

Assessment for lung cancer screening evaluation: EUnetHTA; Non-Financial Interests, Personal, Advisory Role: Spanish National Evaluation network (RedETS); Non-Financial Interests, Personal, Advisory Role, scientific advisory group member for clinical immunological, oncology and lung cancer areas: EMA; Other, Personal, Other: My son is working in the pharma company TEVA as an engineer. I do not have any kind of relationship with TEVA: TEVA. N. Girard: Financial Interests, Personal, Invited Speaker: AstraZeneca, BMS, MSD, Roche, Pfizer, Mirati, Amgen, Novartis, Sanofi; Financial Interests, Personal, Advisory Board: AstraZeneca, BMS, MSD, Roche, Pfizer, Janssen, Boehringer Ingelheim, Novartis, Sanofi, AbbVie, Amgen, Eli Lilly, Grunenthal, Takeda, Owkin; Financial Interests, Institutional, Research Grant, Local: Roche, Sivan, Janssen; Financial Interests, Institutional, Funding: BMS; Non-Financial Interests, Personal, Officer, International Thymic malignancy interest group, president: ITMIG; Other, Personal, Other, Family member is an employee: AstraZeneca. B.C. Cho: Financial Interests, Personal, Other, Consulting role: Abion, BeiGene, Novartis, AstraZeneca, Boehringer Ingelheim, Roche, BMS, CJ, CureLogen, Cyrus therapeutics, Ono, Onegene Biotechnology, Yuhon, Pfizer, Eli Lilly, GI-Cell, Guardant, HK Inno-N, Inmewrun Biosciences Inc., Janssen, Takeda, MSD, Janssen; Financial Interests, Personal, Advisory Board: KANAPH Therapeutic Inc, Bridgebio therapeutics, Cyrus therapeutics, Guardant Health, Oscotec Inc; Financial Interests, Personal, Other, Advisory role: Medpacto, Blueprint medicines, RandBio, Hanmi; Financial Interests, Personal, Invited Speaker: Interpark Bio Convergence Corp., J INTS BIO; Financial Interests, Personal, Stocks/Shares: TheraCanVac Inc, Gencurix Inc, Bridgebio therapeutics, KANAPH Therapeutic Inc, Cyrus therapeutics, Interpark Bio Convergence Corp., J INTS BIO; Financial Interests, Personal, Royalties: Champions Oncology, Crown Bioscience, Imagen; Financial Interests, Institutional, Research Grant: MOGAM Institute, LG Chem, Oscotec, Interpark Bio Convergence Corp, GInnovation, GI-Cell, Abion, AbbVie, AstraZeneca, Bayer, Blueprint Medicines, Boehringer Ingelheim, Champions Oncology, CJ bioscience, CJ Blossom Park, Cyrus, Dizal Pharma, Genexine, Janssen, Eli Lilly, MSD, Novartis, Nuvalent, Oncternal, Ono, Regeneron, Dong-A ST, Bridgebio therapeutics, Yuhon, ImmuneOncia, Illumina, Kanaph therapeutics, Therapex, JINTSbio, Hanmi, CHA Bundang Medical Center; Other, Personal, Other, Founder: DAAN Biotherapeutics. J. Sabari: Financial Interests, Personal, Advisory Board: AstraZeneca, Genentech, Janssen, Pfizer, Regeneron, Sanofi Genzyme, Takeda, Mirati Therapeutics. A. Spira: Financial Interests, Personal, Other, Consulting or Advisory Role: Incyte, Mirati Therapeutics, Gritstone Oncology, Jazz Pharmaceuticals, Janssen Research & Development, Mersana, Gritstone Bio, Daiichi Sankyo/AstraZeneca, Array Biopharma, Blueprint Medicines; Financial Interests, Personal, Other, Consulting or Advisory Role/Honoraria: Amgen, Novartis, Takeda, AstraZeneca/MedImmune, Merck, Bristol-Myers Squibb; Financial Interests, Personal, Other, Honoraria: CytomX Therapeutics, Janssen Oncology, Bayer; Financial Interests, Institutional, Officer, CEO: NEXT Oncology Virginia; Financial Interests, Personal, Stocks/Shares: Eli Lilly; Financial Interests, Institutional, Invited Speaker: LAM Therapeutics, Roche, AstraZeneca, Boehringer Ingelheim, Astellas Pharma, MedImmune, Novartis, Newlink Genetics, Incyte, AbbVie, Ignyta, Trovagine, Takeda, MacroGenics, CytomX Therapeutics, Astex Pharmaceuticals, Bristol-Myers Squibb, Loxo, Arch Therapeutics, Gritstone, Plexikon, Amgen, Daiichi Sankyo, ADCT, Janssen Oncology, Mersana, Mirati Therapeutics, Rubius, Synthekine, Blueprint Medicines. R.E. Sanborn: Financial Interests, Personal, Advisory Board: AstraZeneca, EMD Serono, Daiichi Sankyo, Eli Lilly, Janssen Oncology, MacroGenics, Sanofi Aventis, Regeneron, Mirati Therapeutics, GlaxoSmithKline; Financial Interests, Personal, Invited Speaker: Amgen, GlaxoSmithKline, Janssen Oncology; Financial Interests, Institutional, Funding, Funding for investigator-sponsored trial: Merck, AstraZeneca; Financial Interests, Institutional, Other, Institutional research support: BMS; Financial Interests, Institutional, Funding, Clinical trial funding: Jounce. K. Goto: Financial Interests, Personal, Invited Speaker: Chugai Pharmaceutical Co., Ltd., Amgen K.K., Takeda Pharmaceutical Co., Ltd., Eli Lilly Japan K.K., Amgen Inc., Amoy Diagnostics Co., Ltd., AstraZeneca K.K., Bayer HealthCare Pharmaceuticals Inc., Boehringer Ingelheim Japan Inc., Bristol-Myers Squibb K.K., Daiichi Sankyo Co., Ltd., Eisai Co., Ltd., Guardant Health Inc., Merck Biopharma Co., Ltd., Novartis Pharma K.K., Ono Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Co., Ltd., Thermo Fisher Scientific K.K., Merck Biopharma Co., Ltd., Taiho Pharmaceutical Co., Ltd.; Financial Interests, Personal, Advisory Board: Janssen Pharmaceutical K.K.; Financial Interests, Personal, Expert Testimony: Medpace Japan K.K.; Financial Interests, Personal and Institutional, Funding: Amgen Inc., Amgen K.K., AstraZeneca K.K., Boehringer Ingelheim Japan Inc., Bristol-Myers Squibb K.K., Chugai Pharmaceutical Co., Ltd., Daiichi Sankyo Co., Ltd., Eisai Co., Ltd., Eli Lilly Japan K.K., Haihe Biopharma Co., Ltd., Ignyta, Inc., Janssen Pharmaceutical K.K., Kissei Pharmaceutical Co., Ltd., Kyowa Kirin Co., Ltd., Loxo Oncology, Inc., Medical & Biological Laboratories CO., LTD., Merck Biopharma Co., Ltd., Merus N.V., MSD K.K., Ono Pharmaceutical Co., Ltd., Pfizer Japan Inc., Sumitomo Dainippon Pharma Co., Ltd., Spectrum Pharmaceuticals, Inc., Sysmex Corporation, Taiho Pharmaceutical Co., Ltd., Takeda Pharmaceutical Co., Ltd., Turning Point Therapeutics, Inc., Amgen, Astellas BioPharma K.K., Bayer Yakuhin, Ltd., Blueprint Medicines Corporation., Life Technologies Japan Ltd., NEC Corporation., Novartis Pharma K.K.; Non-Financial Interests, Personal, Member: American Society of Clinical Oncology, The Japan Lung Cancer Society, Japanese Society of Medical Oncology, The Japanese Cancer Association. J. Curtin: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Janssen R&D. X. Lyu: Financial Interests, Personal, Full or part-time Employment: Johnson & Johnson; Financial Interests, Personal, Stocks/Shares: Johnson & Johnson. A. He: Financial Interests, Personal,

