ASX Release

5000 PATIENT STUDY CONFIRMS ARTESUNATE SUBSTANTIALLY REDUCES MORTALITY IN AFRICAN CHILDREN WITH SEVERE MALARIA

Key Points:

- Results have just been published from a 5 year clinical trial (*AQUAMAT*), funded by Wellcome Foundation, which compared intravenous (IV) administration of quinine and artesunate in 5425 children with severe malaria in 9 African countries.
- IV Artesunate substantially reduces mortality in African children with severe malaria and could now become the treatment of choice for severe falciparum malaria pending a WHO review.
- Artesunate and Artemether (ArTiMist™) are both part of the artemisinin group of drugs that treat malaria.
- The AQUAMAT findings and the likelihood that IV Artesunate could now replace IV quinine as the treatment of choice for severe falciparum malaria worldwide is potentially extremely positive for ArTiMist™.
- Administration of IV Artesunate requires trained staff in a hospital setting and carries with it the risks of cross infection.
- According to WHO the majority of deaths from severe malaria in childhood are caused by the delayed administration of effective antimalarial treatment. There is a relentless deterioration in the clinical condition of a young child with malaria who fails to get effective treatment, with death ensuring in a matter of hours or days. WHO states that any successful attempt to reduce mortality will have to explore novel ways to avoid treatment delays.
- ArTiMist™ is an innovative sublingual spray formulation that offers front-line treatment for children with severe or complicated malaria. It has been designed to be rapidly administered in a village setting with minimal training or support. Importantly it is non-invasive, does not require refrigeration and results point to a shelf life exceeding 2 years.
- Whilst the AQUAMAT findings do not negate the need for EMS to continue its clinical and regulatory program, they provide an increased worldwide awareness to the effectiveness of artemesinins in the treatment of severe malaria in children. The findings also reinforce the significant potential commercial value for ArTiMist™ as a potential front-line treatment for severe or complicated malaria.
- Eastland has recently commenced patient dosing in a confirmatory clinical trial in 4 African countries on children with severe and complicated malaria.

Highlights

- **Positive results achieved from Phase I 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.**
- **Very positive successful results achieved from Phase IIa ArTiMist™ trial Clinical Field Trial completed in February 2010 in Rwanda.**

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Highlights

Eastland Medical Systems Ltd (ASX:EMS) after having reviewed the recently published article in the prestigious Medical Journal **THE LANCET** (Volume 376 issue 9753, pages 1647-1657 published online 08/11/2010), are excited by the release of the results from the 5 year *AQUAMAT* study (The Africa Quinine versus Artesunate in Severe Malaria Trial). The findings are very positive for ArTiMist which potentially offers significant advantages using its patented sublingual delivery formulation.

The trial that was carried out over 5 years and enrolled 5425 children in 9 African countries reported that *"Artesunate substantially reduces mortality in African children with severe malaria."* It went on to further state that *"These data, together with a meta-analysis of all trials comparing Artesunate and quinine, strongly suggest that parenteral Artesunate should replace quinine as the treatment of choice for severe falciparum malaria worldwide".*

Historically quinine has been the gold standard treatment for severe malaria. In 2005 a sister trial to *AQUAMAT* was completed in South East Asia (*SEAQUAMAT*). At completion of this trial the recommendation was *"Artesunate should become the treatment of choice for severe falciparum malaria"*. In 2006 WHO changed its guidelines to recommend Artesunate for severe malaria in adults.

It is anticipated that based on the results of the *AQUAMAT* trial that WHO will review its current recommendations for the treatment of severe malaria in children.

EMS believes that this could provide significant benefit to the ArTiMist™ program due to the acceptance of the artemesinins as a treatment of choice for severe malaria.

It should be noted that Artesunate and Artemether (ArTiMist) are both part of the artemisinin group of drugs that treat malaria. Artesunate is water soluble whilst Artemether is oil soluble. Both drugs are derived from Artemisinin and both are transformed in-vivo into the active metabolite dihydroartemisinin (DHA) and therefore have similar modes of action.

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