Phase 1 study to evaluate the feasibility and efficacy of the addition of P1101 (PEG-Proline-Interferon alpha-2b) to imatinib treatment in patients with chronic phase chronic myeloid leukaemia not achieving a complete molecular response

Protocol Number: AGMT_CML 1
EudraCT Number: 2013-000115-24

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Protocol Synopsis:

Indication: Pretreated BCR-ABL positive chronic myeloid leukaemia in chronic phase

Study design: Uncontrolled, open-label phase I pilot study

Planned sample size: 12 patients

Duration: First patient in (FPI): Q3 2013
Last patient in (LPI): Q2 2018 (expected)
Last patient out (LPO): Q4 2019 (expected)

Study medication: P1101 (PEG-P-IFNα-2b)

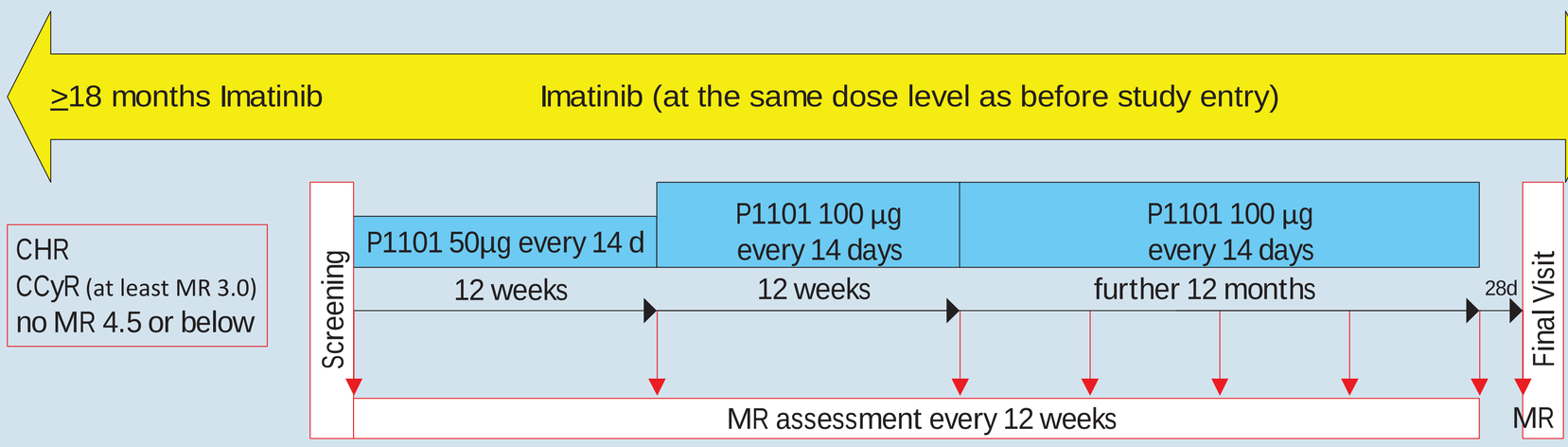
Primary objective:

To determine the safety and tolerability of the addition of P1101 to the currently established dose of Imatinib.

Secondary objectives:

To determine the rate of achievement of ≥ 1 log reduction from the initial BCR-ABL transcript level at study entry and the achievement of molecular remission 4.5 or undetectable BCR-ABL transcripts.

Study Design:



P1101:

P1101 is a new formulation of pegylated interferon alpha-2b.

It will be administered subcutaneously every 14 days.

Due to the new formulation a better tolerability is suspected.

Dosing Regimen:

P1101

P1101 will be added in a dose of 50µg subcutaneously every 14 days. In the absence of a dose limiting toxicity (DLT) at 12 weeks the dose of P1101 will be increased to 100µg subcutaneously every 14 days. 100µg P1101 is considered as the maximum dose, further increase of P1101 is not planned. Maximum treatment duration will not expand 18 months.

DLT

DLT is defined as adverse event grade ≥ 3.

Imatinib

Imatinib will be continued at the same dose level as before study entry. Dose modifications are limited to interferon therapy.

Inclusion Criteria (Selected):

Patients ≥ 18 years of age.

BCR-ABL positive chronic myeloid leukaemia in chronic phase treated with Imatinib as first line therapy.

CHR, CCyR after at least 18 months of Imatinib treatment.

No CMR (molecular remission 4.5 or BCR-ABL transcripts undetectable).

Patient hasn't received any other investigational treatment within 28 days before study entry.

No treatment with a second generation tyrosine kinase inhibitor (Dasatinib, Nilotinib).

No evidence of severe or uncontrolled systemic disease (e.g. unstable or uncompensated respiratory, cardiac, hepatic or renal disease etc.).

No acute chronic infections.

No known autoimmune disease (e.g. collagen disease, polyarthritis, immune thrombocytopenia, thyroiditis, psoriasis, lupus nephritis or any other autoimmune disorder).

Recruitment:

No	*Sites*	*Initiation*	*Patients*
01	Klinikum Wels Grieskirchen / Med. IV	15.07.2013	3
02	PMU Salzburg / III Med.	24.09.2013	2
03	UK Innsbruck / Med. V	23.10.2014	2
04	AKH MUW / Med. I Hämatologie	18.12.2015	0
05	KH Elisabethinen Linz / I Interne	19.10.2016	1
	TOTAL		**8**

Status as of March 2017

An academic clinical trial
Sponsor: Arbeitsgemeinschaft medikamentöse Tumortherapie gemeinnützige GmbH, Clinical-Scientific Director: R. Greil