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ArTiMist™ STUDY HIGHLY SUCCESSFUL IN TREATING CHILDREN WITH SEVERE MALARIA

Eastland Medical Systems Ltd (ASX:EMS) in conjunction with its UK clinical consultants ProtoPharma Limited announces today the very positive results of the recently completed Phase IIa clinical trial of ArTiMist™, a patented sublingual delivery technology designed to administer the drug Artemether. ArTiMist™ was specifically designed to provide a rapid first line treatment of children with severe or complicated *P. falciparum* malaria, or uncomplicated *P. falciparum* malaria with gastrointestinal complications.

The major complications of severe malaria include cerebral malaria, pulmonary edema, acute renal failure, severe anemia, and/or bleeding. Acidosis and hypoglycemia are the most common metabolic complications. Any of these complications can develop rapidly and progress to death within hours or days.

The majority of deaths from severe malaria in young children are caused by the delayed administration of effective malaria treatments. Moreover, oral treatment is not adequate for patients who are suffering from vomiting and diarrhea and oral absorption (tablets) is slower and often not possible. It is a fact that many deaths occur due to delays in transferring a patient to a hospital setting where trained staff are on hand.

RESULT

The Phase IIa clinical study was an open label randomised comparative Trial to establish the efficacy of 3mg/kg ArTiMist™ when compared to Intravenous quinine, which is recommended by the WHO in its treatment guidelines, in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal ccomplications interventional, two arm study (15 children in each) conducted in Kigali, Rwanda.

The results show that ArTiMist™ was rapidly absorbed following first administration via the sublingual route. The new route of administration containing the new formula of Artemether was shown to be safe and well tolerated by patients. The three primary efficacy parameters were met and showed success in the reduction of parasite count within 24 hours after receiving the first dose.

Highlights

- **Positive results achieved from Phase 1 multi and single dose clinical studies for ArTiMist™ indicating the formulation was well tolerated and showed no adverse effects in any of the study subjects.**
- **ArTiMist™ Clinical Field Trial completed in February 2010 in Rwanda.**

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In summary, there were no clinical or statistically relevant differences between the two treatments in any of the study efficacy parameters which is in itself a remarkable outcome. There were also no safety related withdrawals from the study and no adverse events related to ArTiMist™.

Although this study was not designed to investigate the pharmacokinetic (PK)/ pharmacodynamic (PD) relationships, it was observed that ArTiMist™ was rapidly absorbed reaching high plasma concentrations, which in turn correlates well with the rate of parasite reduction and clinical response by those patients that received ArTiMist™.

ArTiMist™ efficacy when compared to intravenous quinine is an extremely important step forward in the treatment modality of the form of malaria targeted by this treatment. There are a number of significant practical, operational and commercial advantages in the patented sublingual delivery mode of ArTiMist™ when compared to IV quinine or other available therapies and administration routes:

- Easy administration and rapid dosing, as ArTiMist™ is ready to use and does not require medically trained personnel for its administration;
- Its use is particularly suitable in rural and/or remote regions where healthcare infrastructure is limited or nonexistent;
- Avoidance of hepatic first-pass metabolism;
- Hygienically safe for patients and personnel alike, as it eliminates the risk of infection derived from the use of needles;
- It does not require refrigeration and currently has >2 years shelf life based on GMP manufactured batches made in the UK;
- The practical advantage of using ArTiMist™ over any IV treatment with any malaria drug due to the often associated risks of infection in IV administration
- Reduction of the cost burden on families and healthcare systems;
- Rural clinics often do not have doctors or IV drugs and may only have tablets. With severe malaria vulnerable patients in many cases will not be able to take oral dosing. ArTiMist™ can be used successfully in all situations.

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These last two points are directly linked to the treatment accessibility. In developing countries medical care is often paid for by patients and/or their families and the medical and associated costs involved in saving a young child's life in rural areas are very high. Typically a family must provide for all food and travel costs. During hospitalisation (typically 7 days) families must also provide food and pay hospital and treatment fees at the time of treatment. Many impoverished families cannot afford these costs and various studies have demonstrated that high out-of-pocket medical spending can plunge the families further into poverty.

