

## **CSL signs agreement with Janssen to progress novel cancer therapy**

**Sydney, Australia** - CSL Limited has today announced an agreement with Janssen Biotech, Inc. that may one day lead to new treatments for haematological cancers and autoimmune diseases.

The agreement grants Janssen an exclusive worldwide license to develop and commercialise CSL362, a novel monoclonal antibody therapy. Currently, CSL362 is being studied in a Phase 1 clinical trial in acute myeloid leukaemia (AML) patients who achieved remission after treatment with chemotherapy and who are at high risk for relapse. AML is a fast growing cancer of the blood and bone marrow and is considered a significant unmet medical need with no new advances in the last few decades.

Laboratory studies have shown that CSL362 specifically targets AML cells and recruits and activates killer cells from the body's innate immune system to attack the cancer cells. It is hoped that these natural killer or NK cells will eliminate residual AML cells, preventing relapse of the disease. The target to which CSL362 binds on AML cells (CD123) is also expressed on other haematological cancers and on rare blood cell populations thought to mediate autoimmune diseases such as lupus.

The agreement with Janssen was announced by CSL's Chief Scientific Officer, Dr Andrew Cuthbertson, at the Company's annual R&D briefing for investors.

"CSL362 is at a very exciting stage of development and required a partner with a proven capability in oncology and autoimmunity to maximise its potential. We are delighted to have attracted such a high quality partner in Janssen who share a deep commitment to developing this promising therapy for the benefit of very ill patients," said Dr Cuthbertson.

CSL362 was engineered by CSL scientists using, as a starting point, a unique antibody developed by Professor Angel Lopez at Adelaide's Centre for Cancer Biology in the late 1990's. The original antibody was able to recognise AML cells preferentially, but was not suitable for use in humans and it lacked the ability to recruit and activate the body's NK cells. CSL scientists engineered the antibody to ensure that it is suitable for use in humans and to enhance its ability to recruit NK cells to kill the AML cells.

"The development of CSL362 to date is another fine example of the power of collaboration and speaks to the outstanding quality of science in Australia's medical research institutions. With the addition of Janssen we have the modern model of drug development which uses the distinctive strengths of all parties to bring new therapies to patients sooner," said Dr Cuthbertson.

The clinical trial for CSL362 is being conducted in Australia and the USA. The Australian study is being led by Professor Andrew Roberts, who is a clinical haematologist at the Royal Melbourne Hospital, Head of Clinical Translation at the Walter and Eliza Hall Institute and Metcalf Chair of Leukaemia Research at the University of Melbourne.

“Acute myeloid leukaemia is a very aggressive type of cancer and has very poor survival rates. Although we can induce remission with chemotherapies there is a high likelihood of relapse, at which point the outcome is often very poor,” said Professor Roberts.

“CSL’s investigational antibody therapy offers a novel treatment approach because it is designed to recruit the body’s immune system to help keep the leukaemia in remission. We are hopeful that what has been seen in the laboratory to date can be replicated in the clinic. If it is, then we will have taken the first key step towards improving survival rates for those with AML” added Professor Roberts.

Under the terms of the agreement with Janssen, CSL will receive a license fee and be entitled to development, regulatory and sales based milestone payments, as well as royalties on sales. CSL will be responsible for the completion of the Phase 1 clinical trial in AML and Janssen will be responsible for all further development and commercialisation in AML and other indications. The parties will continue to work collaboratively on research programs primarily to support the use of CSL362 in other indications.

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### **12.30pm AEDT Media/Wires Conference Call**

Dr Andrew Cuthbertson and CSL’s Senior Vice-President of Research, Dr Andrew Nash, will be available to the media to comment on this announcement.

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### **About CSL**

Headquartered in Melbourne, Australia, CSL Limited is a global biopharmaceutical company that develops, manufactures and markets biotherapies to prevent and treat rare and serious human diseases. CSL owns major facilities in Australia, Germany, Switzerland and the United States, and employs over 11,000 people in more than 25 countries. Visit [www.csl.com.au](http://www.csl.com.au) for more information.