Full or part-time Employment: Johnson and Johnson; Financial Interests, Personal, Stocks/Shares: Johnson and Johnson. J. Penton: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Johnson and Johnson. J. Edwards: Financial Interests, Personal, Full or part-time Employment: Janssen-Cilag Ltd, Novartis Pharmaceuticals UK Ltd; Financial Interests, Personal, Stocks/Shares: AstraZeneca. G. Low Massin: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Johnson & Johnson. K. Xia: Financial Interests, Personal, Full or part-time Employment: Johnson and Johnson; Financial Interests, Personal, Stocks/Shares: Johnson and Johnson. M. Chioda: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Johnson and Johnson. M. Thayu: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Johnson & Johnson. R.E. Knoblauch: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Johnson and Johnson. P. Mahadevia: Financial Interests, Personal, Full or part-time Employment: Janssen R&D; Financial Interests, Personal, Stocks/Shares: Johnson and Johnson. N. Leigh: Financial Interests, Personal, Other, CME/independent lectures: MSD, BMS, Hoffmann LaRoche, EMD Serono; Financial Interests, Personal, Invited Speaker, independent lectures: Novartis, Takeda; Financial Interests, Personal, Advisory Board: Puma Biotechnology; Financial Interests, Institutional, Research Grant: Amgen, AstraZeneca, Array, Bayer, EMD Serono, Guardant Health, Eli Lilly, MSD, Pfizer, Roche, Takeda. All other authors have declared no conflicts of interest.

