

REMARK**MDS low-intermediate IPSS R with anemia TD or non TD**

Contatti: P.I. Elena Crisà elena.crisa@ircc.it - Study Coordinator Sara Donè sara.done@ircc.it

Linea terapeutica: or not candidate to prior ESA treatment /luspatercept/lenalidomide

Coorti: Single ARM Phase 2

Terapia: RVU120

Inclusion:

- Very low, low or intermediate risk disease MDS with up to 3.5 points according to International
- Prognostic Scoring System Score Revised (IPSS-R) classification (to be confirmed during screening assessment).
- Patients with del(5q) and max. one further abnormality (excluding monosomy 7, del(7q), TP53mut) are eligible.
- No available option of an approved MDS therapy according to decision of the treating physician and based on the following:
- Patients must be ESA exposed (and refractory or intolerant) or ESA naïve and serum erythropoietin level >200 U/L
AND/OR
Luspatercept exposed (and refractory or intolerant) or luspatercept naïve and not eligible for treatment (e.g. not approved)
AND/OR
Lenalidomide exposed (and refractory or intolerant) or lenalidomide naïve and not eligible for treatment (e.g. due to non-presence of del(5q))

Exclusion:

- Patient does not accept bone marrow sampling during screening and after the treatment.
- Prior treatment with azacitidine (injectable or oral) or decitabine.
- Iron chelation therapy