



Preclinical Study Results of LBI-1103

LUMINUS has completed several key preclinical studies, including a maximum tolerated dose (MTD) study, a pharmacokinetics study, and biological activities in a breast tumor xenograft model, and in a pancreatic tumor xenograft model. Results, discussed in detail below, show LBI-1103 vs. Taxotere[®] has significantly greater anti-tumor activity with potentially reduced toxicity.

1. Maximum Tolerated Dose (MTD) Determination

Recently, the COMPANY conducted an MTD study of LBI-1103 in mice. The primary goal was to determine the relative MTD compared to Taxotere[®]. The MTD is defined as the highest dose that did not produce either: (1) > 20% reduction in weight for > 7 days, or (2) > 10% mortality. The study showed that LBI-1103 was significantly more tolerable compared to Taxotere[®]. The observed MTD for LBI-1103 was at > 24.5 mg/kg compared to 12 mg/kg for Taxotere[®]. The animals well-tolerated LBI-1103 with no drug-related deaths at 24.9 mg/kg, whereas Taxotere[®] at the same dose concentration experienced 100% drug related deaths.

2. Pharmacokinetics Study

The PK results for LBI-1103 demonstrate a linear dose-dependent increase in docetaxel levels in plasma (Figure I). The maximum drug concentration (C_{max}) (Table I) and area under the curve (AUC) are approximately twofold greater for LBI-1103 compared to Taxotere[®] at the same dose concentration (Figure II). Also, LBI-1103 demonstrated a slower rate of clearance from plasma, correlating to significantly lower total tissue distribution (Figure III), consistent with the observation of a better-tolerated product shown in the MTD studies.

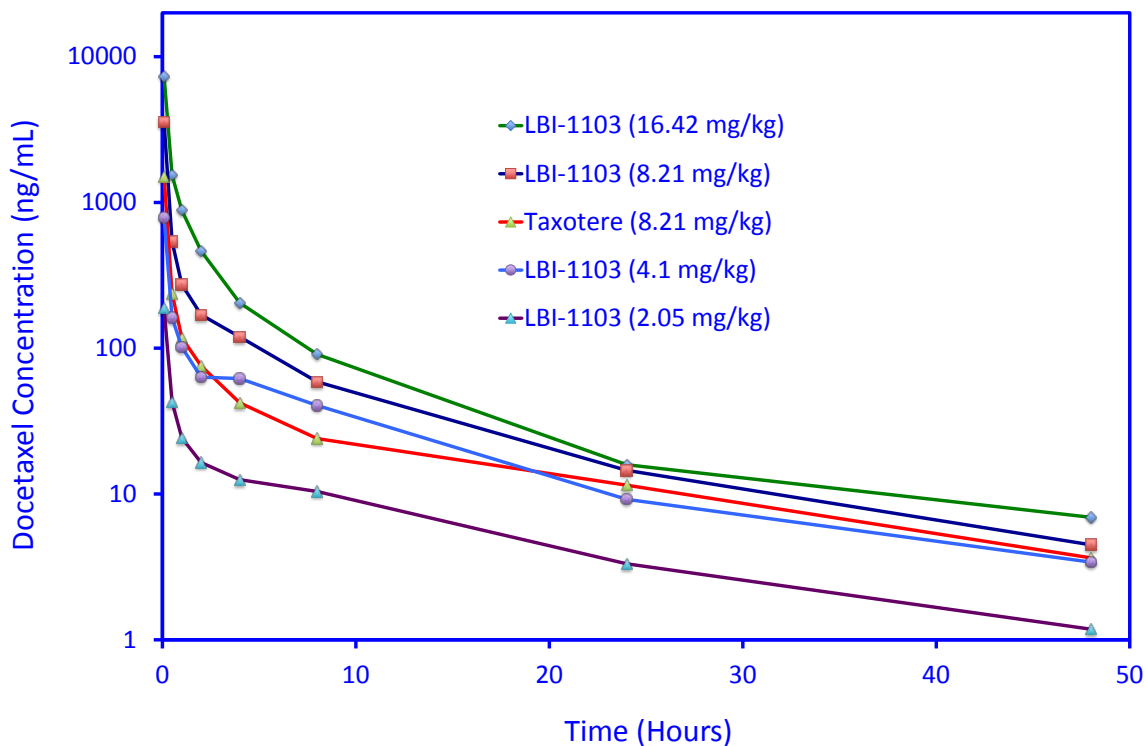


Figure I: Pharmacokinetic profiles of LBI-1103 and Taxotere® showing mean whole blood docetaxel concentration at various doses of LBI-1103 and a single dose of Taxotere® versus time