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Patient-reported outcomes from the CodeBreak 200 phase III trial comparing sotorasib versus docetaxel in KRAS G12C-mutated NSCLC

D.M. Waterhouse¹, S. Rothschild², C. Doms³, B. Mennecier⁴, F. Bozorgmehr⁵, M. Majem⁶, M. van den Heuvel⁷, H. Linardou⁸, B. Chul-Cho⁹, R. Roberts-Thomson¹⁰, I. Okamoto¹¹, N. Blais¹², G. Schvartsman¹³, K. Holmskov¹⁴, I. Chmielewska¹⁵, M. Forster¹⁶, B. Stollenwerk¹⁷, C.C. Obiozor¹⁸, Y. Wang¹⁸, S. Novello¹⁹ ¹Dana-Farber Cancer Institute, Boston, MA, USA; ²Medical Oncology, University of Basel, Comprehensive Cancer Center, Basel, Switzerland; ³Department of Respiratory Diseases, University Hospitals, Leuven, Belgium; ⁴Pulmonology Unit, University Hospital Strasbourg, Strasbourg, France; ⁵Department of Thoracic Oncology, Thoraxklinik at University Hospital of Heidelberg, Heidelberg, Germany; ⁶Medical Oncology, Hospital de la Santa Creu i Sant Pau Servei de Oncologia Medica, Barcelona, Spain; ⁷Department of Respiratory Diseases, Radboud University Medical Center, Nijmegen, Netherlands; ⁸Fourth Oncology Department and Comprehensive Clinical Trials Center, Metropolitan Hospital, Athens, Greece; ⁹Division of Medical Oncology, Department of Internal Medicine, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea; ¹⁰Department of Medical Oncology, Queen Elizabeth Hospital, Woodville, SA, Australia; ¹¹Kyushu University Hospital, Fukuoka, Japan; ¹²Department of Medicine, Centre Hospitalier de l'Université de Montréal, Montréal, QC, Canada; ¹³Centro de Oncologia e Hematologia Einstein Família Dayan-Daycoval, Hospital Israelita Albert Einstein, São Paulo, Brazil; ¹⁴Department of Oncology, Odense University Hospital, Odense, Denmark; ¹⁵Department of Pneumology, Oncology and Allergology, Medical University of Lublin, Lublin, Poland; ¹⁶UCL Cancer Institute, London, UK; ¹⁷Amgen (Europe) GmbH, Rotkreuz, Switzerland; ¹⁸Amgen Inc., Thousand Oaks, CA, USA; ¹⁹Department of Oncology, Università degli Studi Di Torino - San Luigi Hospital, Turin, Italy

Background: In the CodeBreak 200 phase III trial, sotorasib significantly improved PFS (primary endpoint) versus docetaxel in previously treated KRAS^{G12C}-mutated NSCLC. Previously described patient-reported outcomes (PROs) favored sotorasib over docetaxel for global health status, physical functioning, dyspnea, and cough (ESMO 2022, LBA10). Here, we report the severity and impact of symptoms on patients' quality of life (QOL) in response to treatment.

