AN OFFICIAL PRESS RELEASE

Bell Biosystems, Inc.

Bell Biosystems, Inc. Announces Pre-Clinical Results of Major in Vivo Safety Study Milestone

BERKELEY, Calif., January 8, 2018 (Newswire.com) - Bell Biosystems, Inc. (Bell) today presented the results of their latest pre-clinical safety study at the Biotech Showcase in San Francisco that runs concurrently with the annual J.P. Morgan Healthcare Conference. The study was designed in accordance with USP <151> pyrogenicity guidelines, where the safety of intravascularly injected stem cells labeled for MRI tracking using a high dose of Bell's Magnelle(R) brand MRI contrast agent was demonstrated safe in rabbit subjects. This *in vivo* pyrogen study demonstrated that Magnelle-powered(TM) cGMP manufactured human mesenchymal stem cells (hMSCs) do not elicit an *in vivo* pyrogenic response – a key milestone to advancing the commercialization plan.

Magnelle (magnetic organelle) contrast agents are being launched commercially this month, and create magnetic resonance imaging (MRI) beacons in a variety of cell therapies. Magnelle-powering(TM) of therapeutic cells has been shown in small animal studies to provide rich data on transplanted cell location and, unlike alternatives, on cell viability post-transplantation using non-invasive MRI. This is highly enabling for Cell Therapy research scientists and biopharmaceutical development organizations where measuring cell viability and durability post-injection has been challenging in the past, but is critical to translation and clinical realization of this class of therapeutic.

The Magnelle reagents are derived from non-pathogenic, Gram-negative bacteria inspired by the bacterial origin of natural organelles such as the mitochondria and chloroplast. Gram-negative bacteria express one of six types of endotoxin or lipopolysaccharide (LPS), which can potentially induce life threatening pyrogenic reactions depending on the detailed molecular structure of LPS isoforms. To assess this safety concern, Bell subcontracted Pacific BioLabs, Inc. to undertake the rabbit pyrogen study following USP <151>. The double-blinded study included three cohorts: Magnelle-powered hMSCs; unlabeled hMSCs; and injection fluid control. None of the test subjects receiving Magnelle-powered cells exhibited a temperature increase of more than 0.1^{o}C, proving *in vivo* that the Magnelle expressed LPS is not pyrogenic. Note, USP <151> states that a temperature increase of 0.5^{o}C or more constitutes failure of the test.

"We are extremely encouraged by the results of these latest safety assessments as a key step forward in the realization of this technology for labeling and tracking cellular therapies," stated Dr. Caleb B. Bell III Founder and CTO at Bell. With successful completion of rodent safety studies and this latest pyrogen assessment, the company will be undertaking large animal studies as the next step towards clinical uses.

Bell Biosystems, Inc. is a Bay Area-based, emerging biotech company commercializing *in vivo* tracking and contrast agent technologies for cell therapies. Our first product, the Magnelle® cell tracking solution, provides precise location and viability data for *in vivo* transplanted cells. We are positioning Magnelle-powered cell therapies to disrupt the regenerative medicine marketplace by providing actionable insights for therapeutic durability including therapeutic cell viability feedback and localization of transplanted cells. The first product will be commercialized in early 2018. Over the years, Bell has received support from Start-X (a Stanford-affiliated startup accelerator), Breakout Labs (a project of the Thiel Foundation), QB3 and J-Labs. Additionally, Bell Bio was recognized in 2014 by the White House as a "breakthrough life science technology platform;" the 2014 Rising Star Award from BayBio (now CLSA); and were sponsored by JETRO, Japan's Trade Organization, for an exclusive business-matching program in Hiroshima.

Pacific BioLabs (PBL) is a contract research organization (CRO) offering testing and research support services primarily focused on supporting the pharmaceutical, biotech, and medical device industries. Specializing in the biological sciences, PBL is committed to helping its clients deliver lifesaving medicines and medical devices to physicians and patients who need them. PBL conducts all studies in accordance with applicable Current Good Manufacturing Practice (cGMP) and, when requested, Good Laboratory Practice (GLP) regulations. PBL has an outstanding regulatory track record with numerous successful inspections by FDA, EPA, USDA, and international regulatory agencies. Our clients range from small biotech and medical device startups to Fortune 500 pharmaceutical giants.

ENDS

Contact:
Kenneth Harris
ken@bellbiosystems.com
Bell Biosystems, Inc.
626 Bancroft Way, Ste A
Berkeley, CA 94710

Additional links and information:

Follow Bell Biosystems and Biotech Showcase on Twitter: @BellBiosystems and @kharrisCellMed ; @EBDGroup and @Demy_Colton - #BiotechShowcase

Source: Bell Biosystems, Inc.