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Inklusionskriterier

Kriterie	Beskrivelse	Ja	Nej	NA
1	Signed written informed consent form (ICF) before any procedure related to the study			
2	**Target population**			
2a	Men and women, ages 18 to 75 years			
2b	Newly diagnosed (≤ 3 months) BCR-ABL positive chronic myeloid leukemia in chronic phase			
2c	Major BCR-ABL transcripts (p210, i.e. b2a2 (e13a2) and/or b3a2 (e14a2))			
2d	Not previously treated for CML except with hydroxyurea or anagrelide			
2e	ECOG Performance Status (ECOG PS) ≤ 2			
3	**Adequate organ function**			
3a	Total bilirubin < 1,5 times the institutional Upper Limit of Normal (ULN)			
3b	Hepatic enzymes ALAT/ASAT < 2 times the institutional ULN			
3c	Serum Creatinine < 1.5 time the institutional ULN			
3d	Lipase < 1.5 time the institutional ULN			
4	Women of childbearing potential (WOCBP) must be using an adequate method of contraception to avoid pregnancy throughout the study. See Section 9.2.2. Pregnancy			
5	WOCBP must have a negative serum or urine pregnancy test at screening			
6	Free subject, without guardianship nor subordination			
7	Health insurance coverage			

Eksklusionskriterier:

Kriterie	Beskrivelse	Ja	Nej	NA
1	Patients with BCR-ABL transcript different from M-BCR-ABL			
2	Patients previously treated with Tyrosine Kinase Inhibitors (TKIs)			
3	Inability to freely provide consent through judiciary or administrative condition			
4	Ongoing participation in another clinical investigational study			

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5	**Medical history and concurrent diseases**			
5a	Hypersensitivity to any of the excipients of BOS or RoPegIFN			
5b	Prior treatment with Interferon-α, contraindication to interferon-α			
5c	Autoimmune disorder, concomitant immunosuppressive treatment or corticosteroids			
5d	Pre-existing thyroid disease unless controlled with conventional treatment, auto-immune thyroiditis			
5e	Chronic liver disease			
5f	Prior or ongoing severe psychiatric disease			
5g	HIV positivity, chronic hepatitis B or C			
5h	Uncontrolled or severe cardiac (NYHA Class III or IV) or pulmonary disease			
5h-1	Echocardiography with LVF < 45% or LLN, peak velocity of tricuspid regurgitant flow > 2,8 m/s			
5h-2	Pulmonary arterial hypertension (PAH)			
5h-3	QTc>450 ms (by Barrets correction)			
5i	Other malignant disease during the last 5 years prior to the inclusion except non-melanoma skin carcinoma or carcinoma in situ of the cervix			
5j	History of significant bleeding disorder unrelated to CML or diagnosed congenital bleeding disorder			
5k	Subjects with an uncontrolled undercurrent illness or any concurrent condition that, in the investigator's opinion, would jeopardize the safety of the subject or compliance with the protocol			
6	Prohibited treatments and/or therapies: strong inhibitors/inducers of the CYP 3A4			
7	History / any condition for poor compliance to medical treatment			
8	Women who are pregnant or breastfeeding are not eligible for this study			

Dato: _____/_____ 20____ Læge (underskrift): _____