Methods: In this trial, 345 patients who progressed after receiving platinum-based chemotherapy and a checkpoint inhibitor were randomized 1:1 to receive sotorasib (960 mg orally QD) or docetaxel (75 mg/m² intravenously Q3W). Well-established, validated

questionnaires captured patients' perception of their QOL and symptom burden: EuroQOL-5 Dimension Visual Analogue Scale (EQ-5D VAS), PRO-Common Terminology Criteria for Adverse Events (CTCAE), Brief Pain Inventory (BPI), and question GP5 from the Functional Assessment of Cancer Therapy Tool General form (FACT-G). For ordinal outcomes, change from baseline to week 12 was assessed with generalized estimating equations.

Results: Compared with patients receiving sotorasib, those receiving docetaxel were more severely bothered by their side effects (odds ratio [OR] 5.71) and experienced symptoms at a higher severity (pain: OR 2.94, aching muscles: OR 4.40, aching joints: OR 4.17, mouth or throat sores: OR 4.26). Further their symptoms more strongly interfered with their usual/daily activities (pain: OR 3.18, aching muscles: OR 3.90, aching joints: OR 10.68). QOL worsened five days after initial docetaxel treatment while remaining stable with sotorasib (change from baseline in VAS score: -8.4 vs 1.5). The VAS showed a long-term worsening of QOL with docetaxel while the VAS remained stable with sotorasib (-5.8 vs 2.2 at week 12).

Conclusions: Patients treated with sotorasib reported less severe symptoms than those treated with docetaxel; hence, their daily lives were positively affected. In addition to improving clinical efficacy outcomes, sotorasib maintained QOL versus docetaxel suggesting that sotorasib may be a more tolerable treatment option for patients with pretreated, KRAS^{G12C}-mutated advanced NSCLC.

