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Singapore: Ampio Pharmaceuticals has taken its candidate NCE001 from its proprietary methylphenidate derivatives family of compounds to preclinical development for the treatment of glioblastoma multiforme, renal cell carcinoma and inflammatory breast cancer. The move follows the granting of multiple composition of matter and use patents in the USA, Canada, Europe and China.

Ampio is a biopharmaceutical company developing re-purposed drugs and new molecular entities (NMEs) that treat inflammatory diseases, including osteoarthritis, diabetic macular edema (DME) and sexual dysfunction and conducting clinical trials on its four lead drugs (Ampion, Optina, Zertane & Zertane-ED). Ampio has entered into a development agreement with Syngene International in Bangalore, India, to manufacture and conduct all preclinical stages of development of NCE001 all the way to an IND submission to the FDA.

Dr David Bar-Or, Ampio's chief science officer, explained the focus on this particular drug. "NCE001 activates a specific intracellular phosphatase largely involved in inflammation, angiogenesis and cell proliferation pathways and has demonstrated remarkable in vitro effects on aggressive cancer cells of these three lineages. We believe it may play an important role in treating these particularly aggressive cancers," he said. The three cancers do not have adequate treatment options, so NCE001 may qualify for an accelerated approval path by regulatory agencies including the FDA, he added.

Mr Michael Macaluso, Ampio CEO, noted, "Our recent successful financing and our confidence that we will successfully out-license our more advanced drugs means we need to begin development of lead compounds to replace them. The pre-clinical

demonstration of efficacy of NCE001, the accelerated approval process, the relative low cost of development through an IND and the strong composition of matter patents recently granted worldwide make this a prudent decision at this time."