



What do these results mean for people living with multiple myeloma?

People with relapsed or refractory multiple myeloma (RRMM) treated with talquetamab (Tal) in combination with other medicines lived longer without their cancer growing or spreading compared with standard treatment. More people responded to Tal-based treatment, including deep responses with very low or no detectable signs of cancer cells remaining. For most people, side effects were manageable. These results suggest Tal-based combinations may be a new treatment option earlier in the disease.



What was the purpose of this study?

- To find out whether Tal, a bispecific antibody, used together with daratumumab with or without pomalidomide, could help people with RRMM live longer without their cancer growing or spreading



Who was in the study and how was the study carried out?



Participants with RRMM who had received at least 1 prior treatment, including lenalidomide (an immunomodulatory drug) and a proteasome inhibitor; those with only 1 prior treatment no longer responded to lenalidomide

- Participants were randomly assigned to 1 of 3 groups:
 - Tal + daratumumab + pomalidomide (Tal-DP)
 - Tal + daratumumab (Tal-D)
 - Standard treatment: daratumumab + pomalidomide + dexamethasone (DPd)

Primary objective Secondary objectives

- How long participants lived without their cancer growing or spreading
- How many participants responded to treatment
- Whether cancer cells could still be detected after treatment
- Side effects participants experienced

Responses were assessed by an independent review group using standard criteria for multiple myeloma.

Phase 3 MonumenTAL-3 Study of Talquetamab + Daratumumab (With or Without Pomalidomide) Vs Daratumumab + Pomalidomide + Dexamethasone in Relapsed or Refractory Multiple Myeloma

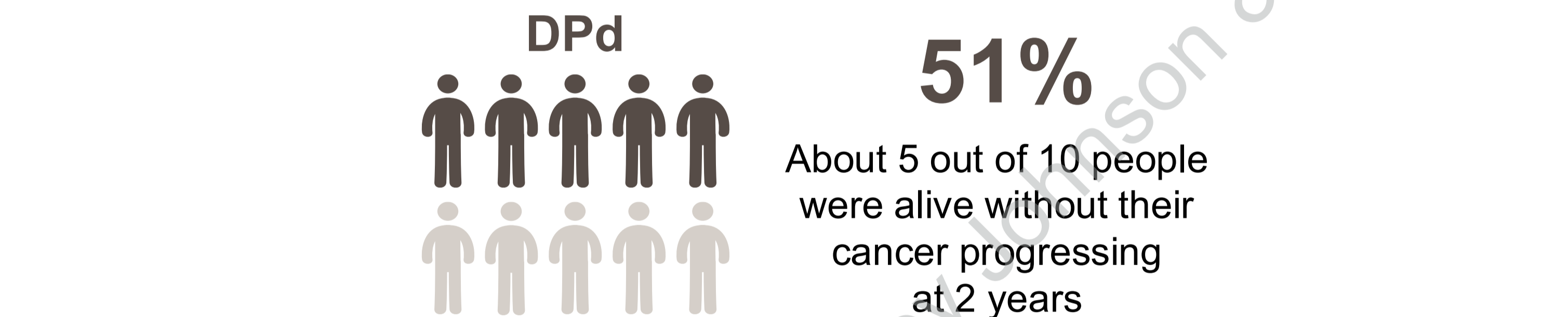
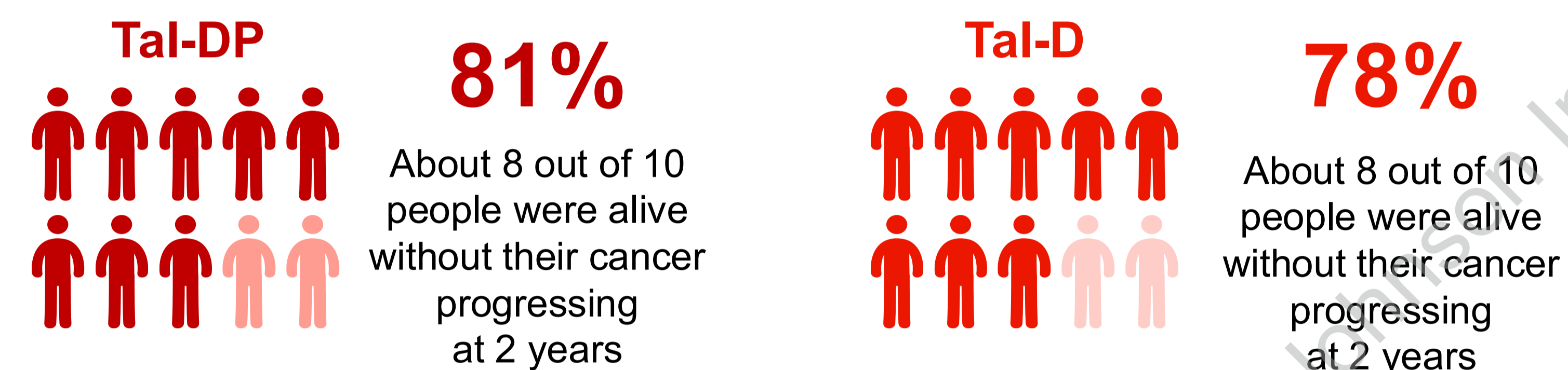
Peter Voorhees^{1*}, Roberto Mina², Paula Rodriguez-Otero³, Wenming Chen⁴, María-Victoria Mateos⁵, Jian Li⁶, Philippe Moreau⁷, Yael Cohen⁸, Chang Ki Min⁹, Roman Hajek¹⁰, Christine Ye¹¹, Hila Magen¹², Sam Rubinstein¹³, Weijun Fu¹⁴, Vania Hungria¹⁵, Guldane Cengiz Seval¹⁶, Joao Samuel Farias¹⁷, Jakub Radocha¹⁸, Senem Maral¹⁹, Mehmet Turgut²⁰, Youngil Koh²¹, Daniel O'Leary²², Jayr Schmidt Filho²³, Raymond Therulien²⁴, Gang An²⁵, Shang Yi Huang²⁶, Sebastian Grosicki²⁷, Agata Tyczynska²⁸, Rahul Banerjee²⁹, Matthew Pianko³⁰, Joaquín Martínez-López³¹, Pawel Steckiewicz³², Dai Maruyama³³, Kentaro Fukushima³⁴, Albert Oriol³⁵, Jordi Lopez Pardo³⁶, Hartmut Goldschmidt³⁷, Charlotte Pawlyn³⁸, Aurore Perrot³⁹, Elena Zamagni⁴⁰, Meletios Athanasios Dimopoulos⁴¹, Leo Rasche⁴², Jaszianna Tolbert⁴³, William Terry⁴³, Christelle Courtoux⁴³, Xiao Liu⁴⁴, Sandra Y Vasey⁴³, Kaitlyn Connors⁴⁵, Mariacristina Festa⁴⁶, Christoph Heuck⁴³, Angélique Langlois⁴³, Lisa O'Rourke⁴³, Jiangxiu Zhou⁴³, Xiang Qin⁴³, Jiashen Lu⁴⁴, Jue Gong⁴³, Diego Vievra⁴³, Meral Beksac⁴⁷

