OMICS Group Conferences
Accelerating Scientific Discovery

2nd World Congress on
Cancer Science & Therapy

September 10-12, 2012 Hilton San Antonio Airport, USA

Safety and efficacy of non-pegylated liposomal doxorubicin (NPLD) at two different dose levels as compared to conventional doxorubicin in patients (pts) with metastatic breast cancer (MBC): A phase II/III open label multicentric randomized trial

R. H. Jani[1], D. D. Gambhire[1], G.V. Daftary[2], H. Panchal[3], M. Basade[4] and C. Tamane[5]
[1]Clinical Research & Development, Cadila Healthcare Limited, India, [2]Zydus BSV Pharma Pvt. Limited, India, [3]Gujarat Cancer Research Institute, India, [4]Jaslok Hospital, India, [5]Seth Nandlal Dhoot Hospitals, India

This study evaluates safety and efficacy of NPLD (Nudoxa®) in Indian pts, and is being conducted in two parts. We report Part A of study that aimed to determine overall response rate (ORR) to Nudoxa® (60 and 70 mg/m^2) in target lesions of MBC using RECIST criteria. Part B of the study is ongoing and will evaluate selected dose of Nudoxa® in determining its safety and efficacy in treatment of MBC compared to conventional doxorubicin.

Female pts aged ≥18 years with ECOG status ≤2, histologically confirmed MBC with at least one measurable lesion as determined by RECIST criteria and life expectancy of minimum 6 months were included. Pts were randomized in 1:1 to 60 mg/m^2 (n= 7) or 70 mg/m^2 (n= 6) of Nudoxa®. The ORR was evaluated as complete response (CR) and partial response (PR) in target lesions.

In 70 mg/m^2 and 60 mg/m^2 group, the ORR (target lesions) was 66% (4/6) and 16% (1/6), respectively (Table).

NPLD dose (mg/m^2)	No. of randomised pts (N)	No. of evaluated pts (N)	CR	PR	SD	PD	ORR (CR+PR)
60	7	6	0	1	4	1	1
70	6	6	1	3	1	1	4

All adverse events were resolved with or without treatment. No death, cardiotoxicity, and hand-foot syndrome (Palmer Planter Erythrodysesthesia) were reported.

Nudoxa® at 70 mg/m2 appeared more effective than 60 mg/m2 with ORR as primary endpoint. This dose is being evaluated in Part B of study in 70 MBC pts in comparison with 70 mg/m2 conventional doxorubicin.

Biography

Dr. Rajendra Jani earned doctorate in pathology and bacteriology. Currently he is working as Head and Senior Vice President, Clinical R&D at Zydus Cadila. He is responsible for clinical research development program (Phase 1-4) with emphasis new drug discovery. He was also a key team member, which clinically developed first orally acting drug, miltefosine, for the treatment of Kala Azar.

rhjani@zyduscadila.com