ELSEVIER

Blood 142 (2023) 3376–3377

The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

652.MULTIPLE MYELOMA: CLINICAL AND EPIDEMIOLOGICAL

Real-World Usage of Hyaluronidase-Facilitated Subcutaneous Immunoglobulin 10% in Patients with Multiple Myeloma Diagnosed with Secondary Immunodeficiency Disease

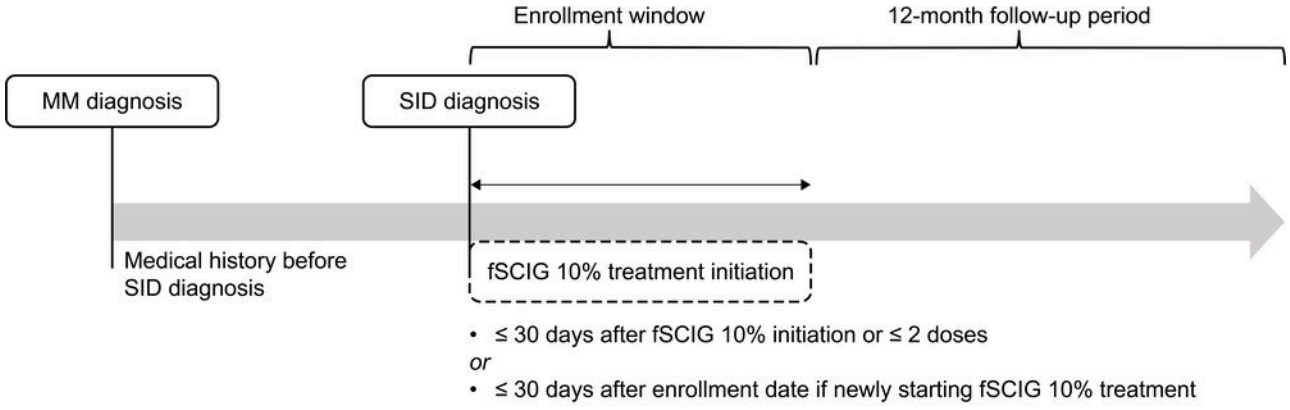
Agoston Gyula Szabo[1], *Silvia Sánchez-Ramón*[2], *Csaba Siffel*[3], *Colin Anderson-Smits*[3], *Barbara McCoy*[4], *Marta Kamieniak*[3]

[1]Department of Haematology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark
[2]Department of Clinical Immunology, Institute of Laboratory Medicine, Hospital Clínico San Carlos, Complutense University of Madrid, Madris, Spain
[3]Takeda Development Center Americas, Inc., Cambridge, MA
[4]Baxalta Innovations GmbH, a Takeda company, Vienna, Austria

Introduction: In patients with mature B-cell malignancies such as multiple myeloma (MM), both the underlying disease and immunosuppressive therapy can result in patients developing secondary immunodeficiency disease (SID). SID often manifests in severe, recurrent, or persistent infections that can impair a patient's quality of life and are a major cause of morbidity and mortality in patients with MM, thereby resulting in significant clinical and socioeconomic burden. The use of immunoglobulin (Ig) replacement therapy is well established for the treatment of hypogammaglobulinemia in patients with primary immunodeficiency disease (PIDD). Hyaluronidase-facilitated subcutaneous immunoglobulin (fSCIG) 10% is a dual-vial unit of IgG 10% and recombinant human hyaluronidase (rHuPH20). fSCIG 10% is approved in the USA for the treatment of adults and children aged 2 years or older with PIDD, and in the EU for adults and children of any age with PIDD or SID. fSCIG 10% is not fully integrated into standard of care for patients with SID in many countries, in part owing to comparatively less familiarity of hematologists and oncologists with the evidence supporting the use of fSCIG 10% than for intravenous IgG therapy in patients with SID. Therefore, the HyMMy study (NCT05879757) aims to generate real-world evidence to gain a better understanding of patterns of fSCIG 10% use and outcomes in patients with MM and SID.
Methods: HyMMy is a prospective, noninterventional, observational study that will be conducted at 30 centers in Europe and South America. It is planned for 100 patients to be enrolled and observed over a 12-month follow-up period. The overall duration of the study will be 38 months. Patients will be eligible for inclusion if they are aged 18 years or older, have a diagnosis of MM, and fulfill the diagnosis criteria for SID: patient suffers from severe, recurrent, or persistent infection despite appropriate anti-infective treatment, and has proven specific antibody failure or a serum IgG trough level of less than 4 g/L (excluding paraprotein). Patients may enter the study after being diagnosed with SID and no more than 30 days after fSCIG 10% treatment initiation, or with no more than 2 doses of fSCIG 10% already infused (**Figure**). Patients newly starting fSCIG 10% have a 30-day window from enrollment to inclusion. Patients will be excluded if they have PIDD, have received Ig treatment or prophylaxis within 3 months of enrollment, have an ongoing serious infection requiring intravenous antimicrobial therapy, have a history of malignancy other than MM within 3 years of enrollment, or have had major surgery within 2 weeks of enrollment. The primary endpoint is to characterize the real-world infusion parameters of fSCIG 10% administration (dosing and administration characteristics; treatment interval; infusion volume, sites, rate, and duration; training visits; and fSCIG 10% discontinuation, interruption, or switch to other treatment). Secondary endpoints will examine the disease course and clinical management of MM (including overall survival and healthcare resource utilization) in patients treated with fSCIG 10%. The exploratory endpoints include: burden of infection; infection rate, type, duration, and severity; patient-reported outcomes pertaining to health-related quality of life, collected via questionnaire at the patients' visit; and overall physician assessment of fSCIG 10% utilization, tolerability, and effectiveness, as measured by a 5-point Likert scale questionnaire.
Results: Patient recruitment started in June 2023. Interim analysis is planned after enrollment of the first 50 patients, and the estimated end of the study is 2026.
Conclusions: HyMMy is the first prospective, observational study that focuses on the assessment of fSCIG 10% utilization patterns in adults with MM diagnosed with SID. The study will help to improve understanding of the treatment patterns and options available for patients with SID and hematologic malignancies, in particular MM.
Takeda Development Center Americas, Inc. funded this study. Takeda Pharmaceuticals International AG funded writing support.

Disclosures Gyula Szabo: *Sanofi:* Consultancy; *Janssen:* Consultancy; *Takeda:* Consultancy, Research Funding; *BMS:* Research Funding; *GSK:* Research Funding. **Sánchez-Ramón:** *Biogen:* Membership on an entity's Board of Directors or advisory committees; *Biotest:* Membership on an entity's Board of Directors or advisory committees; *CSL Behring:* Membership on an entity's Board of Directors or advisory committees; *Grifols:* Membership on an entity's Board of Directors or advisory committees; *Octapharma:* Membership on an entity's Board of Directors or advisory committees; *Pharming:* Membership on an entity's Board of Directors or advisory committees; *Takeda:* Membership on an entity's Board of Directors or advisory committees. **Siffel:** *Takeda Development Center Americas, Inc.:* Current Employment, Current equity holder in private company. **Anderson-Smits:** *Takeda Development Center Americas, Inc.:* Current Employment, Current equity holder in private company. **McCoy:** *Baxalta Innovations GmbH, a Takeda company:* Current Employment; *Takeda:* Current equity holder in private company. **Kamieniak:** *Takeda Development Center Americas, Inc.:* Current Employment, Current equity holder in private company.

Figure. Study design



fSCIG, facilitated subcutaneous immunoglobulin; MM, multiple myeloma; SID, secondary immunodeficiency disease.

Figure 1

https://doi.org/10.1182/blood-2023-188559