MEDIA RELEASE

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PHARMACEUTICALS

Boulos & Cooper Pharmaceuticals requests US FDA pre-IND meeting

Boulos & Cooper Pharmaceuticals, an Australian private company focussed on the development of a new class of antibiotics, has today filed a request to the US Food and Drug Administration (FDA) for a Pre-Investigational New Drug (IND) application meeting in relation to the development plan for Ramizol® indicated for the treatment of *Clostridium difficile* associated disease.

Clostridium difficile infections are among some of the most challenging infections to treat. In the United States, the bacteria is responsible for more than 250,000 hospitalisations annually, costing more than USD 4 billion in health-care expenses. The condition can be caused by the use of non-selective antibiotics and is more prevalent in individuals with a weakened immune system or those undergoing chemotherapy. The condition has been identified by the United States Center of Disease Control as an urgent threat where the development of new therapeutic drugs are in desperate need.

Ramizol® is a first generation antibiotic belonging to a new class of styrylbenzene–based antibiotics. It is a potent antioxidant, has low cytotoxicity, high thermal stability, effective in animal infection models, shows no resistance emergence, and most importantly is non-systemic.

Chief Executive Officer Dr Ramiz Boulos has said: “Discussing the developmental plan of Ramizol® with the FDA is an important milestone for us." He said: "The pre-IND meeting will provide us with clarity around our pre-clinical package and the clinical trials designs, including the registration requirements of Ramizol® for *Clostridium difficile* associated disease."

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