Nplate® (romiplostim) – New indication

- On January 28, 2021, the FDA approved Amgen's Nplate (romiplostim), to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.

- Nplate is also approved for the treatment of thrombocytopenia in:

  — Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
  — Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

- Efficacy studies of Nplate could not be conducted in humans with acute radiation syndrome for ethical and feasibility reasons. Approval for this indication was based on efficacy studies conducted in animals, Nplate's effect on platelet count in healthy human volunteers and on data supporting Nplate's effect on thrombocytopenia in patients with ITP and insufficient response to corticosteroids, immunoglobulins, or splenectomy.

- The recommended dose of Nplate for acute radiation syndrome is 10 mcg/kg administered once as a subcutaneous injection. The dose should be administered as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray.

  — Nplate should be administered regardless of whether a complete blood count can be obtained. A patient's absorbed whole body radiation dose (ie, level of radiation exposure) should be estimated based on information from public health authorities, biodosimetry if available, or clinical findings such as time to onset of vomiting or lymphocyte depletion kinetics.
  — Refer to the Nplate drug label for dosing for ITP.