psiron
innovation in bioscience

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PSIRON'S CAVATAK™ RECEIVES ORPHAN DRUG DESIGNATION FROM THE FDA:

Psiron Limited (ASX: PSX) today announced that it has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for its lead oncolytic virus Cavatak™ (coxsackievirus A21) for the treatment of stage II (T4), stage III and Stage IV melanoma.

Psiron's strategy is to pursue an aggressive timeline to advance Cavatak™ to the market within 3-5 years. This will be achieved by targeting orphan drug indications such as melanoma. 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 Cavatak™, the FDA is essentially acknowledging Cavatak's potential ability to improve the currently low survival rate of metastatic melanoma.

"Receiving orphan drug designation for Cavatak™ is an important step forward in Psiron's mission to expedite the clinical development program of Cavatak™ said Julie Nutting, Psiron's CEO. "Orphan drug designation has the potential to markedly reduce Cavatak's drug registration timeframe and ultimately time to market."

In addition to the potential benefits of orphan drug designation, targeting melanoma will allow Psiron the opportunity to apply to the FDA for "Fast Track" review once Cavatak's clinical program is further advanced.

Cavatak™ is currently in Phase 1 studies.

For further information contact

Ms Julie Nutting
CEO
PSIRON LTD
TEL: 61 2 9889 1200