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Spett.
Incyte Biosciences Italy S.R.L.
Via F. Filzi 25 A
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Attention
Dr. David Boy
Medical Director

Project: Use of serological testing to detect antibodies against SARS-CoV-2 evaluating the viral circulation in patients with chronic myeloid leukemia.

Final report

In the context of COVID-19, serological testing is a valuable strategy for the diagnosis and the characterization of the course of the disease. In this project, we performed serological assays against SARS-CoV-2 in a cohort of CML patients referred to the Hematology Section of University of Perugia. This study was approved by the regional ethics committee in Perugia. We analyzed human serum of CML patients using a chemiluminescent immunoassay intended for the quantitative detection of IgG antibodies to SARS-CoV-2.

A total of 98 CML patients were screened between February and May 2021 before vaccine administration. The cohort consisted of 43 women and 55 men, median age was 62.5 years (range 26 - 86 years) at the time of serological testing.

	Number of patients
Women	43
Men	55
Median age	62.5 years (26-86)
Imatinib	22
Nilotinib	13
Dasatinib	14
Bosutinib	11
Ponatinib	6
Asciminib	1
TFR	31
IgG positive	6
IgG negative	92
Median BAU/ml	586 (38.3-1290)
Total	98

From a treatment standpoint, 22 patients were treated with imatinib, 13 with nilotinib, 14 with dasatinib, 11 with bosutinib, 6 with ponatinib, 1 with asciminib and 31 were in treatment free remission. Serological evidence of progressed SARS-CoV-2 infection was present in 6 out of 98 CML patients. The median IgG levels amongst positive samples was 568 BAU/ml (range 38.3 – 1290). Out of 6 patients with IgG positivity, 5 claimed no symptoms in the preceding 14 days while 1 referred mild symptoms of COVID-19 before IgG testing. IgG positivity was detected in 2 patients under bosutinib, 1 patients under nilotinib, 1 patients under ponatinib and 2 patients in treatment free remission.

Our analysis estimated the SARS-CoV-2 exposure in a vulnerable population as CML patients allowing the identification of around 5% patients with IgG as a demonstration of SARS-CoV-2 asymptomatic infection.

Best regards

President
Stefano Dagioni

A handwritten signature in black ink, appearing to read 'Stefano Dagioni', written in a cursive style.