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Title: Immune Thrombocytopenia: ADVANCE SC, a Global Phase 3 Clinical Trial in Progress

Type: Oral or Poster

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Theme: * Acquired Thrombocytopenias

Abstract text: Please enter text into each field, but not more than 300 words in total.

Background: * Efgartigimod, an FcRn antagonist, was well tolerated compared to placebo and induced a rapid reduction of total IgG levels, which was associated with clinically relevant increases in platelet counts, and a reduced proportion of patients with bleeding in the Phase 2 trial in patients with primary ITP (Newland AC. *Am J Hematol*. 2020;95:178-187. NCT03102593), warranting further evaluation in Phase 3 clinical trials. A subcutaneous (SC) formulation has been developed to offer additional flexibility and convenience for patients.

Aims: * ADVANCE SC, a Phase 3, multicenter, randomized, double-blinded, placebo-controlled trial (NCT04687072), will evaluate the efficacy and safety of efgartigimod PH20 administered SC in adults with persistent or chronic ITP.

Methods: * Eligible patients must have a mean platelet count <30×10^9/L over at least 3 qualifying evaluations and have received at least 2 prior ITP treatments or 1 prior and 1 concurrent treatment, with response to at least one. Patients will enter a 24-week treatment period and receive either efgartigimod (1,000 mg) co-formulated with PH20 or matching placebo (randomization 2:1), administered weekly from visits 1 to 4 and then either weekly or every other week from visits 5 to 16, as determined by platelet counts. Dosing schedule will be fixed from visits 17 to 24. Permitted concurrent ITP treatments include corticosteroids, oral immunosuppressants, dapsone/danazol, fostamatinib and/or oral TPO-RAs.

Results: * The primary endpoint is the proportion of patients with a sustained platelet count response (≥50×10^9/L for at least 4 of the 6 visits between study weeks 19 and 24). Secondary endpoints include safety and tolerability, bleeding severity, quality of life and patient-reported outcome measures, and the immunogenicity and pharmacokinetic/pharmacodynamic effects of efgartigimod.

Conclusions: * Recruitment is ongoing in Asia-Pacific, Europe, Japan, Latin America, the Middle East, Africa and USA. Trial participants will be eligible for continuation into ADVANCE SC$^+$, a long-term open-label extension trial.

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