**Contact:** Kevin Bragaw

**Title:** Executive Director, Society for Clinical Trials

**E-mail:** kevinbragaw@sctweb.org **Phone:** 847-725-2286

**The PALM Trial honored with the Society for Clinical Trials’**

**prestigious David Sackett Trial of the Year Award for 2020**

Arlington Heights, Ill., April 15, 2020 -- The Society for Clinical Trials (SCT) is pleased to announce that the prestigious David Sackett Trial of the Year Award for 2020 has been awarded to the Pamoja Tulinde Maisha (PALM [“Together Save Lives”] in the Kiswahili language) trial, an international group of investigators for their work in identifying safe effective therapies for Ebola – a highly deadly hemorrhagic fever virus.

“Amid the current global burden of COVID-19, the PALM trial not only highlights the critical importance of conducting rigorous clinical trials to establish effective therapies but also the necessary interdisciplinary and collaborative resolve to successfully execute clinical trials under urgent circumstances,” said Dr. Dean Fergusson, Ottawa Hospital Research Institute, President of SCT.

During the second largest Ebola outbreak declared on August 1st, 2018 in the Democratic Republic of Congo, 2,196 of 3,296 cases (67 percent) died as reported on November 17th, 2019. No known therapeutic countermeasures were licensed at the beginning of this outbreak. Clinical trials evaluating interventions for Ebola are difficult to conduct due to the unpredictable and episodic nature of the disease and the lack of research infrastructure in outbreak locations.

The PALM trial evaluated four investigational therapies for Ebola during the outbreak in the Democratic Republic of the Congo. Patients of any age who had a positive result for Ebola virus were enrolled. All patients received standard care and were randomly assigned in a 1:1:1:1 ratio to one of four experimental drugs: intravenous administration of the triple monoclonal antibody ZMapp (the control group), the antiviral agent remdesivir, the single monoclonal antibody MAb114, or the triple monoclonal antibody REGN-EB3. On August 9th, 2019, an independent Data and Safety Monitoring Board recommended discontinuing ZMapp and Remdesivir because 28-day mortality rates in MAb114 and REGN-EB3 were substantially lower. The effective therapies (MAb114 and REGN-EB3) were immediately adopted in the field.

“With results that were published within one year of study start, the PALM trial demonstrated that scientifically and ethically sound clinical research can be conducted during disease outbreaks and can help inform the outbreak response,” said Dr. Scott Evans, George Washington University, Chair of the SCT Trial of the Year Committee.

The PALM trial was jointly led by the [National Institute for Biomedical Research (INRB/DRC)](http://www.inrb.cd/) and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIAID/NIH) as part of an international research consortium coordinated by the World Health Organization (WHO). The consortium included additional support from the Alliance for International Medical Assistance (ALIMA), Doctors without Borders (Médecins Sans Frontières, MSF) and the International Medical Corps (IMC). Pharmaceutical partners included Gilead Sciences Inc, Mapp Biopharmaceutical Inc, Regeneron Pharmaceuticals and Ridgeback Biotherapeutics. The trial was published in the *New England Journal of Medicine* (DOI: 10.1056/NEJMoa1910993).

The SCT will be holding a special webinar on International Clinical Trials Day, May 20th, 2020 to recognize the PALM trial and gain insights into the trial conception and execution. Key PALM trialists will include Professor Jean-Jacques Muyembe and Dr. Placide Mbala from the Institut National pour la Recherche Biomedicale in the Democratic Republic of the Congo; Dr. Lori Dodd from the National Institute of Allergy and Infectious Diseases (NIAID); and Dr. Olivier Tshiani from Leidos Biomedical Research, Inc. (LBR). Discussion will also include how findings and knowledge from PALM can support COVID response efforts. Of note, one of the therapies in the PALM trial, remdesivir, is being studied extensively for treatment of coronavirus infection. Details of the SCT David Sackett Trial of the Year webinar can be found at www.sctweb.org.

Each year since 2008, the SCT has awarded the David Sackett Trial of the Year Award to a randomized, controlled trial published (either electronically or in print) in the previous calendar year that best fulfills the following standards:

* Improves the lot of humankind;
* Provides the basis for a substantial, beneficial change in healthcare;
* Reflects expertise in subject matter, excellence in methodology, and concern for study participants;
* Overcomes obstacles in implementation; and
* Based on the presentation of its design, execution, and results is a model of clarity and intellectual soundness.

Nominations are submitted by Society members, investigators, and interested scholars from around the world. The 2019-2020 Trial of the Year selection committee included: Marc Buyse, Bob Dworkin, Scott Evans (Chair), Toshimitsu Hamasaki, Frank Rockhold, and Yves Rosenberg. Dr. David L. Sackett was a dedicated long-time SCT member and a pioneer in evidence-based medicine and champion of clinical trials.

###

***About the SCT****: The Society for Clinical Trials, created in 1978, is a scientific, educational, and charitable organization established for the purpose of working internationally to advance human health through advocating the use of clinical trials, leading the development and dissemination of optimal methods and practices in clinical trials, and educating and developing clinical trial professionals visit www.sctweb.org*.