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Theraclone Sciences Presents Phase 1 Results of TCN-032, its Therapeutic Antibody Directed at Influenza A, at ICAAC 2012

Seattle, WA – September 10, 2012 – Theraclone Sciences, Inc., a therapeutic antibody discovery and development company, today announced the presentation of data from its Phase 1 clinical trial of TCN-032 in healthy volunteers at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Francisco, CA. The trial was designed to evaluate the safety, pharmacokinetics and immunogenicity of TCN-032, a broadly protective, fully human monoclonal antibody, being developed for the treatment of influenza A infections. TCN-032 was well tolerated throughout the study, with no dose-limiting toxicities or serious adverse events observed, and demonstrated a favorable immunogenicity profile.

“Influenza remains a major threat to global public health, with few treatment options available. TCN-032 is a novel therapeutic antibody drug candidate discovered with our I-STAR™ platform that has the potential to treat both severe seasonal and pandemic forms of influenza A infections,” commented Eleanor Ramos, M.D., Chief Medical Officer, Theraclone Sciences. “Based on our data presented at ICAAC, we are confident moving forward to the next step in the development of TCN-032 and expect to initiate a Phase 2 influenza viral challenge trial in human subjects by the end of 2012.”

The presentation (Poster G-873), entitled “Safety, Tolerability and Lack of Immunogenicity in a Phase 1 Clinical Trial of TCN-032 (Anti-Influenza A mAb)”, was authored by E. Ramos, J. Mitcham, P. Chan-Hui, M. Roberson, M. Al-Ibrahim and P. Patriarca. The randomized, double-blind, placebo-controlled Phase 1 study enrolled 40 healthy adult volunteers in 5 single-dose cohorts. Each cohort consisted of 8 patients, 6 receiving TCN-032 and 2 receiving placebo. Dose levels tested were 1, 3, 10, 20 and 40 mg/kg. Subjects were monitored up to 60 days after study drug infusion for clinical and laboratory evaluations, pharmacokinetics (TCN-032 blood levels) and anti-drug antibody levels. No serious adverse events were observed; most adverse events observed were mild to moderate and unrelated to the study drug. Pharmacokinetic evaluation demonstrated dose proportionality, half-life of ~15 days and other parameters consistent with an IgG antibody therapeutic. In addition, TCN-032 showed no signs of immunogenicity. A proof-of-concept Phase 2 study in human subjects is planned to initiate by the end of 2012.

The trial was supported in part by Zenyaku Kogyo Co., Ltd. through its multi-year research and development agreement with Theraclone to identify conserved, essential antibody targets and develop candidates for the treatment of pandemic and severe seasonal influenza. Zenyaku Kogyo has an exclusive license in the territory of Japan to Theraclone’s influenza monoclonal antibody program. Theraclone retains worldwide development and commercialization rights outside of Japan.

About Influenza



Influenza is a contagious disease affecting the respiratory tract and sometimes other organs, which typically causes mild to severe illness, but, at times, can lead to death. Approximately 36,000 people die each year from flu-related causes in the U.S. Certain populations, including the elderly, young children and people with certain health conditions, are at particularly high risk for serious flu complications.

Influenza A viruses can replicate and mutate very rapidly. Reassortment or recombining of viral genetic material from human, swine and avian influenza strains presents the dangerous possibility of pathogenic strains capable of causing widespread infection including pandemics, as was the case with the swine-origin influenza virus pandemic in 2009. To date, international governments have established multi-billion dollar stockpiles of drugs and vaccines in an effort to provide protection against future influenza pandemics. The development of new, complementary therapeutic approaches is a high international public health priority.

About Theraclone Sciences

Theraclone Sciences is a Seattle-based biotech focused on the development of novel therapeutic antibodies for the treatment of infectious disease and cancer. The Company's I-STAR™ technology harnesses the power of the human immune system to identify rare, naturally evolved monoclonal antibodies from the blood cells of immunologically relevant human subjects. Theraclone has established discovery partnerships with Pfizer, Zenyaku Kogyo and the International AIDS Vaccine Research Initiative. In addition, the Company has two proprietary antibody programs in clinical development for pandemic and seasonal influenza and human cytomegalovirus (HCMV). www.theraclone-sciences.com.

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