Durata Therapeutics Presented Data at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

CHICAGO, Sept. 9, 2014 (GLOBE NEWSWIRE) -- Durata Therapeutics, Inc. (Nasdaq:DRTX) today announced that data from its recently launched product, DALVANCE™ (dalbavancin) for injection, was presented during the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), which took place in Washington DC from September 5-9, 2014.

The following posters were presented:

**Sunday, September 7, 2014**

**Title: Standardization of a Modified Broth Microdilution Methodology for Dalbavancin against Neisseria gonorrhoeae** Authors: L. Koeth, J. Fisher

Poster #: D-859

Conclusions: Both GC broth +5% lysed horse blood (LHB) and MTGE broth provide sufficient growth and reproducible dalbavancin, ceftriaxone and ciprofloxacin MIC results of N. gonorrhoeae. Although growth was sufficient in GC broth (without addition of blood) for the isolates tested in this study, prior studies demonstrated poor or no growth in GC Broth. Additional testing with a larger set of isolates against dalbavancin and comparator agents using the GC with 5% lysed horse blood and MTGE with and without P80 compared to agar dilution and GC broth (comparator agents only) is recommended.

**Title: Dalbavancin and Azithromycin Synergy/Antagonism Study by Checkerboard MIC** Authors: L. Koeth, J. Fisher, M. Dunne

Poster #: D-877

Conclusions: Overall, the combination of dalbavancin and azithromycin showed no significant increase or decrease in each agent's in vitro activity by checkerboard methodology based on the FIC index evaluation.

**Title: Surrogate Analysis of Vancomycin to Predict Susceptible Categorization of**
**Dalbavancin**  Authors: RN Jones, RE Mendez, HS Sader, DJ Farrell (JMI Laboratories)

**Poster #:** D-875b

**Conclusions:** Dalbavancin, in recent (2011-2013) surveillance studies from the USA and Europe, demonstrated potent activity with MIC90 results ranging from ≤0.03 to 0.12 μg/ml for staphylococci and streptococci. Due to VRE strains, dalbavancin MIC90 values for enterococci were at >4 μg/ml, but MIC50 results ranged from only 0.06 to 0.25 μg/ml (highest for E. faecium). Vancomycin susceptibility test results can be used as a surrogate marker with high confidence/accuracy to predict dalbavancin activity at ≤0.12 μg/ml (97.72 to 100.0% accuracy for indicated species). These surrogate uses of vancomycin to predict dalbavancin activity susceptibility at ≤0.12 μg/ml per USA-FDA) generally confirm a similar analysis of 16,749 Gram-positive isolates published in 2006 (Jones et al.). This cited publication found only 22 errors among 11,867 analyzed S. aureus strains (99.81% surrogate accuracy; 99.86% in this report), applying the recently established clinical breakpoint of ≤0.12 μg/ml. These data demonstrate the sustained dalbavancin potency against indicated species without evidence of MIC creep across nearly a decade of resistance surveillance studies.

**Monday, September 8, 2014**

**Title:** Efficacy of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections in Patients Meeting SIRS Criteria at Baseline  Authors: S. Puttagunta, H. Boucher, G.H. Talbot, M. Dunne

**Poster #:** L-1730

**Conclusions:** Clinical response rates (cessation of spread and absence of fever) at 48–72 hours in patients with SIRS were lower than in those without SIRS; this difference disappeared by EOT. Rates of early clinical response and investigator assessment of success at EOT for dalbavancin-treated patients with ABSSSI who met SIRS criteria were comparable to those treated with vancomycin/linezolid. Although patients with SIRS criteria had a higher frequency of all-causality adverse events, treatment related adverse events occurred at a similar frequency in both groups.

**Title:** Safety and Efficacy of Dalbavancin in Patients with Renal Impairment Treated for Skin Infections  Authors: S. Puttagunta, G.H. Talbot, M. Wilcox, H. Boucher, M. Dunne

**Poster #:** L-1731

**Conclusions:** Clinical outcomes for dalbavancin-treated patients with ABSSSI did not vary by degree of renal impairment and were similar to those for dalbavancin-treated patients with normal renal function. Dalbavancin demonstrated comparable rates of treatment emergent adverse events in patients with and without moderate to severe renal impairment.

**Title:** Factors Associated with Hospital Admission for Patients with Skin and Skin Structure Infections (SSSI) seen in Emergency Departments (ED)  Authors: D. Patel, J. Stephens, K. Johnson, A. Patel, D. Talan
Conclusions: Hospital admission for SSSI from the ED was significantly associated with type of infection, region/type of hospital, insurance status, age, and comorbidities. Given the high proportion of SSSI patients admitted from the ED without comorbidities (>40%), variability based on non-patient factors, and the low inpatient mortality, identifying specific patient subpopulations in the ED that may be treated on an outpatient basis could result in decreases in the overall burden to the healthcare system.

Copies of these posters are available on Durata's website: www.duratatx.com.

About DALVANCE (dalbavancin) for injection

DALVANCE is a second generation, semi-synthetic lipoglycopeptide, which consists of a lipophilic side-chain added to an enhanced glycopeptide backbone. DALVANCE is the first and only IV antibiotic approved for the treatment of ABSSSI with a two-dose regimen of 1000 mg followed one week later by 500 mg, each administered over 30 minutes. DALVANCE demonstrates bactericidal activity in vitro against a range of Gram-positive bacteria, such as Staphylococcus aureus (including methicillin-resistant, also known as MRSA, strains) and Streptococcus pyogenes, as well as certain other streptococcal species.

For important prescribing and safety information, see www.dalvance.com.

DALVANCE is a trademark of Durata Therapeutics Holding C.V.

About Durata Therapeutics

Durata Therapeutics is a pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses.

Forward-looking Statements

Any statements in this press release about Durata's future expectations, plans and prospects constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended. Actual results may differ materially from those indicated by such forward-looking statements. Durata anticipates that subsequent events and developments will cause its views to change. However, while Durata may elect to update these forward-looking statements at some point in the future, Durata specifically disclaims any obligation to do so.

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