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ASX Release

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Avexa Presents Data from Apricitabine and Antibacterial Programs at two International Conferences

- *ATC provided significant and durable antiviral activity over the 48-week treatment period, with a favorable safety profile and no evidence of resistance development*
- *Antibacterial program shows activity particularly against drug-resistant Staphylococcus pathogens*

Melbourne, Australia, November 13, 2008, Australian biotechnology company Avexa (ASX: AVX) today announced the presentation of 48 week data from its apricitabine program at the Ninth International Congress on Drug Therapy in HIV Infection held in Glasgow, UK, 9-13 November 2008. The previous week the company presented data on its antibacterial program at the 48th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) / Infectious Diseases Society of America (IDSA) 46th annual meeting, held October 25-28, 2008, in Washington, D.C.

At the Ninth International Congress on Drug Therapy in HIV Infection, the company presented the 48-Week Data from Study AVX-201 – A Randomised Phase 2b Study of Apricitabine (ATC) in Treatment-Experienced Patients with M184V and Nucleoside Reverse Transcriptase Inhibitors, or NRTI, Resistance. The data was selected for both an oral presentation and a supporting poster.

The data demonstrated that ATC provided significant and durable antiviral activity over the 48-week treatment period, with a favorable safety profile and no evidence of resistance development. Sustained and improved responses in viral load and CD4 cells were seen from Week 24 to Week 48. The greatest improvements were seen in the patients switching from 3TC to ATC at Week 24 nearly doubling their CD4 cell increase from Week 24 to 48, but they still lagged behind those receiving ATC for the full 48 weeks. Patients receiving 3TC for the first 24 weeks underwent a greater number of anti-retroviral treatment (ART) re-optimisations than those receiving ATC. ATC has the potential to provide significant, very well tolerated antiviral activity and to enable construction of a potent, durable regimen in treatment-experienced patients.

"ATC continues to show robust data to support its ongoing use as an effective treatment against HIV," said Julian Chick, PhD, CEO of Alchemia. "We are pleased with ATC's Phase III progress and this data that shows the high genetic barrier resistance to be robust at 48 weeks. This has the potential to make ATC a valuable drug in the long term treatment of HIV."

The data presented from Avexa's antibacterial program at the ICAAC/IDSA showed the potent *in vivo* antibacterial activity of Avexa's lead antibacterial candidate AVX13616, particularly against drug-resistant *Staphylococcus* pathogens. AVX13616 was as active as mupirocin in a nasal decolonization model but required only a single application. The compounds are being developed for topical indications and/or wound infection/catheter-related infections.

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"The data demonstrate that this class of compounds, represented by our lead compound AVX13616, possesses strong bactericidal activity in particular against gram-positive pathogens such as *Staphylococcus aureus*. These pathogens are becoming of increasing importance, particularly in nosocomial infections, and there is a dearth of new antibiotics in development to combat the increasing occurrence of antibiotic resistant infections. The activity of AVX13616 against drug-resistant bacteria demonstrates its potential as an agent to combat these serious and difficult-to-treat infections" continued Dr. Chick."

Vancomycin is a glycopeptide that binds to the terminal D-Ala-D-Ala dipeptide of peptidoglycan precursors, abrogating cell wall synthesis. Resistance to vancomycin is a recognised clinically significant problem. A series of compounds were synthesised with antibacterial activity *in vitro* against a range of gram positive organisms, including organisms resistant to vancomycin, linezolid and methicillin. The compounds were designed to retain binding activity against a D-Ala-D-Lac terminal peptide, where vancomycin binding is reduced. AVX13616 and other compounds showed broad spectrum antibacterial activity against a range of isolates with MICs of 2-4 µg/mL against *S. aureus*, coagulase negative staphylococci, enterococci, MRSA, VISA and VRSA. A single application of 5% (w/w) AVX13616 (approximately equimolar to 2% mupirocin) was as effective as 2% mupirocin administered twice a day for 5 days in nasal decolonisation of MRSA in mice.

About Apricitabine (ATC)

ATC is a nucleoside reverse transcriptase inhibitor and has a mechanism of action that is similar to the traditional NRTIs that make up the backbone of the first line therapy for HIV-infection. ATC's successful Phase IIb trial positions the drug as the leading therapy for patients that are failing the first line of therapy used in the treatment of HIV. The Phase IIb trial enrolled patients with M184V mutant HIV, which is a drug-resistant virus that results from the treatment of patients with Efavir[®], Combivir[®] or Trizivir[®] (currently marketed by GlaxoSmithKline) or Emtriva[®], Truvada[®] and Atripla[®] (currently marketed by Gilead Sciences). The majority of patients that were enrolled in ATC's Phase 2b trial opted to enter the extension study, and some of these patients have now been receiving ATC for very nearly three years. The Phase 3 study is well underway, with over 130 sites initiated in 15 countries throughout North America, Europe, Israel, Australia and South America.

About AVX13616

AVX13616, Avexa's lead antibacterial candidate, is a compound that was identified in collaboration with the University of Wollongong NSW for the treatment of serious drug-resistant bacterial infections. The suitability of AVX13616 as a topical antibiotic preparation is supported by data which clearly demonstrates stability of the compound to light and a lack of irritancy when applied to the skin. This compound is currently being developed as a topical medicine for the treatment of skin infections. AVX13616 is currently in preclinical studies, and has demonstrated acceptable safety profiles to date. Antibacterial activity has been demonstrated against both sensitive and drug-resistant strains in well established preclinical infection models. These include the treatment of infected wounds and nasal MRSA decolonization.

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Avexa Limited is a Melbourne-based biotechnology company with a focus on research and development of drugs for the treatment of infectious diseases. Avexa has dedicated resources and funding for key projects including its HIV integrase program and an antibiotic program for antibiotic-resistant bacterial infections which have both entered the IND-enabling study stage. The Company's lead program is apricitabine (ATC), an anti-HIV drug which has successfully completed the 48 week dosing of its Phase 2b trial and is currently in Phase 3 trials.

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