Table I: Summary of pharmacokinetic parameters for LBI-1103 compared to Taxotere®

Test Article	Dose (mg/kg)	AUC _{0-∞} (h*ng/mL)	AUC ₀₋₂₄ (h*ng/mL)	D_AUC _{0-∞} (*kg*ng/mL/m)	C _{max} (ng/mL)	D_C _{max} (kg*ng/mL/m)	T _{max} (h)	t _{1/2} (h)	CL (mL/h/kg)	Vd (mL/kg)
Taxotere®	8.21	1186.6	1254.4	152.8	1517.9	184.9	0.22	13.55	6997.9	137116
	2.04	308.48	331.5	161.7	195.64	94.9	0.22	13.1	6343.9	118033
LBI-1103	4.1	1133.31	1185.6	289.2	808.5	197.2	0.22	11.7	3460.6	58858
	8.21	2554.7	2607.2	317.8	2544.7	431.8	0.06	9.55	2162.8	43164
	16.42	5220.1	5291.5	322.3	7316.1	445.6	0.08	9.26	3151.1	41704

Luminus Biosciences, Inc. is sole owner of this study and the findings are intended to demonstrate Luminus scientific expertise and use only for its applications. The study is protected by our patent and considered intellectual property. Any infringements will be subject to legal action.

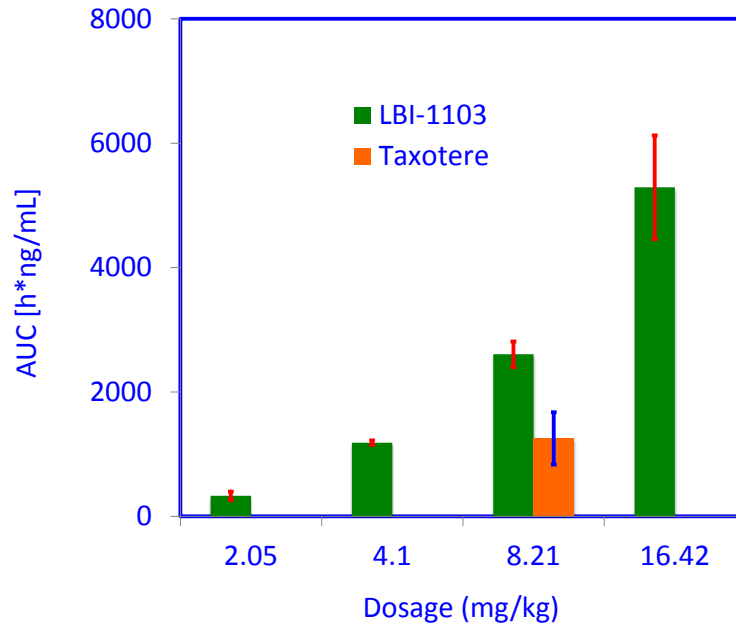


Figure II. Correlation between the mean $AUC_{0-\infty}$ and dose level for LBI-1103 and Taxotere[®]

