

## **Abstract: P666**

### **Title: 1 YEAR RESULTS OF DASATINIB 70MG/DAY VERSUS 100MG/DAY IN NEWLY DIAGNOSED PATIENTS WITH CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE(CML-CP):A PROSPECTIVE RANDOMIZED CONTROLLED STUDY.**

#### **Abstract Type: Poster Presentation**

#### **Session Title: Chronic myeloid leukemia - Clinical**

#### **Background:**

Dasatinib 100mg/d first-line for patients with chronic myeloid leukemia has a positive effect, but the side effects cannot be ignored. 2 single-arm phase 2 clinical studies using dasatinib from 100mg/d to 50mg/d were carried out in Japan and the study exploring the optimal trough concentration of dasatinib in South Korea. At present, research on the first-line low-dose dasatinib treatment of CML is in the ascendant.

#### **Aims:**

In this study, we compared the efficacy and adverse effects of dasatinib 70 mg/day versus standard dose 100 mg/day in patients with newly diagnosed CML-CP. Primary endpoints: 12-month rate of complete cytogenetic response (CCyR) and major molecular response (MMR); Secondary endpoints: 1) The proportion of patients who achieved the best efficacy at the 3rd, 6th and 12th months, refer to the ELN guidelines; 2) 12-month MMR and MR 4.0 rates; 3) Drug-related hematologic and non-hematologic toxicity analysis.

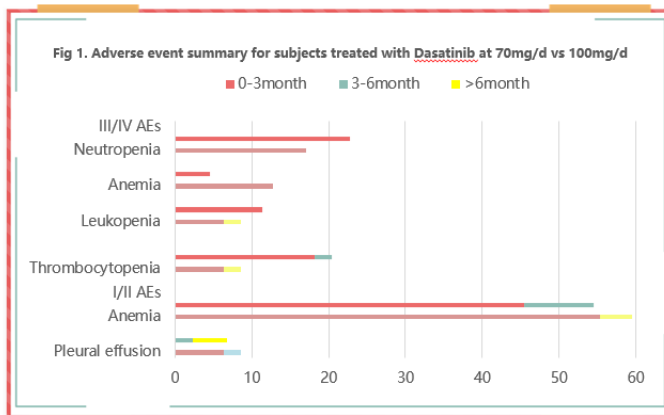
#### **Methods:**

This is a head-to-head multicenter open-label Phase IV clinical study. A total of 91 patients newly diagnosed with CML-CP Asian from Jul. 2019 to Sep. 2022 were randomly divided into dasatinib 70 mg/d group (N=47 ) and dasatinib 100 mg/d group (N=44), and the efficacy and adverse events were observed and compared between the two groups.

#### **Results:**

All 91 patients with CML-CP achieved hematologic remission at 3 months of treatment, and the best response, CCyR and MMR rates at 3mos in the 70mg/d group and 100mg/d group were 93.94% vs 88.24% , 60.61% vs 70.59% , 15.15% vs 35.29%; At 6 months, the ORR, CCyR, MMR and MR4.0 rates were 92.86% vs 83.87% , 92.86% vs. 83.87%, 53.57% vs 70.97% , 35.71% vs 32.26%; At 9 months, the CCyR, MMR rates and MR4.0 were 94.74% vs 84.00%, 63.16% vs 68.00%, 26.32% vs 44.00%. At 12 months, CCyR, MMR (best response rate), and MR4.0 were 100% vs 100.00%, 83.33% vs 83.33%, 54.17% vs. 58.33%. When the follow-up reached 12 months, CCyR, MMR (also the best response rate), and MR4.0 were 100% vs. 100.00% , 83.33% vs 83.33%, 54.17% vs. 58.33%.

Table 1. Response Rates With 3, 6, 9 and 12 Months of Dasatinib at 70mg/d vs 100mg/d				
		Dasatinib 70mg/d (N=47)	Dasatinib 100mg/d (N=44)	P值
		No. of Responses/Total (%)		
3 mo	Best response rate	31/33 (93.94)	30/34 (88.24)	P=0.4137
	CCyR	20/33 (60.61)	24/34 (70.59)	P=0.3896
	MdMR	5/33 (15.15)	12/34 (35.29)	P=0.0582
6 mo	Best response rate	26/28 (92.86)	26/31 (83.87)	P=0.2865
	CCyR	26/28 (92.86)	26/31 (83.87)	P=0.2865
	MdMR	15/28 (53.57)	22/31 (70.97)	P=0.1676
9 mo	MR4.0	10/28 (35.71)	10/31 (32.26)	P=0.7794
	CCyR	18/19 (94.74)	21/25 (84.00)	P=0.2663
	MdMR	12/19 (63.16)	17/25 (68)	P=0.7371
12 mo	MR4.0	5/19 (26.32)	11/25 (44)	P=0.2271
	CCyR	24/24 (100)	24/24 (100)	-
	MdMR*	20/24 (83.33)	20/24 (83.33)	P=1.0000
	MR4.0	13/24 (54.17)	14/24 (58.33)	P=0.7711



The most common adverse reactions were 27 cases (57.44%) of anemia grade 1/2, which did not affect the treatment of TKIs; There were 4 cases of pleural effusion, all of which were grade 1-2 adverse reactions, including 8 cases (17.02%) with neutrophil count decreased, 6 cases (12.77%) were depleted, 4 cases (8.51%) were reduced in white blood cell count, and 4 cases (8.51%) were reduced in platelet count. The most common adverse reaction of 44 patients in the 100mg/d group was anemia grade 1/2 in 24 cases (54.55%), which did not affect the treatment of TKI. There were 4 cases (9.09%) of pleural effusion, all of which were grade 1/2; Among the grade 3/4 hematological adverse reactions, the number of white blood cells decreased in 5 cases (11.36%), the number of neutrophils decreased in 10 cases (22.73%), anemia decreased in 5 cases (11.36%), and platelet count decreased in 10 cases (22.73%). Except for the increase in LDH, there was no significant difference in the incidence of AEs between the two groups ( $P > 0.05$ ).

**Summary/Conclusion:** Our study suggests that there was no significant difference in the efficacy and safety of dasatinib 70mg/d and 100mg/d in patients with CML-CP, and the dose-reduced treatment of dasatinib 70mg/d was positive and safe in Asian patients with CML for the first-line treatment.

**Keywords:** Chronic myeloid leukemia