European LeukemiaNet
SHORTPROTOCOL
BUM-5/GVH

Public Title	Efficacy and Safety Study of Budesonide to Treat Oral Chronic GvHD
Scientific Title	Double-blind, Randomised, Placebo-controlled Multicentre Phase III Clinical Study Followed by Open-label Phase on the Efficacy and Tolerability of Budesonide 3 mg Effervescent Tablet in Patients With Resistant Oral Chronic GvHD
Short Title	BUM-5/GVH
Id KN/ELN	LN_NN_2009_503
Trialgoup	NN
Type of Trial	multicentric, randomized, prospective, double-blind, double-group
Phase	Phase III
Disease	Miscellaneous(Miscellaneous) Supportive Care
Stage of Disease	not specified / all stages
Outcomes	- Rate of patients with objective response [12 weeks] (Primary Outcome) - Rate of complete/partial response, stable disease, progressive disease [12 weeks] - Time to initial objective response - Rate of subjective improvement [12 weeks]
Inclusion Criteria	- Karnofsky >= 70 - Oral chronic GvHD after allogeneic haematopoietic stem cell transplantation - Oral cGvHD of erosive and/or ulcerative type - NIH scale >= 3 - Resistant oral cGvHD with no oral response to conventional primary treatment
Exclusion Criteria	- Uncertain diagnosis of resistant oral cGvHD - Symptomatic oral cGvHD of hyperkeratotic type solely - Current active oral bacterial, viral, or fungal infection - Unwilling to forego concurrent treatment for mucosal lesions and/or related oral pain - Requiring addition of new systemic therapy including steroids, or radiation therapy - Local intestinal infection - Abnormal hepatic function or liver cirrhosis - If careful medical monitoring is not ensured: tuberculosis, cardiovascular disease, diabetes mellitus, osteoporosis, active peptic ulcer disease, glaucoma, cataract, infection - Second line treatment of oral cGvHD with topical steroids
Age	<= 75 years
Status	No longer recruiting
start of Recruitment	01.04.2009
Recruiting countries	Germany Israel
Target Sample Size	225
Leader	Wolff, Prof. Dr., Daniel Universitätsklinikum Regensburg Hämatologie und internistische Onkologie Tel: +49 (0)941 944-5531 Fax: +49 (0)941 944-5543 Email: Daniel.Wolff@ukr.de
Sponsors	Dr. Falk Pharma GmbH (Main Sponsor)

Other Registers	ClinicalTrials.govNCT00887263 (Primary Register) European Clinical Trials Database - EUDRACT2008-004562-10