420 million[1] people globally. CSL346 may also be beneficial for diabetic nephropathy; one of the most common kidney complications associated with Type 2 diabetes.

The three therapies will be showcased today at CSL's R&D investor briefing in Sydney, and form part of a strong pipeline of prospective therapies in various stages of development.

"CSL has worked hard to build appropriate R&D skills and capacity to support what has now become a A$45.1 billion global biotech company. In FY2016-17, CSL will spend more than US$600 million (~A$800 million) on research and development, backed by an R&D workforce of approximately 1400 people worldwide.

"We anticipate that our investment in translational research – taking drug targets from benchtop to bedside – will contribute to Australia's capacity to develop early research into commercial medicines for global markets," said Dr Cuthbertson.

CSL has a significant R&D presence in Australia, led from the company's global hub for Early Research and Translational Medicine based at the University of Melbourne's Bio21 Institute. Earlier this year, CSL confirmed plans to double its tenancy at Bio21 over the next three years to around 150 researchers. In addition, over the past few years the Company has expanded its onshore early-development capabilities in order to both produce clinical trial materials and provide the regulatory and quality resources to support clinical trial development in Australia.

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Note: *CSL's R&D presentation for investors will be webcast from 9.00am–12pm Thursday 1 December. Media can listen to the presentation live via the following link: www.csl.com.au/investors/briefings-presentations/operational-briefing.htm*

About CSL: CSL (ASX:CSL) is a leading global biotherapeutics company with a dynamic portfolio of life-saving innovations, including those that treat haemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL — including our two businesses CSL Behring and Seqirus — operates in over 30 countries with more than 15,000 employees. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest.

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[1] *WHO Global Report on Diabetes, 2016*: http://bit.ly/1REa7Gv