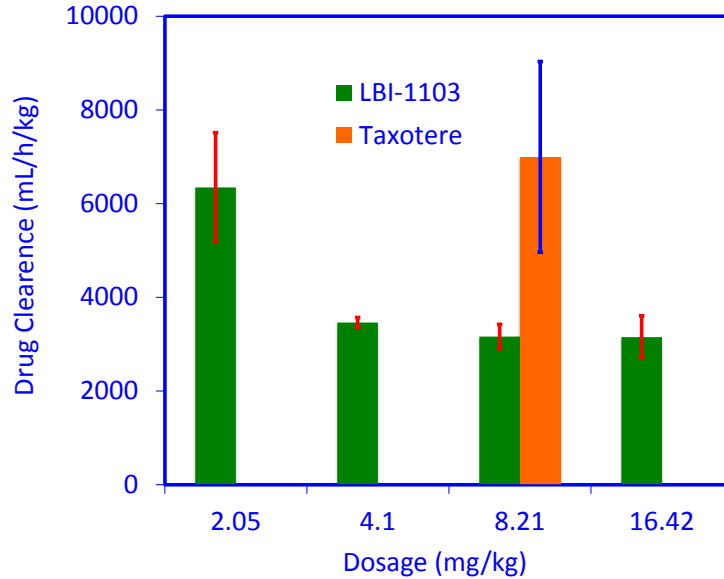


Figure III. Correlation between the mean drug clearance and dose level for LBI-1103 and Taxotere[®]

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3. Preclinical Xenograft Studies

To further differentiate and benchmark LBI-1103 to the standard docetaxel formulation, LUMINUS completed two xenograft studies to evaluate biological activity using research grade drug material.

LUMINUS completed the anti-tumor efficacy studies of LBI-1103 in the MDA-MB-468 xenograft model as compared to Taxotere[®] and in the PANC-1 xenograft model as compared to Taxotere[®] and Gemcitabine. The controls and LBI-1103 were injected intravenously once every other day for three treatments except for the Gemcitabine treated PANC-1 xenograft animals, which received Gemcitabine once every third day for three treatments.

In the MDA-MB-468 xenograft models, the animals were dosed once every other day for three treatments and then observed for two weeks. Animals showed a significant reduction in the tumor volume after Day 1 of dosing and the trend continued until the end of the study for animals treated with LBI-1103, 12mg/kg, and 24.5mg/kg. None of the animals exhibited tumor regrowth, two weeks after the completion of LBI-1103 dosing.

However, in animals treated with Taxotere[®] (12mg/kg) showed tumor regrowth two weeks after the completion of dosing. On the last day of study, animals treated with LBI-1103 (25.4 mg/kg) exhibited a tumor regression by 97.4% and those treated with LBI-1103 (12 mg/kg) showed a reduction by 75.4% of the mean tumor volume compared to the respective mean tumor volume on day 1 (Figure IV).

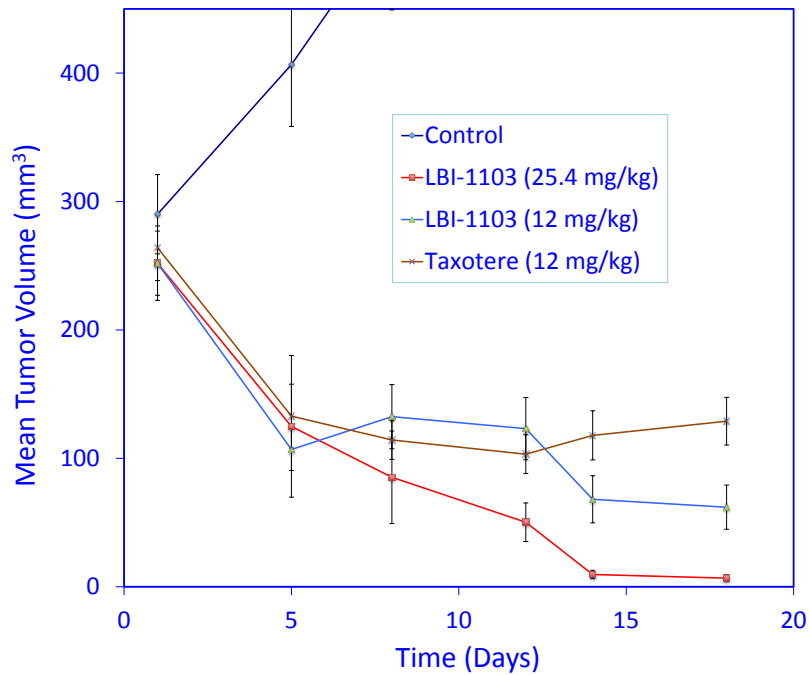


Figure IV: Mean Tumor Volume (mm³) in MDA-MB-468 Xenograft Model (Q2DX3 Dosing Challenge)

