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Company announcement

Avexa Company update

Melbourne, Australia, Thursday 21st February 2013: Australian biotechnology company Avexa Limited [ASX:AVX] today provided an update on its operations.

For the six months to December 2012, Avexa's main focus has been on continuing to establish a solid foundation to facilitate completing the development of ATC and its subsequent launch and marketing. Having established the regulatory landscape with both the FDA and EMA, the focus has been on the commercial aspects of securing the necessary funding to complete the agreed development and the necessary commercial partners to market the finished product once approved. At the Annual General Meeting in December 2012, plans were outlined to invest in the North Pratt coal mine in Alabama which, for a US$4M investment and a US$6M interest bearing loan, is projected to generate substantial returns which would significantly contribute to funding the final development of ATC. Avexa's Board looked carefully at a number of avenues to fund ATC's development over many months. In the current harsh economic climate, this opportunity stood out for its potential to underpin the funding of ATC's development and progression of Avexa's other R&D assets.

The resolution to pursue this investment was passed at the AGM on the 14th December. Avexa has substantially completed its due diligence of the North Pratt coal mine investment opportunity and, as a result, expects to commence investing in the second quarter of calendar year 2013, subject to, amongst other things, the issuance of the requisite mining permits.

The following update details the status and progress of:

- Investments
- ATC commercialization
- HIV integrase inhibitor programme
- Antibacterial programme

Financial summary

Avexa recorded a net loss of $1.9 million for the half year ended 31 December 2012 and there were no equity movements in the Company for the period. At 31 December 2012 the Company had a net asset position of $15.1 million, including cash of $11.9 million and listed investments of $3.0 million.

With regard to Avexa's investment in Allied Healthcare (AHZ), Avexa sold its remaining holding of 81,689,680 shares on the 8th of February 2013. The initial opportunity to invest in AHZ in 2010 was identified whilst Avexa was reviewing its business and investment strategy. The objective of the initial investment was to assist AHZ to secure a larger share of the Coridon vaccine research and development business and also to help AHZ secure a listing on the ASX. In the period since, Avexa has refined its business strategy with regard to its intellectual property assets (ATC, HIV integrase inhibitors and the antibiotic project) and has altered its investment strategy. Accordingly, in agreement with AHZ's Board and management we have undertaken an orderly exit from this investment. While the initial investment was of assistance to the growth of AHZ, it has also yielded a significant return. This will be used to promote Avexa's R&D programmes, for the benefit of Avexa's shareholders.

ATC commercialization

To date, a number of different companies have concluded the confidential due diligence process and have signed option agreements to market ATC in a number of jurisdictions. This includes agreements with: DEM Ilac (www.demilac.com.tr) a specialist pharmaceutical company servicing the Turkish and surrounding regions, Dongwha Pharmaceuticals (www.dong-wha.co.kr) one of the major Korean pharmaceutical companies servicing Korea and other international regions, LinkHealthcare

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(www.linkhealthcare.com.au), servicing the markets of Australia, New Zealand and South Africa, Sanfer (www.sanfer.com.mx), a specialist pharmaceutical company servicing the Latin American region, and Shiner (www.shinerpharm.com), based in Taiwan and focused on hospital specialty products.

The option agreements include a commitment from the partner to market ATC in specified jurisdictions, once Avexa has completed the remaining development and obtained regulatory approval. This process is continuing and we expect to secure additional partners covering different market regions, in particular the key markets of North America and Europe. This will ensure that, once ATC development is complete, marketing partners are already in place to expedite the launch and sale of the product.

Avexa continues to interact with both scientific and medical experts and with Community Groups representing patients' needs. As a result, a very positive article on ATC was published in a well-known HIV information website ("Minutes to Midnight", HIV Haven: *http://www.hivhaven.com/2012-04-13-23-40-58/noteworthy/4336-minutes-to-midnight-why-the-quad-is-no-win-for-the-drug-resistant-and-treatment-experienced*). The article describes the lack of new drugs (especially NRTIs) in development, and describes ATC as "the most promising and advanced NRTI candidate" and calls for federal assistance to complete its development. The article has been shared and Tweeted a number of times, and is ranked 6th from more than 10 000 posts on the website that month. We continue to work to raise the profile of ATC and gather further support.

