

## PATIENT REGISTRY

### Metastatic breast cancer in Austria

Protocol Number: AGMT\_MBC-Registry

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#### Protocol Synopsis:

<b>Indication:</b>	Metastatic breast cancer	<b>Primary Endpoints:</b>	Epidemiology
<b>Planned sample size:</b>	1500 - 3000		Therapies
<b>Design:</b>	Retrospective and prospective, observational, multicenter research initiative		Response
<b>Recruitment:</b>	First patient in (FPI): Q2 2015		Survival
			Predictive factors

#### Rationale:

Breast cancer is the most common cancer among women worldwide. More than 5,000 cases are diagnosed in Austria each year (STATISTICS AUSTRIA, Austrian cancer registry as at 24.09.2012). Of these, already 5% to 10% have distant metastases at the time of initial diagnosis, and up to 30% of the node-negative tumours and up to 70% of the node-positive tumours metastasise at a later date. Metastatic breast cancer has not been systematically assessed in Austria to date. This medical registry of the AGMT is thus the first Austrian-wide standardised documentation of this disease.

#### Design:

This registry is a prospective and retrospective, multicentre collection of data on patients with metastatic breast cancer in Austria. All tumour characteristics, medical histories and also treatment sequences are documented in anonymised form. For documentation in the registry, no further diagnostic or therapeutic measures are required than those already necessary in general. Participation in the registry must not interfere with treatment routines. A written consent must be obtained prior to the input of data. No informed consent is required from deceased patients.

#### Objectives:

##### Epidemiological evaluations:

- General characteristics of metastatic stage patients in Austria
- Assessment of metastatic stage breast cancer subtypes in Austria
- Assessment of the specific characteristics and frequency of metastatic breast cancer
- Data on survival of female patients with metastatic breast cancer in Austria

##### Therapy-specific evaluations:

- Assessment of metastatic breast cancer therapies in Austria
- Assessment of therapy response outside clinical studies (first-line therapy, second-line therapy and third and higher lines of therapy)

##### Specific questions:

Specific questions are also investigated, such as the frequency of histology preparations from metastases, the frequency of histological discrepancies between primary tumour and metastasis, the importance of metastasis surgery and operation of the primary tumour in primary metastatic breast cancer.

#### Data Input:

*Prospective:* The focus of the AGMT\_MBC registry is on the prospective assessment of patients with metastatic breast cancer who have given their consent to participation in the registry. The input of prospective data will be performed by all sites.

*Retrospective:* Every site may also enter patient data retrospectively. "Retrospective" is defined as metastatic disease having been determined before 01.01.2015.

#### Inclusion Criteria:

- Histological evidence of breast cancer
- Histological and/or radiological evidence of metastases
- Metastasis within 10 years of registry initiation
- Signed informed consent (if a patient has already died at the time of entry, the entry can be made without a declaration of consent)

Due to the non-interventional design of the registry there are no specific inclusion or exclusion criteria.

#### Recruitment (Status as of March 2017):

No	Sites	Patients
01	PMU Salzburg / III Med.	412
02	UK Innsbruck / Gynäkologie	41
03	Klinikum Wels Grieskirchen / Med. IV	52
04	Kepler UK, Med Campus III./ Interne 3	37
05	KH Kufstein / Interne II	22
06	LKH Feldkirch / Interne E	33
07	AKH Wien/ Gynäkologie	13
08	BHS Linz / Interne I	46
09	LKH Steyr / Med II	1
10	UK Graz / Innere Med.	0
	<b>TOTAL</b>	<b>657</b>