Introduction: Transplant ineligible patients (pts) with relapsed/refractory (R/R) FL or DLBCL have poor outcomes. Polatuzumab vedotin (pola), an antibody drug conjugate that targets delivery of the microtubule inhibitor MMAE to cells expressing CD79b, + rituximab (R) has shown promising responses in R/R FL and DLBCL. Adding bendamustine (B) to pola-R and substituting obinutuzumab (G) for R could improve outcomes. We report updated results from the Phase (P) 1b/2 study evaluating pola + BR or BG and the P2 expansion cohorts evaluating pola + BG in patients (pts) with R/R FL and DLBCL (ClinicalTrials.gov NCT02257567).

Methods: All pts provided informed consent to participate in the study and were treated with pola (1.8 mg/kg) + B (90 mg/m²) and R (375 mg/m²) or G (1000 mg) every 28 days (FL) or 21 days (DLBCL) for 6 cycles. Responses were assessed by modified Lugano 2014 criteria after 3 cycles, end of treatment (tx), and every 6 months (mo) for 2 years during follow-up (fu).

Results: As of 14 Nov 2016, 65 pts were enrolled: 24 pts (12 FL, 12 DLBCL) in P1b and 41 pts (20 FL and 21 DLBCL) in P2. In safety evaluable pts, FL pts (N = 32) were median age 63 yr (37–86), 82% ECOG 0–1, 6% ECOG 2, 44% FLIPI 1–5, 78% Stage III/IV, 2 (1–7) median lines of prior tx, 38% refractory to last tx, 13% prior transplant (BMT). DLBCL pts (N = 32) were median age 66 (30–86), 88% ECOG 0–1, 13% ECOG 2, 59% IPI 3–5, 75% Stage III/IV, 2 (1–7) median lines of prior tx, 82% refractory to last tx, 3% prior BMT.

Among 64 pts who received ≥1 dose, adverse events (AEs) that occurred in >20% of pts were fatigue (67%), nausea (54%), diarrhea (54%), vomiting (42%), pyrexia (39%), and constipation (39%). As expected, grade (Gr) 3/4 cytopenias were common: neutropenia (34% FL, 28% DLBCL), thrombocytopenia (16% FL, 13% DLBCL), and anemia (6% FL, 9% DLBCL). Tx emergent neutropenia occurred in 19/64 (30%) of pts, with 1 Gr 3 event, and led to pola discontinuation in 1 pt, dose reduction in 2 pts, and interruption in 1 pt.

In FL (N = 32), 75% (24/32) had Gr 3/4 AEs and 41% (13/32) had serious AEs (SAEs). The only SAE occurring in ≥10% was infection (22%). The most common Gr 3/4 non-heme AEs were infection (16%) and hypokalemia (9%). AEs led to study tx interruption in 6 pts. B was stopped in 2 pts due to Gr 3 thrombocytopenia. Of 4 deaths, 2 were PD and 2 were Gr 5 AEs (1 tx related: PML). In DLBCL (N = 32), 88% (28/32) had Gr 3/4 AEs and 63% (20/32) had SAEs. SAEs occurring in ≥10% of pts were infection (33%) and pyrexia (22%). The most common Gr 3/4 non-heme AEs were febrile neutropenia (13%), fatigue (13%), and diarrhea (13%). AEs led to study tx interruption in 19 pts and discontinuation in 8 pts. There were 13 deaths: 9 PD, 4 AE (all unrelated to tx).Responses are shown in Table 1.

Median duration of response (DoR) for FL P1b pts was 16 mo (median fu 14.5 mo) but not reached for FL P2 (median fu 6.5 mo) and DLBCL P1b/2 (median fu 13.7 mo P1b, 6.4 mo P2).

Conclusions: Updated evaluation of pola + BR and pola + BG shows promising durable responses and an acceptable safety profile in heavily pre-treated R/R FL and DLBCL pts. Safety and efficacy data will be updated at the time of presentation.

Keywords: antibody-dependent cytotoxicity (ADC); non-Hodgkin lymphoma (NHL); obinutuzumab.

285 YourTreatmentChoices: FAST ACCESS TO TRIALS PROGRAMME


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Introduction: YourTreatmentChoices aims to develop an innovative approach to patient access to cancer clinical trials, including blood malignancies. The YourTreatmentChoices website is integrated with a bespoke clinical trial database of more than 86,000 recruiting trials. The Fast Access to trials Programme was conducted as part of YourTreatmentChoices and is comprised of 25 blood cancer clinical trials (SADAL, Epizyme/Eisai, Polatuzumab, SGN35-023, TAK659, PIX-R, ACERTA, INCA, TIER, ROMICAR, DI-B4, UKALL 11, UKALL 14, MMY0007, TOURMALINE, AML 18, VITAL, AML19, MUK 7, FLAIR, Fusion NHL001, PRONTO, Chemo T, ReThink, RIALTO), including lymphomas, from 20 sponsors. The studies were conducted at 4 trial sites: 1) The Christie Hospital, The University of Manchester and the Christie NHS Foundation Trust, Manchester, UK; 2) Cancer Research UK Centre, Southampton General Hospital, University of Southampton, Southampton, UK; 3) Centre for Clinical Haematology, Queen Elizabeth Hospital Birmingham, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK; and 4) Barts Cancer Institute, Centre for Haematology-Oncology, Queen Mary University of London, London, UK.

Methods: Six and 2-month social media campaigns were conducted by Bloodwise and Tomorrow’s Medicines Ltd, respectively. Bloodwise utilised Twitter, Facebook, blogs, and newsletters as part of their campaign while Tomorrow’s Medicines Ltd used only Facebook. The data-base architecture was developed to accommodate for the differences in language used by patients, oncologists, and clinical trial sponsors simultaneously translating lay terminology, medical terminology (WHO-ICD 0-3) and clinical trial terminology. The programme utilised 3 eligibility algorithms, which were developed by Tomorrow’s Medicines Ltd, to facilitate patient interaction with research nurses at clinical trial sites. The algorithms developed, which connect eligible patients and trial sites, iteratively execute a bespoke combination of functions including translation, screening, matching, and messaging with increasing specificity.
Results: Between June 2016 and December 2016, Bloodwise sent 102 tweets and 6 Facebook posts. Tomorrow’s Medicines Ltd sent 135 Facebook posts during October and November 2016. The website received 23,000 visits from 9,704 patients with blood cancer worldwide. The engagement rate (patients who answered screening questions) was 6.7% and the match rate was 53 patients per month. The average number of messages between the patient and the trial nurse was 8.6. The number of matches generated to at least one trial was 446 while 204 profiles were not matched to any of the 25 trials in the programme. Eligibility rate of matched patients compared with the single trial industry standard was 75% compared with 4.7% for the Echelon1 trial (an international phase 3 frontline trial of therapy in advanced classical Hodgkin Lymphoma) used as comparison.

Conclusions: Our data demonstrate that the YourTreatmentChoices website effectively connects eligible patients with clinical trials and research sites enabling patients to participate in their own treatment choices by providing improved access to clinical trials. It also gives the clinical research community improved access to patients who may be eligible for enrolment in certain clinical trials where eligibility criteria may be difficult to fulfill. These results suggest that use of social media linked to an online matching tool can be a powerful adjunct to clinical trial recruitment and potentially accelerate the development of new medicines.

Keywords: Hodgkin lymphoma (HL); multiple myeloma (MM); non-Hodgkin lymphoma (NHL).

286 INCREASING CROSS-REFERRAL AND RECRUITMENT TO CLINICAL TRIALS: A NEW APPROACH


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ABSTRACT

Figure 1a

Figure 1b.