SUDA Pharmaceuticals Ltd

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SUDA Pharmaceuticals anagrelide oral spray formulation supported by new study results

SUDA Pharmaceuticals Ltd (ASX:SUD) (FRA:E4N) has welcomed study results that support the company's hypothesis that an anagrelide oral spray formulation may offer a safer alternative to the current commercial capsule to treat metastatic disease in patients with certain solid tumour cancers.

A final report was recently received for a canine pharmacokinetic study completed at Covance Inc, Harrogate, UK, where three carefully selected experimental oral spray formulations of anagrelide were compared with the commercial capsule form of the drug, Xagrid.

The objective of the study was to compare plasma levels of anagrelide and its cardiostimulatory metabolite following administration of the oral spray formulations with those after dosing with the capsule.

Increase in bioavailability

One of the novel formulations, SS-101, resulted in a statistically significant increase in bioavailability of the drug of 43%, suggesting buccal absorption through the cheek and showed an increase of only 28% in exposure to the cardiostimulatory metabolite relative to the capsule formulation.

According to Covance, this provides evidence that a proportion of the drug from formulation SS-101 reaches the bloodstream by crossing the lining of the cheek and suggests that a lower dose of anagrelide could be administered to cancer patients.

"Exciting development"

Project director Dr Richard Franklin said: "This is a very exciting development for the project.

"While we were hoping that all three of the oral spray formulations tested would have superior properties to the capsule form of the drug, we are delighted that one formulation, in particular, showed evidence of buccal absorption, increased bioavailability and reduced exposure to the cardiostimulatory metabolite."

The other two formulations, EF-164 and EF-169, displayed a 27% increase and an 8% decrease in bioavailability over the capsule, respectively.

Price: 0.04

Market Cap: $12.27 m

1 Year Share Price Graph

Share Information

Code:	SUD	
Listing:	ASX	
52 week	**High**	**Low**
	0.097	**0.0245694**
Sector:	**Medical technology & services**	
Website:	**www.sudapharma.com**	

Company Synopsis:

SUDA Pharmaceuticals Ltd (ASX:SUD) is a drug delivery company focused on oro-mucosal administration. The Company is developing low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals.

