BACKGROUND

• Multifocal (SMP), particularly intermediate (2-3) or high-risk disease by Dynamic International Prognostic Scoring System (DIPSS) criteria, is a life-threatening disease for which the Janus kinase inhibitor (JAK) rituximab, and currently only alemtuzumab therapy, are available.

• There is increased interest in developing novel therapies for patients with intermediate disease, particularly in combination with alemtuzumab, who have not achieved remission with alemtuzumab or who relapse after alemtuzumab.

• Alemtuzumab is generally recommended as the standard of care for patients with intermediate disease, to achieve deep remission or complete remission with minimal adverse events.

• Novel targeted therapies are under investigation for patients with intermediate disease, with the aim of improving outcomes and reducing adverse events.

RESULTS

Patient Population

• Patients who were included in MYF2001 had high- or intermediate-risk disease, as defined by the DIPSS criteria, and were refractory or intolerant to previous therapy.

• Patients were enrolled in the MYF2001 study if they had failed to achieve remission or complete remission with previous therapy, or if they had relapsed after achieving remission.

• Patients were treated with alemtuzumab and either lenalidomide or rituximab in combination with lenalidomide, as determined by the investigator.

• Patients were monitored for a minimum of 1 year post treatment, with continuing follow-up for at least 2 years.

• The primary endpoint was complete remission or complete remission with minimal adverse events, as defined by the International Myeloma Working Group (IMWG) criteria.

• Secondary endpoints included overall response rate, duration of response, and progression-free survival.

• The study showed that the combination of alemtuzumab and lenalidomide achieved higher complete remission rates compared to lenalidomide alone for patients with intermediate-disease myeloma.

• The combination also improved progression-free survival compared to lenalidomide alone.

• Overall response rates were higher for patients treated with the combination therapy compared to lenalidomide alone, with a median duration of response of 31 months versus 12 months, respectively.

• The combination therapy also had a lower incidence of adverse events compared to lenalidomide alone, with a lower incidence of grade 3 or 4 adverse events.

• The combination therapy was well tolerated, with a manageable safety profile.

• The combination therapy demonstrated a survival benefit compared to lenalidomide alone, with a median overall survival of 66 months versus 48 months, respectively.

• The combination therapy was associated with a lower risk of death compared to lenalidomide alone, with a hazard ratio of 0.65.

• The combination therapy was associated with a lower risk of serious adverse events compared to lenalidomide alone, with a lower incidence of grade 3 or 4 adverse events.

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