¹Atrium Health/Levine Cancer Institute, Wake Forest University School of Medicine, Charlotte, NC, USA; ²Department of Hematology and Medical Oncology, Winship Cancer Institute, Emory University, Atlanta, GA, USA; ³Cancer Center, Clínica Universidad de Navarra, Cima, Pamplona, Spain; ⁴Beijing Chaoyang Hospital, Capital Medical University, Chaoyang District, Beijing, China; ⁵Hospital Clínico Universitario de Salamanca, Servicio de Salud de Castilla y León (SACYL), Salamanca, Castilla and León, Spain; ⁶Department of Hematology, Peking Union Medical College Hospital, Peking Union Medical College, Chinese Academy of Medical Sciences, Beijing, China; ⁷Hematology Clinic, University Hospital Hôtel-Dieu, Nantes, France; ⁸Tel Aviv Sourasky (Ichilov) Medical Center, Tel Aviv, Israel; ⁹Gray Faculty of Medical & Health Sciences, Tel Aviv University, Tel Aviv, Israel; ¹⁰St. Mary's Hospital, The Catholic University of Korea, Seoul, Republic of South Korea; ¹¹Department of Hematology, University Hospital Ostrava, Ostrava Czech Republic; ¹²Department of Hematology, Faculty of Medicine, University of Ostrava, Ostrava, Czech Republic; ¹³MD Anderson Cancer Center, University of Texas, Houston, Texas, USA; ¹⁴Chaim Sheba Medical Center, Ramat-Gan, Israel; ¹⁵Sackler Faculty of Medical and Health Sciences, Tel Aviv University, Israel; ¹⁶Division of Hematology and Oncology, Department of Medicine, University of North Carolina School of Medicine, Chapel Hill, NC, USA; ¹⁷Department of Hematology, Shanghai Fourth People's Hospital, School of Medicine, Tongji University, 200434 Shanghai, China; ¹⁸Clinica Médica São Germano, São Paulo, Brazil; ¹⁹Ankara University Faculty of Medicine, Department of Hematology and Oncology, Ankara University, Ankara, Turkey; ²⁰Liga Paranaense de Combate ao Câncer (LPEC), Curitiba, Paraná, Brazil; ²¹4th Department of Internal Medicine - Hematology, University Hospital Hradec Králové, Faculty of Medicine in Hradec Králové, Charles University, Czechia; ²²Medipol Mega University Hospital, Bagcilar, Istanbul, Turkey; ²³Onkoloji Myo University Samsun Turkey; ²⁴Seoul National University Hospital, Seoul National University, Jongno-gu, Seoul, Republic of Korea; ²⁵University of Minnesota, Minneapolis, MN, USA; ²⁶CAO Gamagou Cancer Center, São Paulo, SP, Brazil; ²⁷Navarra Health Cancer Institute, Winton Salem, NC, USA; ²⁸Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences, Tianjin, China; ²⁹National Taiwan University Hospital, National Taiwan University College of Medicine, Zhongzheng District, Taipei, Taiwan; ³⁰Department of Cancer Prevention, Medical University of Silesia, Katowice, Poland; ³¹Medical University of Gdańsk, Department of Hematology and Transplantation, University Clinical Center Gdańsk, Department of Hematology and Transplantation, Gdańsk, Poland; ³²Fred Hutchinson Cancer Center, Seattle, WA, USA; ³³University of Michigan Health, Ann Arbor, MI, USA; ³⁴Hospital Universitario 12 de Octubre, Ims12 Complutense University of Madrid/CNIO/Madrid, Spain; ³⁵Holy Cross Cancer Center, Department of Hematology and Bone Marrow Transplantation, Kielce, Poland; ³⁶Cancer Institute Hospital, Japanese Foundation for Cancer Research (JFCR), Koto-ku, Tokyo, Japan; ³⁷The University of Osaka Graduate School of Medicine, Suita, Japan; ³⁸Hospital Universitari Germans Trias i Pujol (HUGTIP), Institut Català de la Salut (ICS), Badalona, Barcelona, Spain; ³⁹Hospital de la Santa Creu i Sant Pau, Barcelona, Catalonia, Spain; ⁴⁰Internal Medicine V, Hematology, Oncology and Rheumatology, GMMG Study Group, Heidelberg University Hospital and National Center for Tumor Diseases, Heidelberg, Germany; ⁴¹The Institute of Cancer Research, London, UK, and The Royal Marsden NHS Foundation Trust, London, UK; ⁴²Université de Toulouse, Centre Hospitalier Universitaire de Toulouse, Service Hematologie, IUCT Oncopole, Toulouse, France; ⁴³University of Bologna, Bologna, Italy; ⁴⁴National and Kapodistrian University of Athens, Athens, Greece; ⁴⁵University Hospital of Würzburg, Würzburg, Germany; ⁴⁶Johnson & Johnson, Spring House, PA, USA; ⁴⁷Johnson & Johnson, Shanghai, China; ⁴⁸Johnson & Johnson, Raritan, NJ, USA; ⁴⁹Johnson & Johnson, Leiden, Netherlands; ⁵⁰Tejnye University, Ankara University, Ankara, Turkey

