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RRx-001, a novel ROS-mediated epigenetic modulator: 'Episensitization' to previously failed therapies

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Acquired resistance to chemotherapies in cancer results in early disease progression that translates to lower survival. Resensitization of tumors to previously effective but now failed therapies is an established paradigm in ovarian cancer, which could be expanded to include other solid tumors, such as colorectal, NSCLC, SCLC and cholangiocarcinoma, leading to across-the-board improvements in patient survival and radiologic response. Although epigenetic agents hold the promise of priming tumors to subsequent chemotherapy, many agents are too toxic for chronic use. RRx-001, a novel ROS-mediated epigenetic modulator with activity against DNMTs and HDACs, is systemically non-toxic, with improvements in QOL observed in clinical trials making it an ideal candidate for 'episensitization' applications. RRx-001 resensitization was observed in phase 1 and is being investigated in multiple Phase 2 studies: "ROCKET" is a two stage clinical study in metastatic colorectal cancer investigating resensitization to irinotecan-based therapies. Patients who previously responded, then progressed on irinotecan-based therapies are randomized to receive RRx-001 (1x week) or regorafenib (target ~190 pts.) until progression or unacceptable toxicity (Stage 1). Patients then receive irinotecan-based therapies (stage 2). The primary endpoint is overall survival with secondary endpoints to investigate resensitization. The trial is continuing. RRx-001 patients entering stage 2 are showing improving survival, marked CEA decreases and radiological responses. In contrast, regorafenib patients eligible for stage 2 were too systemically unwell to proceed. Early results suggest that RRx-001 may resensitize patients to irinotecan-based therapies and appear to be generalized, potentially translating to increased overall survival.

Biography

Jan Scicinski has 30 years experience in the pharmaceutical and biotech industries in drug discovery and development. He is Senior VP & Chief Scientific Officer at EpicentRx, Inc., leading drug discovery, basic research and preclinical development efforts. He oversees regulatory affairs, CMC and QA. Prior to EpicentRx, he held leadership positions in research on drug delivery and discovery at DURECT and ALZA and in drug discovery and chemical technology at Nuada and GSK. He holds a BSc degree from Imperial College, London and a PhD from Cambridge University and has co-authored over 90 peer-reviewed publications, abstracts and book chapters.

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