SUDA LTD

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SUD
Innovations in Pharm


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Suda Ltd., a publicly-listed company on the Australian Stock Exchange (ASX:SUD), focused on the commercialization of low-risk pharmaceuticals, is taking its success with oro-mucosal drug delivery methods to develop a roster of innovative projects for more efficient medical care.

SUDA LTD'S BUSINESS model is designed around the development of low-risk pharmaceutical reformulation off-patent drugs into novel patentable formulations with advantages such as faster onset of action, lower dosages and improved patient convenience. With its first major project, an oral spray used for the treatment of malaria, Suda Ltd is expecting similar results with a pipeline of oral spray projects in various stages of clinical trials.

ArTiMist

The project currently in the most advanced stage of trails is ArTiMist™, a ready-to-use, sub-lingual sprayable reformulation of Artemether used to treat malaria. Arthemether, recognized for its effectiveness in the fighting of blood parasites associated with malaria, is traditionally given intravenously, a method that is not without adverse risk and drawbacks.

Typically, a patient with severe malaria requiring treatment is in a state of distress, dehydration and possibly comatose. This creates difficulty for intravenous delivery of treatment for many reasons, including difficulty finding an injection site, and the consequential risk of infection.

Suda Ltd's ArTiMist™ is innovative in its simplicity. "It is a very simple product which is a spray delivered under the tongue of a patient with malaria," says Executive Chairman and CEO Stephen Carter.

Results from a phase III clinical trial conducted in Rwanda and Ghana comparing ArTiMist™ with intravenous quinine have been overwhelmingly positive. "The findings show that ArTiMist™ worked much faster and was much more efficient in reducing the malarial parasites," says Carter.

In the first 24 hours of treatment, 96 per cent of patients showed a greater than 90 percent reduction in amount of parasites in their blood drug, versus 41 percent of the patients in the quinine arm.

Additionally, 17 percent of patients who received quinine had early treatment failures while patients who received ArTiMist™ had none, and after 30 hours all ArTiMist™ patients were free of parasites, while it took 68 hours for the patients in the quinine arm of the trial to have the same results.

"Its intrinsic characteristics (efficacy, user-and-patient friendly, hygienic and non-toxic) could make ArTiMist™ the treatment of choice in urban and in rural locations, as its initial administration could be done at the community level by individuals that are not necessarily medically trained," says Carter.

These results provide convincing evidence

for the use of ArTiMist™ as an effective treatment for patients suffering from severe malaria, which is common in children under the age of five. Over one million children die of malaria every year, and it is with pharmaceutical innovations such as ArTiMist™ that these numbers can be reduced.

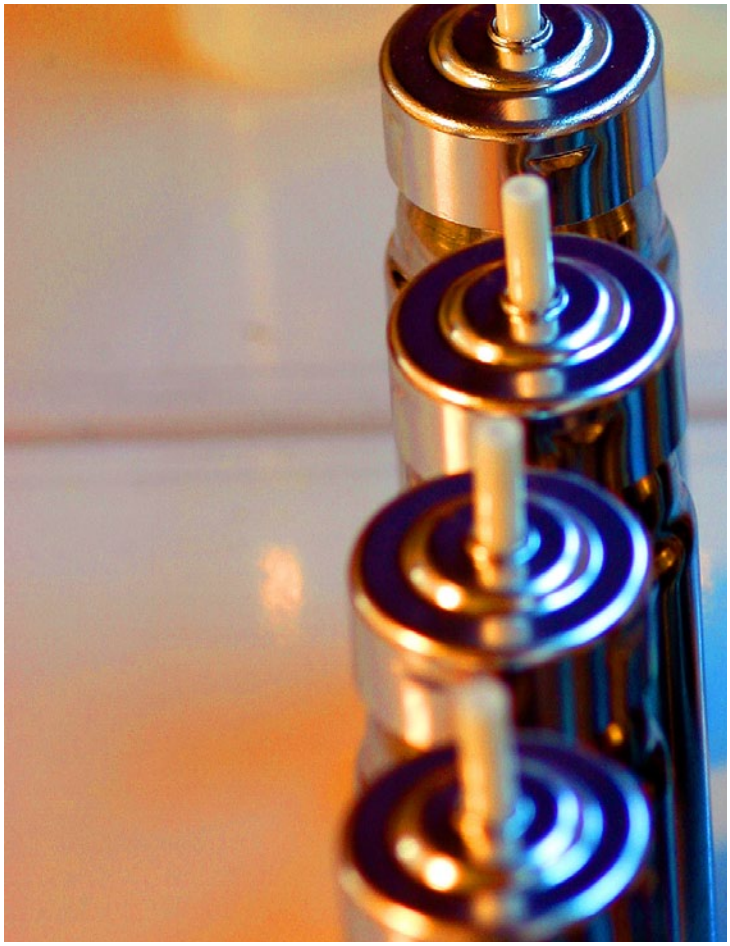
Suda Ltd has the exclusive clinical development, manufacturing and distribution right for ArTiMist™ in Africa, India, Asia and Asia Pacific. "It is an exciting time for Suda Ltd," says Chief Business Officer, Nick Woolf. "We are looking to engage with groups like the World Health Organization and other foundations that help fund and distribute treatments to developing countries, particularly in Africa."