What were the results?

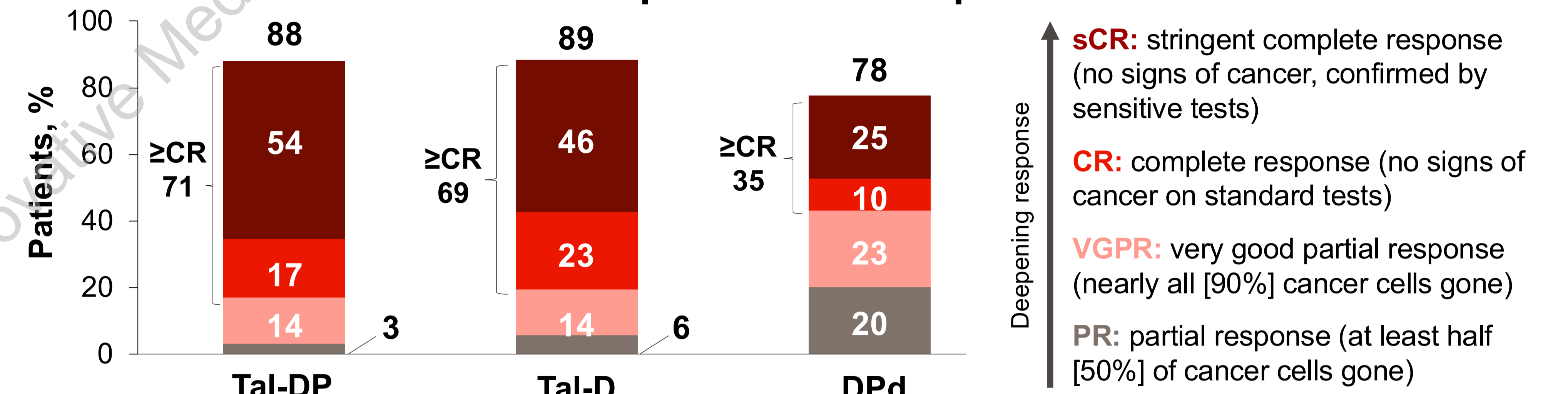
How many people were alive without their cancer growing or spreading at 2 years?

