



Company Announcement

Avexa to partner with Link Healthcare for the development and commercialisation of apricitabine

Melbourne, Australia, June 20th 2013: Australian biotechnology company Avexa Limited [ASX:AVX] today announced that it has signed a binding term sheet with Link Healthcare Pte Ltd (LINK) for the development and commercialization of Avexa's lead HIV drug apricitabine (ATC). "Avexa is delighted to expand our collaboration with Link" said Mr Iain Kirkwood, Chairman of Avexa, "We look forward to bringing ATC to market". A previous independent review commissioned by Avexa in late 2010 advised that peak sales of ATC in the USA alone could range from US\$94-271M/year. Avexa also announced today that, in parallel with completing the final clinical development, the company has initiated the requisite steps to commence the manufacture of ATC for both the remaining clinical development and for potential early clinical requests for treatment doses. Initially, Avexa will access its existing inventory of drug which is currently being stored in France.

Avexa – LINK partnership

The collaboration covers the development, registration, and commercialization of ATC worldwide, including the major markets of North America and Europe but excluding certain territories for which regional partners were previously announced by Avexa (ASX release 10th December 2012).

"Link has a proven track record of marketing specialist products in niche disease areas and growing substantial sales for these products in markets around the world" said Mr Iain Kirkwood. Link is particularly strong through their South African, Australian, Asian and Japanese subsidiaries. "The opportunity for ATC, for example, in Sub-Saharan Africa is considerable, given the numbers of people with HIV and the failure of first line therapies in this region" said Mr Kirkwood. "Link brings a number of highly complementary skills to the table, especially the ability to provide early access for patients and Avexa is excited to work more closely with Link to move ATC forward".

Executive Chairman of Link, Mr. John Bacon confirmed that the company is delighted to be expanding its relationship with Avexa. "We believe that ATC has a potentially important role in the treatment of a well identified subset of HIV patients. The combination of our core focus on specialist medicines and an existing competence in supply of antiretrovirals in Southern Africa puts us in a good position to work with Avexa to see ATC through the final stages to commercialisation" said Mr. John Bacon.

ATC (apricitabine)

ATC is very well suited to meet the needs of patients who have failed other treatments. In a Phase 2b study, ATC showed a highly significant reduction in viral replication in patients who had failed other treatments, including lamivudine (3TC), which is extensively used in first line therapy in South Africa and elsewhere. After 14 days treatment, patients treated with 800mg ATC showed a mean reduction in viral load of $0.8\log_{10}$ compared to a reduction of $0.15\log_{10}$ in the control arm ($p=0.005$). 58.8% of patients treated with 800mg ATC achieved a reduction of at least $0.5\log_{10}$ compared to none of patients in the control arm ($p=0.007$). Patients continued on ATC (in combination with other HIV medications as clinically required) for up to 144 weeks, at which point the mean reduction in viral load was greater than $2.5\log_{10}$; in fact more than 90% of patients had undetectable levels of virus. No patients developed resistance to ATC. The safety and tolerability of ATC

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were excellent: more than 90% of patients did not experience any adverse event thought to be owing to ATC during 144 weeks treatment. Adherence to therapy was also extremely high, with 95% of patients continuing to consistently take all their ATC doses. "This alone attests to the potential for ATC" said Dr Jonathan Coates, Chief Scientific Officer and interim CEO. "One of the major difficulties in HIV therapy is that patients stop taking some or all of their drugs, usually because of side effects, and this may lead to the development of resistance. The safety and durability of ATC indicates that this drug could make a major, long term impact in the daily life of people with HIV".

In discussions with both the FDA and EMA, Avexa has reached agreement on the design of a final confirmatory study for approval of ATC. The primary endpoint of the new study is the number of patients achieving a 0.5log₁₀ reduction in viral load at day 14. "In the previous clinical study ATC has already met and indeed exceeded this endpoint," said Dr Coates. "We are therefore very confident that this study will produce the required data for approval".

Funding for the clinical trial will be underpinned by revenues from Avexa's investment in the North Pratt coal mine, as previously announced (14th November 2012). "Avexa's board and management continue to craft innovative strategies that will move ATC towards regulatory approval and marketing" said Mr Kirkwood. "As we have emphasised previously, the coal investment is simply a means to an end. Revenues from coal will move us closer towards our end game, which remains the marketing and sale of ATC." Mr Kirkwood said.

About Avexa Limited

Avexa Limited is a Melbourne-based biotechnology company with a focus on discovery, development and commercialization of small molecules for the treatment of infectious diseases. Avexa's key projects include apricitabine (ATC) for the treatment of drug resistant HIV, an HIV integrase program and an antibiotic program for antibiotic-resistant bacterial infections.

About Link Healthcare

Link Healthcare is a privately owned specialist Pharmaceutical and Medical Technology business. Link's mission is to strive for excellence in the marketing of a vitally important and unique range of specialist therapeutic products. Link provides exceptional sales and marketing infrastructure and is partnered with blue chip pharmaceutical companies from around the world. This allows the group to offer a unique and substantial portfolio of 'medicine that matters.'

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