CAMN107AIT15 -DANTE: A phase II, single-arm, multicenter study of full treatment-free remission in patient with chronic myeloid leukemia in chronic phase treated with nilotinib in first-line therapy who have archived a sustained deep molecular response for at leats 1 year

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Sindromi MIELOPROLIFERATIVE CRONICHE target: leucemia mieloide cronica

Trattamento: Nilotinib + asciminib

Criteri inclusione:

1) Diagnosis of CP-CML according to the WHO and no previous history of progression to AP/BP CML.
2) First-line treatment with nilotinib for at least 3 calendar years, followed by first TFR attempt.
3) Failed first TFR attempt followed by at least 1 year of nilotinib retreatment before enrollment in TFR2 stage.
4) MR4 or better (BCR-ABL ≤ 0.01% IS) assessed at screening.
5) Patient must meet the following laboratory
a. Absolute neutrophil count ≥1.0 x 109/L
b. Platelets ≥75 x 109/L
c. Hemoglobin (Hgb) ≥ 9 g/dL
d. Serum creatinine < 1.5 mg/dL
e. Total bilirubin ≤ 2 x ULN except for patients with Gilbert's syndrome who may only be included if total bilirubin ≤ 3.0 x ULN or direct bilirubin ≤ 1.5 x ULN
f. AST and ALT ≤ 3.0 x ULN
g. ALP ≤ 2.5 x ULN
h. Serum lipase ≤ 1.5 x ULN.
j. Serum levels of potassium, magnesium, total calcium within the normal limits. Correction of electrolytes levels with supplements to fulfil enrolment criteria is allowed.

Criteri esclusione:

1) Patients with known atypical transcript.
2) CML treatment resistant mutation(s) (T315I, E255K/V, Y253H, F359C/V) detected if testing was done in the past (there is no requirement to perform mutation testing at study entry if it was not done in the past).
3) Dose reductions/interruptions due to neutropenia or thrombocytopenia in the past 6 months
4) History of acute pancreatitis within 1 year prior to study entry or past medical history of chronic pancreatitis
5) Patients actively receiving therapy with strong CYP3A4 inhibitors and/or inducers, and the treatment cannot be either discontinued or switched to a different medication prior to study entry.