Based on 25 months of follow-up, Tal-based combinations improved outcomes compared with standard treatment across different groups of patients, including those with disease that may be harder to treat



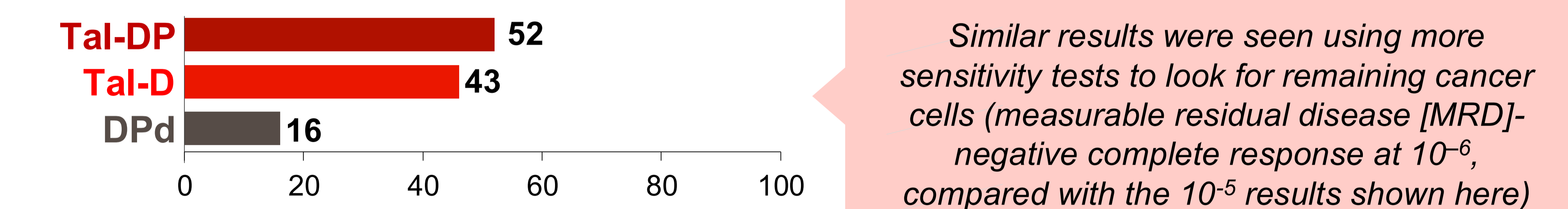
Tal combinations helped more people live significantly longer without their cancer growing or spreading compared with standard treatment

How many people responded to treatment, and how deep were those responses?



Tal combinations led to higher response rates and deeper responses compared with standard treatment

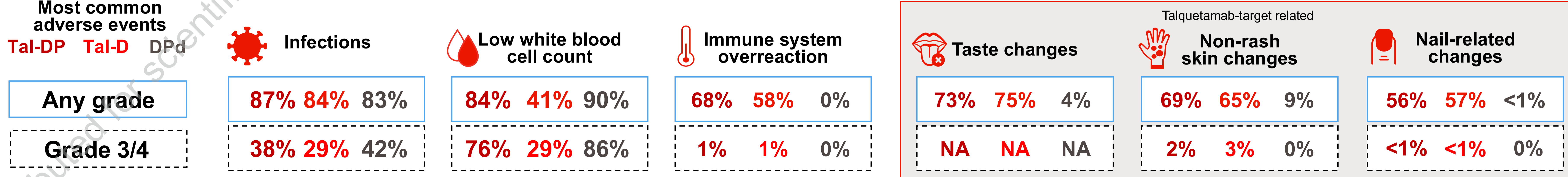
How many people had no detectable signs of cancer?



Similar results were seen using more sensitivity tests to look for remaining cancer cells (measurable residual disease [MRD]-negative complete response at 10⁻⁶, compared with the 10⁻⁵ results shown here)

Tal combinations led to deeper responses and fewer detectable cancer cells compared with standard treatment

What side effects were seen with these treatments?



Side effects with Tal combinations were similar to the known effects of each medicine alone, and few people stopped treatment because of side effects

NA, not applicable (the scale for measuring taste changes only includes grades 1 and 2). Immune system overreaction refers to cytokine release syndrome (CRS), a side effect that can occur with some immune-based cancer treatments and may be associated with fever and other symptoms but can usually be treated. Few people stopped treatment because of side effects (11% with Tal-DP, 8% with Tal-D, and 7% with DPd).

Glossary of terms	
Multiple myeloma / RRMM	A type of blood cancer that affects plasma cells in the bone marrow; relapsed or refractory multiple myeloma (RRMM) is when it returns or stops responding to treatment
Talquetamab (Tal)	A bispecific antibody that targets a protein on myeloma cells called GPRC5D and a protein on white blood cells called CD3 and is used in the treatment of RRMM
Measurable residual disease (MRD)-negative complete response	A deep treatment response where no multiple myeloma cells could be detected using sensitive laboratory tests. 10 ⁻⁵ means no myeloma cells were detected among 100,000 cells; 10 ⁻⁶ means none were detected among 1,000,000 cells
Tal-D / Tal-DP	Treatments that combine talquetamab with daratumumab (a monoclonal antibody) with or without pomalidomide (an immunomodulatory drug) to help the immune system target multiple myeloma in different ways
Grade 3 or 4 adverse events	Severe or life-threatening side effects that happen during or after treatment Grade 3 = severe; Grade 4 = life threatening
DPd	A standard treatment commonly used for RRMM that combines daratumumab, pomalidomide, and dexamethasone (a steroid)

*AI was used in the preparation of these summaries.