**Supplemental Digital Content (SDC) for Alegre et al. Results of an early access treatment protocol of daratumumab monotherapy in Spanish patients with relapsed or refractory multiple myeloma.**

**SDC, MATERIALS AND METHODS**

**European Quality of Life Five Dimensions Questionnaire (EQ-5D-5L)**

The EQ-5D-5L is a 5-item questionnaire that serves as a generic measure of health status and generates utility scores for use in cost-effective analyses. EQ-5D-5L assesses 5 dimensions of health, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression in addition to a visual analog scale rating overall health.1 The 5 dimensions of health are rated by patients on a scale with graded severity that can be used to compute a single utility score. The utility score provides an index of the general health status of each patient, with a maximum score of 1 representing a high level of utility. The visual analog scale rating is selected by patients using an illustration of a health status scale bar ranging from 0 to 100, with 0 being equivocal to the worst health imaginable and 100 being equivocal to the best health imaginable.

**European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30 and Multiple Myeloma Module (QLQ-MY20)**

The EORTC QLQ-C30 is a widely used, clinically meaningful questionnaire that includes 30 questions addressing patient functional ability, symptoms, and overall health status.2-3 The EORTC Multiple Myeloma Module (QLQ-MY20) was also administered in conjunction with the EORTC QLQ-C30, and contains an additional 20 questions that are more relevant to myeloma patients.4 EORTC QLQ-C30 and QLQ-MY20 scores are summated using the Likert method and presented on a 0 to 100 scale. For global health status and functioning scales, a decrease means a reduction in functioning or utility, whereas a decrease in a symptoms score indicates an improvement in symptoms.

**References**

1. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011; 20(10): 1727-1736.

2. Wisloff F, Hjorth M. Health-related quality of life assessed before and during chemotherapy predicts for survival in multiple myeloma. Nordic Myeloma Study Group. *Br J Haematol* 1997; 97: 29-37.

3. Wisloff F, Eika S, Hippe E, et al. Measurement of health-related quality of life in multiple myeloma. Nordic Myeloma Study Group. *Br J Haematol* 1996; 92(3): 604-613.

4. Cocks K, Cohen D, Wisloff F, et al. An international field study of the reliability and validity of a disease-specific questionnaire module (the QLQ-MY20) in assessing the quality of life of patients with multiple myeloma. *Eur J Cancer* 2007; 43(11): 1670-1678.

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| **SDC, Table 1. Summary of EORTC QLQ-C30: Global health status, functioning, and financial difficulties.** |
|  |  | **Change from baseline** |
|  | **Baseline** | **Cycle 2 Day 1** | **Cycle 3 Day 1** | **Cycle 6 Day 1** | **Cycle 8 Day 1** |
|  Na | 68 | 46 | 40 | 27 | 17 |
| Global health status |  |  |  |  |  |
|  Mean | 54.04 | –5.62 | –1.88 | 4.32 | 6.37 |
|  Standard deviation | 20.34 | 20.64 | 21.64 | 22.09 | 19.44 |
|  Median | 50.00 | 0.00 | 0.00 | 0.00 | 8.33 |
| Functioning |  |  |  |  |  |
|  Cognitive |  |  |  |  |  |
|  Mean | 80.15 | 1.09 | 0.42 | 0.62 | 1.96 |
|  Standard deviation | 24.81 | 17.71 | 13.86 |  23.79 | 15.46 |
|  Median | 83.33 | 0.00 | 0.00 | 0.00 | 0.00 |
|  Emotional |  |  |  |  |  |
|  Mean | 68.01 | 6.88 | 2.08 | 0.31 | 3.92 |
|  Standard deviation | 24.42 | 15.84 | 24.15 | 20.61 | 15.90 |
|  Median | 75.00 | 4.17 | 0.00 | 0.00 | 8.33 |
|  Physical |  |  |  |  |  |
|  Mean | 64.71 | –4.93 | 0.17 | –1.23 | 2.35 |
|  Standard deviation | 24.25 | 20.77 | 17.96 | 16.33 | 15.45 |
|  Median | 66.67 | 0.00 | 0.00 | 0.00 | 6.67 |
|  Role  |  |  |  |  |  |
|  Mean | 57.35 | –6.16 | –1.67 | –2.47 | 1.96 |
|  Standard deviation | 33.63 | 29.68 | 30.85 | 22.98 | 29.98 |
|  Median | 66.67 | 0.00 | 0.00 | 0.00 | 0.00 |
|  Social |  |  |  |  |  |
|  Mean | 62.25 | 2.90 | 1.25 | 6.79 | 11.76 |
|  Standard deviation | 30.42 | 32.45 | 27.83 | 25.43 | 22.64 |
|  Median | 66.67 | 0.00 | 0.00 | 0.00 | 0.00 |
| Financial difficulties |  |  |  |  |  |
|  Mean | 20.59 | –9.42 | –2.50 | –3.70 | –5.88 |
|  Standard deviation | 29.38 | 27.81 | 19.08 | 16.88 | 21.20 |
|  Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30.

aThe number of patients shown are those who completed the assessment at both baseline and each respective time point.