The fact that an ampoule of quinine is inexpensive- (US$0.17 per ampoule as listed by the Kenya Medical Supplies Agency (KEMSA) and it is estimated that between 7 and 10 ampoules are used over a period of about 60 hours until possible resumption of oral therapy)- masks the real costs. For a local healthcare system, overall treatment cost per patient is high as these are acute patients and the associated financial and human resources required to care for them are considerable.

ArTiMist™ has been expressly developed to manage the unmet and specific needs of this highly vulnerable patient group and their families in low-income countries and to fit within the existing social and healthcare infrastructure.

The addressable market for ArTiMist™ is large. It is estimated that alone there are over 90 million children under the age of 5 (the most vulnerable patient population) in sub-Sahara Africa at "high risk" of contracting malaria. It is further reported that children are prone to between 1.6-5.4 episodes of malaria each year. Data relating to the more virulent *P. falciparum* malarial strain indicate 86 million reported cases in Africa annually and 287 million estimated cases in the overall population. Based on these figures and on the distinct advantages of ArTiMist™ over IV quinine, we have internally estimated a potential market size of between 80 -100 million units in Africa for the <5 years old demographic alone. Asia represents also a large potential market even though the socio-economic and healthcare infrastructure are generally in better shape than in sub-Sahara Africa.

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FORWARD PROGRAM

Eastland announces that, following review of these Phase IIa results in consultation with ProtoPharma Limited UK, it has instructed ProtoPharma to move forward and conduct a confirmatory multi centre study later this year in a larger group of patients. The study will be conducted in two or more countries. Protocols are currently being finalised and arrangements have been made for preparation of study drug that is now ready for shipping to the study clinics. Clinical meetings took place earlier this month with the respective clinical advisors and staff.

The Eastland Board has formed a view that commitment to the confirmatory study will provide additional valuable information that will enable us to present an even stronger clinical file to any interested parties. This will ultimately result in a significantly high-value partnering agreement and its success will add substantial value to the project when measured against the costs involved.

The confirmatory study has an estimated cost of $1.3m and field trials are expected to commence in September 2010. The majority of the cost of the study will be funded via proceeds from the disposal of Eastland's medical supply business West Coast Surgical, which is performing above expectation, and augmented from working capital.

APPOINTMENT OF ADVISERS

The Board is pleased to announce the appointment of the Sydney based AFG Ventures Group to advise the company on commercialization options for ArTiMist™ including sub-licensing, strategic partnerships and earn-in arrangements. Ms. Karen Dado, who has an extensive background and experience in the international pharmaceutical arena and has provided advice to this sector for over twenty years, will be the principal advisor.

ACKNOWLEDGEMENT

The Board of Eastland would like to acknowledge the outstanding contribution made by Mr Calvin Ross and his team of scientists in co-ordinating the clinical trial program in Rwanda and overseeing the overall clinical development of ArTiMist™.

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Editor's Notes

Malaria is a serious, infectious disease spread by the female Anophele mosquito. According to the World Malaria Report 2008, the World Health Organisation (WHO) has estimated that about half of the global population (3.3bn) is at risk of getting malaria with 247 million malaria cases reported worldwide and almost 900,000 fatalities. Of the malaria cases reported approximately 91% of the people suffering from malaria live in Africa. 85% of all malaria deaths are of children <5 years of age with a child <5 dying every 30 seconds. In the African region 90% of the malaria deaths are concentrated in 18 countries. The major infection regions include Ethiopia, Kenya, Congo, Nigeria and Tanzania.

As mentioned, young children bear the brunt of malaria mortality and for those children who survive an episode of severe malaria without having received adequate treatment, there is the risk that they may end-up suffering from learning impairments or brain damage.

Malaria is a key barrier to economical development. A number of international initiatives have been developed and adopted to facilitate the procurement and supply of anti-malarial drugs.