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Board of Directors, W40-Hellas- Legal Representative Member of Board of Directors, FAIRLIFE LCC- Member of Board of Directors; Financial Interests, Personal and Institutional, Other, PI in sponsored clinical trials: Bristol Myers Squibb, Boehringer Ingelheim, Roche, AbbVie, Eli Lilly, Novartis, AstraZeneca, Amgen, PPD, Parexel LLC, Qualitix, Health Data Specialist. B. Chul-Cho: Financial Interests, Personal, Royalties: Champions Oncology, Crown Bioscience, Imagen; Financial Interests, Personal and Institutional, Funding: MOGAM Institute, LG Chem, Oscotec, Interpark Bio Convergence Corp, GILInnovation, GI-Cell, Abion, AbbVie, AstraZeneca, Bayer, Blueprint Medicines, Boehringer Ingelheim, Champions Oncology, CJ bioscience, CJ Blossom Park, Cyrus, Dizal Pharma, Genexine, Janssen, Eli Lilly, MSD, Novartis, Nuvalent, Oncother, Ono, Regeneron, Dong-A ST, Bridgebio therapeutics, Yuhon, ImmuneOncia, Illumina, Kanaph therapeutics, Therapex, JINTSbio, Hanmi, CHA Bundang Medical Center; Financial Interests, Personal, Advisory Role, Consultant: Abion, BeiGene, Novartis, AstraZeneca, Boehringer Ingelheim, Roche, BMS, CJ, CureLogen, Cyrus therapeutics, Ono, Onogene Biotechnology, Yuhon, Pfizer, Eli Lilly, GI-Cell, Guardant, HK Inno-N, Imnewrun Biosciences Inc., Janssen, Takeda, MSD, Medpacto, Blueprint medicines, Blueprint medicines, Hanmi; Financial Interests, Personal, Full or part-time Employment: Yonsei University Health System; Financial Interests, Personal, Advisory Board: KANAPH Therapeutic Inc, Bridgebio therapeutics, Cyrus therapeutics, Guardant Health, Oscotec Inc; Financial Interests, Personal, Invited Speaker: ASCO, AstraZeneca, Guardant, Roche, ESMO, IASLC, Korean Cancer Association, Korean Society of Medical Oncology, Korean Society of Thyroid-Head and Neck Surgery, Korean Cancer Study Group, Novartis, MSD, The Chinese Thoracic Oncology Society, Pfizer; Financial Interests, Personal, Stocks/Shares: TheraCanVac Inc, Gencurix Inc, Bridgebio therapeutics, KANAPH Therapeutic Inc, Cyrus therapeutics, Interpark Bio Convergence Corp., J INTS BIO; Financial Interests, Personal, Other, Founder: DAAN Biotherapeutics; Financial Interests, Personal, Member of the Board of Directors: Interpark Bio Convergence Corp., J INTS BIO. R. Roberts-Thomson: Financial Interests, Personal, Advisory Board: Novartis, Bristol Myers Squibb, Merck Sharp and Dohme, Pfizer, AstraZeneca; Financial Interests, Personal, Other, Honoraria: Bristol Myers Squibb, Roche, AstraZeneca, Pierre Fabre, Merck Sharp and Dohme. I. Okamoto: Financial Interests, Institutional, Research Grant: Amgen, Astellas Pharma, Novartis, AbbVie; Financial Interests, Personal and Institutional, Research Grant: AstraZeneca, Taiho Pharmaceutical, Boehringer Ingelheim, Ono Pharmaceutical, MSD Oncology, Eli Lilly, Bristol-Myers Squibb, Chugai Pharma; Financial Interests, Personal, Other: Pfizer. N. Blais: Financial Interests, Personal, Advisory Role, Consulting: Amgen, AstraZeneca, Bayer, BeiGene, BMS, EMD Serono, Ipsen, Merck, Novartis, Pfizer, Roche, Sanofi, Servier, Takeda. G. Schwartzman: Financial Interests, Personal, Advisory Role, Consulting: Amgen, Bristol-Myers Squibb, Merck, Sharp and Dome, AstraZeneca, Sanofi, Takeda, Novartis. I. Chmielewska: Financial Interests, Personal, Other, Honoraria: AstraZeneca, MSD, Roche, BMS, Takeda. M. Forster: Financial Interests, Personal and Institutional, Research Grant: CRUK, AstraZeneca, Boehringer Ingelheim, MSD, Merck; Financial Interests, Personal, Advisory Board: Transgene; Financial Interests, Personal, Advisory Role, Consulting: Achilles, Amgen, AstraZeneca, Bayer, Boxer, Bristol-Myers Squibb, Celgene, EQRx, Guardant Health, Immunet, Ixogen, Janssen, Merck, MSD, Nanobiotix, Novartis, Oxford VacMedix, PharmaMar, Pfizer, Roche, Takeda, UltraHuman. B. Stollenwerk: Financial Interests, Personal, Full or part-time Employment: Amgen; Financial Interests, Personal, Stocks/Shares: Amgen. C.C. Obiozor: Financial Interests, Personal, Full or part-time Employment: Amgen; Financial Interests, Personal, Stocks/Shares: Amgen. Y. Wang: Financial Interests, Personal, Full or part-time Employment: Amgen; Financial Interests, Personal, Stocks/Shares: Amgen. S. Novello: Non-Financial Interests, Personal, Speaker's Bureau: AstraZeneca, Amgen, BI, MSD, Eli Lilly, Takeda, Pfizer, Roche, Novartis, Sanofi, GSK; Financial Interests, Personal, Advisory Role: AstraZeneca, Amgen, BI, MSD, Eli Lilly, Takeda, Pfizer, Roche, Novartis, Sanofi, GSK. All other authors have declared no conflicts of interest.

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Cemiplimab plus chemotherapy versus chemotherapy alone in non-small cell lung cancer: Longer follow-up results from the phase III EMPOWER-Lung 3 trial

T. Makharadze¹, M. Gogishvili², T. Melkadze³, A. Baramidze³, D. Giorgadze⁴, K.D. Penkov⁵, K. Laktionov⁶, G. Nemsadze⁷, M. Nechaeva⁸, I. Rozhkova⁹, E. Kalinka¹⁰, S. Li¹¹, Y. Li¹¹, M. Kaul¹¹, J-F. Pouliot¹¹, F. Seebach¹¹, I. Lowy¹¹, G. Gullo¹¹, P. Rietschel¹¹ ¹LTD High Technology Hospital Medcenter, Batumi, Georgia; ²High Technology Medical Centre, Tbilisi, Georgia; ³Acad. F. Todua Medical Center, Tbilisi, Georgia; ⁴David Tvildiani Medical University, Tbilisi, Georgia; ⁵Private Medical Institution "Euromedservice", St. Petersburg, Russian Federation; ⁶Federal State Budgetary Institution "N.N. Blokhin National Medical Research Center of Oncology" of the Ministry of Health of the Russian Federation, Moscow, Russian Federation; ⁷The Institute of Clinical Oncology, Tbilisi, Georgia; ⁸Chelyabinsk Regional Clinical Oncology Center,