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| **SDC, Table 2. Summary of EORTC-QLQ-C30: patient-reported symptoms.** |
|  |  |  | **Change from baseline** |
|  | **Baseline** | **Cycle 2 Day 1** | **Cycle 3 Day 1** | **Cycle 6 Day 1** | **Cycle 8 Day 1** |
|  Na | 68 | 46 | 40 | 27 | 17 |
| Appetite loss |  |  |  |  |  |
|  Mean | 21.57 | 5.07 | 4.17 | 0.00 | –7.84 |
|  Standard deviation | 30.35 | 35.81 | 21.60 | 29.24 | 32.34 |
|  Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Constipation |  |  |  |  |  |
|  Mean | 17.16 | 0.72 | 1.67 | 6.17 | –5.88 |
|  Standard deviation | 30.20 | 28.54 | 18.41 | 22.72 | 13.10 |
|  Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Diarrhea |  |  |  |  |  |
|  Mean | 18.14 | –2.17 | –5.83 | 0.00 | –5.88 |
|  Standard deviation | 31.25 | 21.55 | 26.03 | 16.01 | 13.10 |
|  Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Dyspnea |   |  |  |  |  |
|  Mean | 18.14 | –4.35 | 0.00 | 8.64 | –7.84 |
|  Standard deviation | 25.39 | 29.49 | 22.65 | 27.10 | 22.14 |
|  Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Fatigue |  |  |  |  |  |
|  Mean | 44.61 | 2.17 | 0.28 | 0.41 | –0.65 |
|  Standard deviation | 27.52 | 21.93 | 25.10 | 21.24 | 22.39 |
|  Median | 44.44 | 0.00 | 0.00 | 0.00 | 0.00 |
| Nausea and vomiting |  |  |  |  |  |
|  Mean | 5.39 | 1.09 | 1.67 | 3.09 | –2.94 |
|  Standard deviation | 14.24 | 13.79 | 12.40 | 15.36 | 14.71 |
|  Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Pain  |  |  |  |  |  |
|  Mean | 48.77 | –6.88 | –5.00 | –7.41 | –2.94 |
|  Standard deviation | 30.92 | 27.12 | 25.09 | 21.85 | 29.01 |
|  Median | 50.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Sleep disturbance |  |  |  |  |  |
|  Mean | 30.39 | 1.45 | 0.00 | 0.00 | -9.80 |
|  Standard deviation | 32.95 | 32.93 | 32.03 | 26.15 | 22.87 |
|  Median | 33.33 | 0.00 | 0.00 | 0.00 | 0.00 |

EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30.

aThe number of patients shown are those who completed the assessment at both baseline and each respective time point.

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| **SDC, Table 3. Summary of EORTC QLQ-MY20.** |
|  |  |  | **Change from baseline** |
|  | **Baseline** | **Cycle 2 Day 1** | **Cycle 3 Day 1** | **Cycle 6 Day 1** | **Cycle 8 Day 1** |
|  Na | 69 | 45 | 40 | 26 | 17 |
| Body image |  |  |  |  |  |
|  Mean | 71.01 | 2.22 | 0.83 | 5.13 | 7.84 |
|  Standard deviation | 35.20 | 26.02 | 27.72 | 26.15 | 18.74 |
|  Median | 100.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Disease symptoms |  |  |  |  |  |
|  Mean | 33.98 | –2.84 | –5.00 | –1.92 | –5.56 |
|  Standard deviation | 23.75 | 19.38 | 23.66 | 19.43 | 18.11 |
|  Median | 33.33 | 0.00 | 0.00 | –2.78 | 0.00 |
| Future perspective |  |  |  |  |  |
|  Mean | 57.97 | 5.68 | 2.22 | 7.69 | 5.23 |
|  Standard deviation | 26.40 | 22.30 | 26.05 | 22.39 | 18.05 |
|  Median | 66.67 | 0.00 | 0.00 | 11.11 | 11.11 |
| Side effects of treatment |  |  |  |  |  |
|  Mean | 24.07 | –0.22 | –2.37 | 0.63 | –1.02 |
|  Standard deviation | 16.91 | 12.36 | 13.85 | 12.19 | 11.74 |
|  Median | 22.22 | 0.00 | 0.00 | 0.00 | –3.70 |

EORTC QLC-MY20, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30 and Multiple Myeloma Module.

aThe number of patients shown are those who completed the assessment at both baseline and each respective time point.