Perpetual innovation in pharmaceuticals

ArTiMist™ has proven to be the launching pad for Suda Ltd. who has now focused on acquisition and technology development to increase its roster of pharmaceutical developments for licensing and commercial applications. Suda Ltd has brought on a new portfolio of assets all based on oral spray, oro-mucosal delivery.

Carter says the company has a number of programs that have been through clinical development as part of this acquisition of assets from U.S. pharmaceutical company, NovaDel in August, 2013. "We knew that ArTiMist™ would be completing clinical trials, so we needed some other projects to move on once ArTiMist™ got

Nick Woolf, Chief Business Officer



there. It wasn't until the NovaDel opportunity came along that we got excited."

Suda Ltd's considerable expertise in the sublingual administration of drugs to children and others and knowledge in the development requirements for oro-muccosal drug administration made NovaDel's catalogue very attractive. The company's broad patent estate covers over 300 compounds, the majority of which were U.S. focused, which is the largest market in the world.

Since the NovaDel acquisition was secured, Suda Ltd's strategy group has been researching those 300 compounds and has identified a short list of compounds for maximum near-term commercial potential for the company's shareholders.

Suda Ltd. is focusing on five projects in different stages of clinical trials. DuroMist™ is one, and has been evaluated in a pilot pharmacokinetic clinical trial. DuroMist™ is a lingual spray form of Viagra® for the treatment of erectile dysfunction which represents a $4 billion market worldwide..

Suda's anti-migraine oral spray of the world's most effective migraine drug, Sumatriptan, has completed two pivotal clinical trials which have shown the oral spray to be much more effective than tablet versions of Sumatriptan. Market studies already conducted on less-effective nasal sprays show great potential for Suda Ltd oral spray technology.

Another of Suda Ltd.'s product, the first oral spray of Ondansetron, used for the treatment

ArTiMist™ being filled

of chemotherapy-induced nausea and vomiting, positions the company to tap into the of $3.6 billion global market for alleviation of these types of symptoms.

Midazolam and Sildenafil Citrate, an anti-pre-procedural anxiety drug and Pulmonary Arterial hyerptension drug, have completed the initial formulation and are ready for the next stage of pharmacokinetics.

For the administration of these drugs, "It makes a lot of sense to move to something as simple as an oral spray," says Carter. "Typically, the oral spray method requires a lower dosage and takes less time to be effective."

In the midst of transfer of information from NovaDel, Suda Ltd is cataloguing the data to move forward on licensing deals. It is also seeking partners or an acquirer to launch and commercialize ArTiMist™ for end-patient use.

"This is a transformational period for Suda Ltd. We anticipate in the next 12 to 18 months a number of partnership deals and the continued development of our acquired assets." Suda Ltd will continue to focus on the reformulation of existing off-patent products into a user-friendly, patent-compliant and high-value oral sprays, contributing greatly to the pharmaceutical innovation of Australia. **AUBJ**

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AS SEEN IN THE NOVEMBER/DECEMBER 2013 ISSUE OF THE AUSTRALIAN BUSINESS JOURNAL

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