In animals with the PANC-1 xenografts and treated with LBI-1103, Taxotere[®] and Gemcitabine, showed a significant reduction in tumor volume after the first day of dosing, and the trend continued until the end of the study (Figure V). After Day 15 of the study, three animals treated with LBI-1103 (24.5mg/kg), and one animal each from LBI-1103 (12mg/kg) and Taxotere[®] (12mg/kg) showed a complete regression of the tumor. None of the animals exhibited tumor regrowth, two weeks after the completion of dosing. On the last day of study, animals treated with LBI-1103 (25.4 mg/kg), LBI-1103 (12mg/kg), Taxotere[®] (12mg/kg) and Gemcitabine (28mg/kg) showed a tumor regression by 97.4%, 84%, 79% and 73%, respectively, of the mean tumor volume compared to the respective mean tumor volume on Day 1 (Figure V).

The results suggest that LBI-1103 is highly effective against both MDA-MB-468 human breast and PANC-1 human pancreatic tumor models. In comparison to docetaxel, LASSN[™] technology allows for the administration of higher doses of LBI-1103, producing enhanced antitumor activities in these models.

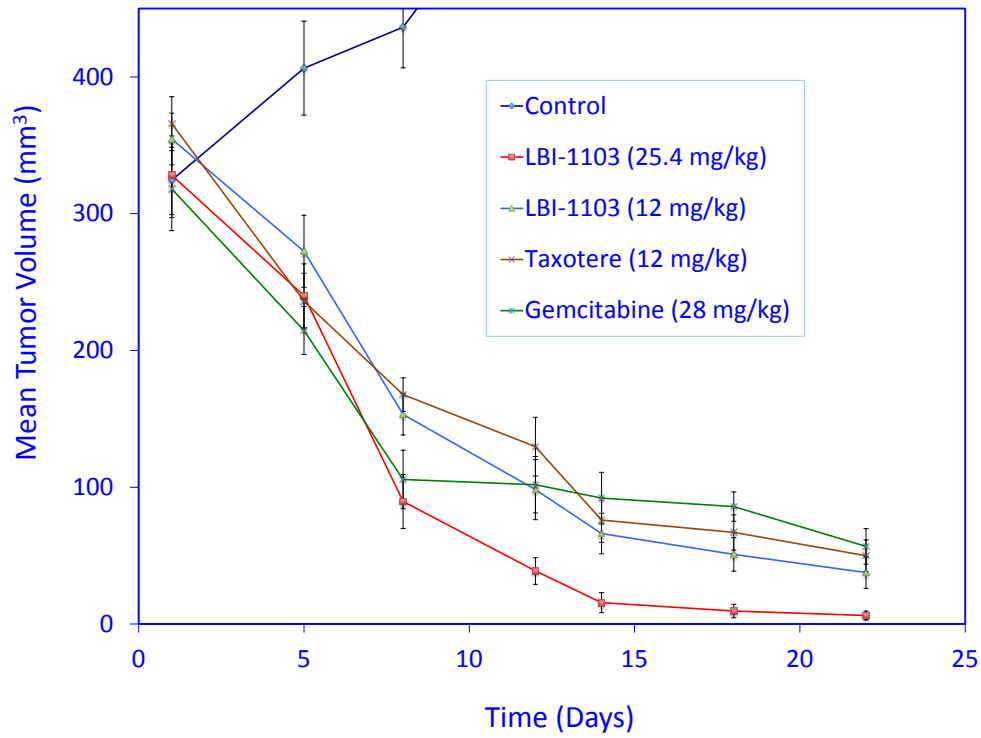


Figure V: Mean Tumor Volume (mm³) in PANC-1 Xenograft Model (Q2DX3 Dosing Challenge)

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