



CalciMedica to Present Results of PD/PK Study in Acute Pancreatitis Patients for Its CRAC Channel Inhibitor CM4620 at APA Annual Meeting

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LA JOLLA, CA, November 7, 2019 /PRNewswire/ — Kenneth Stauderman, Ph.D., CalciMedica's Chief Scientific Officer, is presenting a poster at the American Pancreas Association annual meeting November 7-10 in Wailea, Hawaii, entitled "Pharmacodynamic (PD)/Pharmacokinetic (PK) Study of CM4620 Injectable Emulsion in Acute Pancreatitis Patients". The study was performed at the Henry Ford Health System in Detroit, MI, and the Principle Investigator was Dr. Joseph Miller, MD, MS.

The poster describes work using a novel pharmacodynamic (PD) assay to evaluate blood samples drawn from acute pancreatitis patients at various times after receiving a single dose of the calcium release-activated calcium (CRAC) channel inhibitor CM4620-Injectable Emulsion (CM4620-IE). Effects in this assay were matched with plasma levels of CM4620-IE. The results showed an excellent correlation – the greatest inhibition in the PD assay, indicative of the greatest inhibition of the drug target by CM4620-IE, occurred at the highest blood levels of drug, measured just after completion of the infusion of the drug. In addition, as blood levels of CM4620-IE dropped, as determined by the pharmacokinetic (PK) assay, inhibition in the PD assay declined and returned to baseline.

The PD assay was developed in conjunction with Confluence Discovery Technologies, Inc., of St. Louis, MO, and took advantage of the fact that the activity of CM4620-IE in acute pancreatitis is believed to derive from two sites of action – inhibition of CRAC channels on pancreatic acinar cells, limiting pancreatic necrosis, and inhibition of CRAC channels on immune cells, limiting local and systemic inflammation. Because pancreatic tissue is difficult to access, the PD assay looked at whole blood samples, containing different immune cell types, taken from acute pancreatitis patients treated with CM4620-IE. The blood samples are stimulated with specific pharmacological agents to cause the release of the cytokine IL-2 in a manner inhibited by CRAC channel blockade.

Dr. Stauderman said, "We are quite happy with the results, which accomplished the two main objectives of this study – demonstration of target engagement, and demonstration of reversal of the pharmacological drug effect in the PD assay in a relatively short period of time, by hospital discharge, which on average was day 3. The amount of inhibition seen corresponded well with the IC50 determined in in vitro assays". Dr. Stauderman continued, "We also measured a panel of cytokines in serum samples from these patients, and showed that endogenous IL-6 levels, which appeared to correlate with disease severity, declined after dosing in 5 of 7 patients, suggestive of CM4620-IE's effects on inflammation. This supports similar results seen in Phase 2a open-label study completed earlier this year and positions us well for a significantly larger blinded Phase 2b study planned to start in the first half of next year".

About CM4620

CM4620 is a potent and selective small molecule inhibitor of calcium release-activated calcium (CRAC) channels. CRAC channels are found on many cell types, including immune cells and pancreatic acinar cells, where aberrant activation of these channels is thought to play a key role in the pathobiology of acute pancreatitis. CM4620 arose from CalciMedica's internal R&D, is patent-protected, and is being developed for patients with acute pancreatitis and accompanying SIRS.

About CalciMedica, Inc.

CalciMedica is a privately-held, clinical stage biotechnology company focused on CRAC channel drug discovery and development for the treatment of acute and chronic inflammatory diseases. CRAC channels control the entry of calcium into immune and other cell types, and calcium is an important intracellular signaling molecule that modulates normal cellular function but can be detrimental when levels are too high. CalciMedica is headquartered in San Diego, CA. For more information, please visit the company website at www.calcimedica.com.

Contact:

Michael Dunn, President and Chief Operating Officer
CalciMedica, Inc.
858-952-5514
michael@calcimedica.com