

PATIENT REGISTRY

Registry on Hypomethylating Agents in Myeloid Neoplasms, including Myelodysplastic Syndromes (MDS), Chronic Myelomonocytic Leukemia (CMML) and Acute Myeloid Leukemia (AML)

Protocol Number: AGMT_HMA Reg

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Protocol Synopsis:

Indication:	Myeloid Neoplasms, including MDS, CMML, AML	Objectives:	Number of Cycles and Dosage of VIDAZA® and/or DACOGEN® therapy
Design:	Retrospective and prospective, observational, multi-center, multi-national research initiative		Response evaluation
Recruitment:	First patient in (FPI): Q1 2009		Toxicities
Number of patients:	1500 (planned)		Severe adverse reactions
			Overall survival
			Prognostic factors for overall survival and response

Design:

This registry is set up to collect real-world experience in the management of patients with myeloid neoplasms, in particularly in patients with MDS, CMML or AML, treated with hypomethylating agents in Austria and potentially other participating countries. This registry will collect data in a retrospective as well as in a prospective manner at various sites. The aim is to gain valuable insights on both efficacy and toxicity of these drugs in a routine clinical setting in patients with various comorbidities.

An estimated 1500 patients are expected to be included; these numbers may be revised over time as interest and demand dictates. No pre-defined visits, medical tests, laboratory tests, procedures, or interventions are required. Physicians who have already treated patients with hypomethylating agents or are planning to initiate treatment with hypomethylating agents can include patient data in this registry. Electronic Case Report Forms (eCRF) will be used for data collection.

Additionally from some patients with myeloid neoplasms, blood or tissue samples will be stored for further analyses. These samples will also be obtained from patients, who are not or not yet treated with hypomethylating agents, to comprise a control.

Recruitment:

Between February 2009 and March 2017 a total of 1030 patients at 20 sites have been documented in this registry.

No	Sites	Patients
01	Uniklinik PMU Salzburg	264
02	Uniklinik Graz	102
03	Klinikum Wels Grieskirchen	104
04	Uniklinik Innsbruck	91
05	Elisabethinen Linz	92
06	Wilhelminenspital Wien	41
07	Hanusch KH Wien	75
08	LKH Feldkirch	49
09	LKH Hochsteiermark	39
10	KH Hietzing	26
11	KH Klagenfurt	14
12	AKH Wien	13
13	LKH Fürstenfeld	12
14	Kepler Uniklinik, Med Campus III.	29
15	LKH Steyr	8
16	Rudolfsstiftung	3
17	SMZ Ost	47
18	UK Krems	9
19	BHS Linz	1
20	Clinical Hospital Mekur, Zagreb	11
	TOTAL	1030

Publications:

Pleyer L, Dohner H, Dombret H, Seymour JF, Schuh AC, Beach CL, et al. Azacitidine for Front-Line Therapy of Patients with AML: Reproducible Efficacy Established by Direct Comparison of International Phase 3 Trial Data with Registry Data from the Austrian Azacitidine Registry of the AGMT Study Group. International journal of molecular sciences. 2017;18(2).

Pleyer L, Burgstaller S, Stauder R, Girschikofsky M, Sill H, Schlick K, et al. Azacitidine front-line in 339 patients with myelodysplastic syndromes and acute myeloid leukaemia: comparison of French-American-British and World Health Organization classifications. J Hematol Oncol. 2016;9:39.

Pleyer L, Burgstaller S, Girschikofsky M, Linkesch W, Stauder R, Pfeilstocker M, et al. Azacitidine in 302 patients with WHO-defined acute myeloid leukemia: results from the Austrian Azacitidine Registry of the AGMT-Study Group. Annals of hematology. 2014;93(11):1825-38.

Pleyer L, Germing U, Sperr WR, Linkesch W, Burgstaller S, Stauder R, et al. Azacitidine in CMML: matched-pair analyses of daily-life patients reveal modest effects on clinical course and survival. Leukemia research. 2014;38(4):475-83.

Pleyer L, Stauder R, Burgstaller S, Schreder M, Tinchon C, Pfeilstocker M, et al. Azacitidine in patients with WHO-defined AML – Results of 155 patients from the Austrian Azacitidine Registry of the AGMT-Study Group. Journal of Hematology & Oncology. 2013;6(1):1-13.