SensaPharm Ltd makes key reference standards, 9- epi artemisinin and artemisitene available for artemisinin quality assessment

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With the support of Medicines for Malaria Venture (MMV), SensaPharm Ltd of Sunderland, UK, has produced the key impurities which are found during artemisinin production, 9- epi artemisinin and artemisitene. These are now being made available as validated reference standards together with specific assays for both molecules.

In the past few years there has been considerable debate over the quality requirements applicable to the API artemisinin, which is used as the starting material for the production of the highly important artemisinin-based combination therapies (ACTs).

The major concern is in the presence and level of certain defined impurities, which have the ability to affect the purity of the APIs.

It is known that artemisinin quality varies according to, for example, agricultural conditions, extraction steps and purification conditions.

The impurities, identified as 9- epi artemisinin and artemisitene, may carry forward to impact the purity of the final API and as such, their measurement is of critical importance.

These standards are available in various pack sizes for analytical laboratories and the assays, based upon both HPLC and LCMSMS, are available as a service from SensaPharm Ltd.

In addition, and among a range of other relevant standards, the company has produced reference grade deoxy-artemisinin. This compound has been suggested to increase if storage conditions for the artemisinin API are poor.

SensaPharm Ltd Director Neil Sullivan said, “We are pleased to support the industry by supplying reference standards and definitive assays for these known impurities. Ensuring high quality artemisinin for API production is absolutely vital in the fight against malaria and we hope our efforts will in some way make a contribution”.

Dr Ian Bathurst, Director of Drug Discovery at Medicines for Malaria Venture* said, “These reference materials will be critical to ensuring that quality guidelines for starting materials are met and will help considerably in securing the high quality supply of APIs.”

The key document in which these issues are debated is as follows:


* We regret to announce that Dr Bathurst passed away on 26 July 2011. His mentorship and support to this project has been invaluabale.
For further information regarding supply of these compounds and assay services, please see our new website; [www.sensapharm.eu](http://www.sensapharm.eu) or contact:
Dr Neil Sullivan, Director, SensaPharm Ltd
+44 (0) 191 516 6969/ +44 (0) 7906 667354 / [neil@sensapharm.eu](mailto:neil@sensapharm.eu)

**MEDICINES FOR MALARIA VENTURE (MMV)**

MMV is recognized as the leading product development partnership (PDP) in the field of anti-malaria drug research and development. It was established as a foundation in 1999, and registered in Switzerland.

**MMV’s mission** is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable anti-malaria drugs.

**MMV’s vision** is a world in which these innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria, and help to ultimately eradicate this terrible disease.

MMV’s strength comes from its product development partnership (PDP) model reflected in its network of more than 140 pharmaceutical, academic and endemic-country partners in 37 countries. MMV also works in close partnership with a number of WHO programmes that include TDR, the Global Malaria Programme (GMP) and Roll Back Malaria (RBM).

The key to MMV’s success lies in the focus of its mission, and the diversity of its team of almost 50 personnel from more than 20 countries, handpicked for their expertise and commitment to global health. Governed by the values of respect, integrity, trust and excellence, MMV is recognized for its industry-style portfolio management and wise administration of funds. It manages over USD 515 million received and committed from long-term donors such as government agencies, private foundations, international organizations, and corporate foundations. In addition, it receives in-kind donations in the form of staff, facilities, and technology from its industry partners, estimated to be equal in dollar value to the funds from donors.

MMV is currently managing the largest portfolio of antimalarial R&D projects ever assembled. Of over 50 promising projects, two MMV-supported artemisinin combination therapies (ACTs), dihydroartemisinin-piperaquine and pyronaridine-artsunate, are awaiting regulatory approval by the European Medicines Agency in 2011. In November 2010, Guilin’s artesunate injection for the treatment of severe malaria was approved by the WHO’s Prequalification programme with assistance from MMV. In addition, a child-friendly version of the ACT Coartem, Coartem® Dispersible, was developed by Novartis in partnership with MMV and launched in 2009. Since then, more than 65 million courses of treatment have been supplied to 35 malaria-endemic countries.

For further information please contact
Jaya Banerji, Director, Advocacy & Communications
Tel: +41 22 799 4071 Mob: +41 79 707 7181
email: [info@mmv.org](mailto:info@mmv.org)   [www.mmv.org](http://www.mmv.org)