

ID # 281327



82-34866



**SOLBEC
PHARMACEUTICALS LTD**

RECEIVED

2005 NOV 23 P 2:59

OFFICE OF INTERNATIONAL
CORPORATE FINANCE

**SOLBEC'S CORAMSINE® RECEIVES ORPHAN DRUG
DESIGNATION FROM THE FDA**

SUPPL

Summary

Coramsine® receives Orphan Drug Designation for the treatment of metastatic Renal Cell Carcinoma from the United States Food and Drug Administration

Perth, Australia. 11 November 2005: Solbec Pharmaceuticals Limited (ASX: SBP) today announced that it has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for its lead anti-cancer compound Coramsine® for the treatment of metastatic renal cell carcinoma.

Solbec's strategy is to pursue an aggressive timeline to advance Coramsine® to the market within 3-5 years. This will be achieved by targeting orphan drug indications such as metastatic renal cell carcinoma. Orphan drug status is a useful method for compressing the clinical development timeframe from 5-9 years down to as little as 2-3 years. Other benefits include: market protection upon registration (7 years against generic products), a reduction in clinical data required for product registration, tax incentives and reduced filing fees.

In granting orphan drug status for Coramsine®, the FDA is essentially acknowledging Coramsine's® potential ability to improve the currently low survival rate of metastatic renal cell carcinoma. Coramsine's® proposed new mode of action has the potential to redefine cancer chemotherapy for advanced stage cancers such as renal cell carcinoma.

"Receiving orphan drug designation for Coramsine® is an important step forward in Solbec's mission to expedite the clinical development program of Coramsine®." said Stephen Carter, Solbec's Managing Director. "Orphan drug designation has the potential to markedly reduce Coramsine's® drug registration timeframe and ultimately time to market."

In addition to the potential benefits of orphan drug designation, targeting renal cell carcinoma allows Solbec the opportunity to apply to the FDA for "Fast Track" review of Coramsine's® clinical dossier. Once registered, Coramsine's® clinical development program may then be expanded to demonstrate its efficacy in treating an extensive range of cancer types.

(end)

PROCESSED

NOV 23 2005 E

THOMSON
FINANCIAL

Handwritten signature and date: Jlw 11/23

Further information:

Stephen Carter CEO/Managing Director Tel: (08) 9446 7555 Mob: 0412 154 029 Email: stephen.carter@solbec.com.au	Media: Justine Lamond Tel: (02) 9237 2800 Email: jlamond@bcg.com.au
--	--

About Solbec

Solbec Pharmaceuticals Ltd identifies naturally-occurring compounds with potential in the development of better therapies for debilitating conditions and life-threatening diseases. The company is currently progressing its key project, Coramsine[®], through Phase I/IIA clinical trials for the treatment of advanced solid tumours; and as a topical treatment for psoriasis. The two proprietary ingredients of Coramsine[®] were isolated from the fruit of a weed known as the Devil's Apple (*Solanum linnaeanum*). They show activity against some cancers and cause potentially therapeutic changes to the immune system. In addition to human health, Coramsine[®] has potential application to animal health and diagnostics. Solbec's business strategy is to partner or out-license Coramsine[®] for the final stages of pre-commercial development and marketing.

www.solbec.com.au