HIV integrase inhibitor programme

The HIV integrase project continues to move forward towards a new once daily integrase inhibitor for drug-resistant HIV patients. Although at a much earlier stage than the ATC project, steady progress is being achieved in this exciting area. HIV integrase inhibitors are the newest emerging class of HIV medicines. Global sales of Merck's raltegravir were US$1.5 billion in 2012, an 11 percent increase compared to 2011. It is worth noting that raltegravir is a twice daily standalone drug. Despite many years of intense effort, its developers (Merck) have not succeeded in developing a once daily version or alternative. Raltegravir also undergoes significant glucuronidation, which varies not only from person to person but even within the same person, leading to a wide variation in drug levels. Inconsistent drug levels may increase the risk of drug-resistance if too low, or side effects if too high.

Gilead's HIV integrase inhibitor elvitegravir can only be dosed once daily if it is accompanied by an additional drug (cobicistat) which blocks the metabolism of elvitegravir through a common pathway. However, drugs such as cobicistat (called pharmacological boosters) are not specific and block the metabolism of any substance which is metabolized through that common pathway, such as other HIV drugs. Elvitegravir is only available in a combination pill with other drugs, and therefore cannot be used if patients are resistant to, or intolerant of, any of the components. After a long search, GSK discovered an integrase inhibitor which may be dosed once daily in naïve patients, but in patients who have resistance mutations (usually after prior treatment with one of the other integrase inhibitors) it must be given twice daily.

Avexa's integrase project is wholly owned by Avexa, well protected by a long and solid IP position, and unrestricted both commercially and scientifically.

Antibacterial programme

Avexa's antibacterial project has made good progress, with an exciting potential opportunity in the area of Clostridium infections. Clostridium infections are increasing owing to the increasing use of broad spectrum antibiotics, and are becoming a significant problem, especially in hospitals. The average cost of a hospital stay owing to Clostridium infection has been estimated at US$25,000. Avexa's lead molecule shows good activity against clinical isolates of Clostridium difficile, and our partner Valevia is pursuing this possible new indication.

Further details on Avexa's portfolio

Apricitabine (ATC)

Avexa's nucleoside reverse transcriptase inhibitor (NRTI), apricitabine (ATC) is a novel drug for the treatment of human immunodeficiency virus (HIV) infection, the virus which causes Acquired

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Immunodeficiency Syndrome (AIDS). HIV targets primarily cells of the immune system, leaving infected individuals progressively less able to fend off otherwise common diseases. In the three decades since the identification of the first case of AIDS, over 30 million people have been infected with the virus worldwide, and many millions have died.

The course of the disease can be dramatically slowed down by treatment with a combination of antiviral drugs which inhibit the replication of the virus. However, resistance to these drugs often develops and in many cases, resistance to one drug causes cross-resistance to other, as yet unused, drugs of the same class. The result of this is becoming more and more evident in patients who have been treated for a long time, often called “experienced patients”. These experienced patients may have very few, or even no, active drugs available to them in practice. A significant yet often understated problem is the unwanted and sometimes unpleasant side effects of many of the currently used anti-HIV drugs, which can be impossible to take for some patients or even life threatening in others. This places a considerable restriction on the drugs any individual HIV-infected patient can take. Lastly, many current drugs have significant unwanted interactions if they are given at the same time as other drugs the patient may need, such as drugs for diabetes, heart disease, hypertension, or bacterial infections. In essence, while HIV is an infection easily controlled by current drugs in newly infected patients and those with limited drug experience, there are many individual long term patients that in practice have very few appropriate drugs available.