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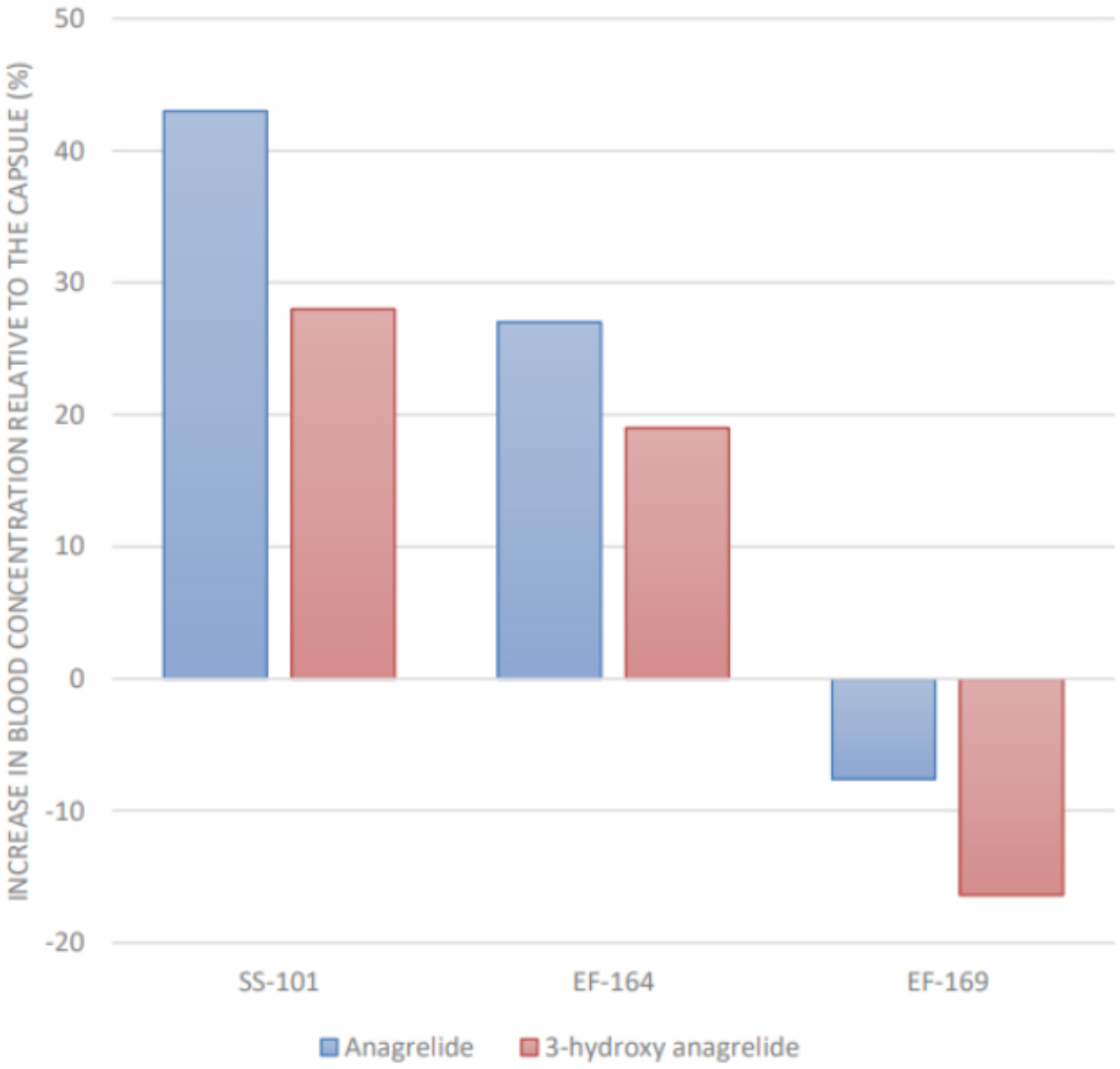

Formulation SS-101 displayed a statistically significant increase in bioavailability over the capsule of 43%.

Treatment of metastatic disease

SUDA is developing anagrelide for the treatment of metastatic disease in patients who have certain solid tumour cancers.

Clinical experience has shown that increased platelet numbers associated with several solid tumour cancers decrease progression-free life expectancy.

Furthermore, anagrelide not only advantageously lowers blood platelets but it has also been shown to inhibit cancer cell movement towards platelet-producing cells, megakaryocytes, principally found in the bone marrow but also the lung, two likely sites of metastases.

Anagrelide has already been approved for the treatment of Essential Thrombocythemia (ET), in which patients have elevated platelet numbers and are at risk of thrombosis.

Oral spray benefits

A limiting factor for the widespread use of anagrelide in cancer in its current capsule form is the production of a cardiostimulatory metabolite that is generated during first-pass metabolism of the drug in the liver.

SUDA has shown that using one of its novel oral spray formulations, a proportion of the drug reaches the bloodstream by crossing the buccal membrane in the mouth, enabling increased levels of the drug to reach the bloodstream directly, while reducing the relative exposure to the cardiostimulatory metabolite that is generated.

This supports SUDA's hypothesis that such a novel formulation of anagrelide may serve as a safer way to treat metastatic disease in cancer patients.

Next steps

SUDA will continue to optimise formulation SS-101 to ensure its stability and to produce a pharmaceutical-grade product.

Once the final formulation has been established, SUDA intends to complete the required pre-clinical toxicology studies prior to initiating clinical trials.

As the drug itself has previously been approved by both the FDA and the EMA for ET, it is anticipated that a reduced package of preclinical testing will be required for the development of an oral spray version of anagrelide.

As of June 30, 2020, and taking into account a recent capital raising, SUDA had a solid cash position of $4.9 million which will be used to develop anagrelide.

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