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Karen L Smith

Jazz Pharmaceuticals, USA

Liposomal encapsulation for improved drug delivery and patient outcomes

Vyxeos (cytarabine:daunorubicin) liposome for injection, also known as CPX-351, is a nano-scale co-formulation of cytarabine and daunorubicin at a synergistic 5:1 molar ratio. Vyxeos represents a novel approach to developing combinations of drugs in which molar ratios of two drugs with synergistic anti-tumor activity are encapsulated in a nano-scale liposome in order to maintain the desired ratio following administration. The FDA granted Breakthrough Therapy designation to Vyxeos for the treatment of adults with therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC). Vyxeos was granted orphan drug status for the treatment of AML by the FDA and the European Commission. Vyxeos was also granted Fast Track designation for the treatment of elderly patients with secondary AML by the FDA. Taking two cytotoxic agents that are currently standard of care (known as 7+3) and encapsulating into a liposomal formulation produced statistically significant results with a 3.6 month improvement in favor of Vyxeos. The hazard ratio (HR) was 0.69 ($p=0.005$), which represents a 31% reduction in the risk of death versus 7+3. This review will focus on the potential for drug liposomal encapsulation and utilizing this approach for better patient outcomes.

Biography

Karen L Smith joined Jazz in 2015 as Global Head R&D and CMO and is also a member of Jazz' Executive Committee. She Chairs the R&D Development and Portfolio Committees and is accountable for the strategy and execution of all pre-clinical and clinical programs, overseeing staff in the UK, Ireland, Canada and the USA. She brings significant experience running large R&D organizations and has previously held a variety of physician executive and R&D positions in Australia, Japan, Canada, Europe and the US, working for companies including Bristol-Myers Squibb, AstraZeneca and Allergan. She has been extensively involved in launch planning/execution as well as business development, including numerous acquisitions, integrations and joint venture deals. Her experience also extends across several patent litigation proceedings. During her 20 years in industry, she has been instrumental in over 15 major drug and device product approvals in multiple therapeutic areas including cardiology, oncology, neuroscience/CNS, hematology, anti-infectives, rheumatology, dermatology, diabetes/metabolics and aesthetic medicine. She is also a published Scientist, Reviewer for several clinical journals, and has been an Advisor for various academic, government and corporate entities including the Institute of Medicine and PhRMA. Her qualifications include an MD degree in Cardiology, PhD in Molecular Genetics and Breast Cancer, an MBA, and a Master's in Law. She has Board experience on both private and public companies as well as not-for-profits, and is currently a Board Director for Forward Pharma (NASDAQ: FWP) and on the Advisory Board for Ironman Inc.

Karen.Smith@jazzpharma.com