The safety profile, activity and lack of drug-drug interactions demonstrated by ATC both in the lab and more importantly in the clinic shows that ATC has significant potential to be a valuable new treatment for HIV as it addresses those pivotal issues which are unmet for many experienced HIV-infected patients. As well as showing antiviral activity against natural (wild-type) HIV, ATC is active against HIV which has various genetic changes (mutations) that cause the virus to be resistant to other NRTIs. Such mutations include the M184V change (associated with resistance to the currently used NRTIs lamivudine and emtricitabine) and thymidine analogue mutations (TAMs, associated with resistance to zidovudine and stavudine). These mutations are common in patients who have taken first line therapies, as the use of these existing NRTIs is widespread. Thus in patients whose current treatments are no longer effective due to the development of drug resistance, ATC has the potential to be a valuable treatment option.. In addition, even in patients who have been treated with ATC for three years, resistance to ATC itself has not been identified suggesting that the useful lifespan of ATC may be subsequently longer. Clinical trials of ATC have shown it to be a safe and very well tolerated antiviral agent. ATC is easy to dose and is not affected by when the patient has taken a meal. Importantly for patients who also have other ailments, which is more common than not, ATC does not produce deleterious interactions when dosed with a variety of different drugs known to produce interactions with other current HIV medications. These key properties of ATC, lack of resistance, safety, and ease of dosing, are exactly those which are required in patients who have developed resistance to the currently used drugs.

An extensive search for co-marketing partner(s) to market and sell ATC on a global or regional basis is being pursued. Avexa has sought to find potential partners from the specialist product sales groups around the world who can sell and market ATC to the relatively small number of HIV specialists who control and direct the prescription of anti-HIV drugs. This is a detailed process, involving confidential due diligence from both Avexa and the potential partner, to assess the opportunity presented by ATC in different markets and the ability of the partner to realise that opportunity. Option agreements to market ATC have been concluded in a number of marketing regions, and discussions are ongoing in several other regions. These agreements are important as they not only establish the commercial viability of ATC across different market regions, but also ensure that, together with our partners, preparations can be made towards launching ATC once the final development has been concluded.

HIV Integrase

In order to replicate, HIV must undergo a series of essential processes that utilise a number of key enzymes. As these processes and enzymes are essential they are therefore good targets for the discovery of effective antiviral drugs. One of the most recent key targets to yield an effective medicine is the HIV integrase enzyme. This enzyme is responsible for taking the viral genome of HIV and splicing it into the host cell DNA, which is a required step in HIV replication. Raltegravir (Merck) was the first inhibitor of HIV integrase to be approved in 2009. Raltegravir is effective in reducing the viral load in HIV-infected patients. However, mutations in the viral integrase emerge that confer resistance to raltegravir. Also, raltegravir is dosed twice daily, and drug levels vary considerably between patients and even within the

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same patient from day to day. Raltegravir is also at risk of interaction with certain other drugs that are metabolised in the same way, which may cause jaundice. Despite these limitations, global sales of raltegravir in 2012 exceeded US$1 billion. A second integrase inhibitor (elvitegravir; Gilead) has recently been approved, but is cross-resistant with raltegravir, and requires pharmacokinetic boosting to obtain sufficient drug levels. Dolutegravir (ViiV Healthcare) is new integrase inhibitor with an activity profile different from raltegravir that is in clinical trials, which has activity against raltegravir-resistant virus, but must also be dosed twice daily in resistant patients.

The primary goal of Avexa's integrase project is to discover compounds that a) maintain activity against virus that is resistant to raltegravir and other integrase inhibitors and b) have improved pharmacokinetic properties compared to the currently marketed integrase inhibitors.

Avexa's first generation compounds had improved metabolic stability but were only active against the wild type virus. Second generation compounds were then discovered which possessed potent activity against both wild type and resistant HIV integrase but were very rapidly cleared when dosed in rats. Recently, however, two classes of compounds were discovered which showed surprisingly good levels of drug after both oral and intravenous dosing in rats, out to 24h after dosing, indicating that once daily dosing is possible. These results have now been extended to non-human primates, where very similar results were achieved. Both compounds were well tolerated, and showed good levels of drug even 24h after dosing. These compounds have the potential to be the first once daily integrase inhibitors for resistant patients.

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